List of Approved Medical Devices

April 2004 to December 2024

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"Review Category" in the list shows the review team which reviewed the product. It is usually decided on the therapeutic area the product is indicated for. Please refer to the following table.

Review Category	Products
Robotics, IoT, and other devices (not classified as other categories)	Mainly innovative medical devices utilizing robotics and advanced IoT technologies, multicategory medical devices, and other uncategorized medical devices
Orthopedic and Plastic Surgery	・Medical devices mainly pertaining to hips, knees, upper extremities, hands, and digits, etc. among orthopedic devices ・Medical devices such as plates, screws, intramedullary nails, spinal implants and related instruments, as well as medical devices used in plastic surgery, dermatology, etc.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	・Materials used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry ・Mechanical appliances used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry
Gastroenterology, Genitourinary, and Reproductive Medicine	Mainly devices pertaining to the fields of gastroenterology, urology, and obstetrics/gynecology (OB/GYN)
Dentistry and Oral Medicine	Mainly devices used in the field of dentistry
Ophthalmology and Otorhinolaryngology	Mainly devices pertaining to the fields of ophthalmology and otorhinolaryngology
Cardiopulmonary Circulation	・Mainly cardiology-related materials used in medical devices pertaining to the circulatory system ・Mainly cardiology-related mechanical appliances pertaining to the circulatory system
Bio-derived Devices (Quality)	Devices subject to "partial change" applications related to the Standards for Biological Ingredients, viral safety, etc.

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An "Orphan Medical Device" is defined as a medical device designated by Minister of Health, Labour and Welfare as an orphan device, based on the PMD Act. Orphan Medical Devices receive priority review.

Orphan Medical Devices are those with number of targeted patients less than 50,000 in Japan. In addition, the medical device has to meet one of the following requirements to show its clinical value to obtain Orphan Medical Device designation:
- no other medical devices or treatments are considered appropriate for the indication
- significant efficacy or safety is expected compared to the treatment/therapy provided with available medical devices

The medical devices described as [Orphan device] in the list are those designated as an Orphan Medical Device.

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"Priority Review" is a review process under which priority is given. Besides orphan-designated medical devices, those satisfying one of the following requirements are given with priority review:
- its indication is considered serious
- significant efficacy or safety is expected compared to the treatment/therapy provided with available medical devices

For medical devices that are not Orphan Medical Devices, whether the priority review is applied or not is judged by Ministry of Health, Labour and Welfare based on "How to manage the priority review" (PFSB/ELD Notification No. 0227016 dated February 27, 2004).

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The medical devices described as [Priority review] in the list are those to which the priority review was applied.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

New Medical Devices Approved from April to December 2024

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 2, 2024	Approval status related to this change Apr. 11, 2023 K230402/Enroute Transcarotid Neuroprotection System	ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Inc.)	Change	Instrument & apparatus 51	A central circulatory catheter for trapping embolus used to prevent embolization by transcarotid vascular access during carotid angioplasty and stent placement in patients with carotid stenosis. The application was submitted to improve the efficiency of the manufacturing process by consolidating some components of the transcarotid arterial sheath and venous return sheath into single-piece units (A "partial change" application).
	Total review time: 407 days Regulatory review time: 118 days	No clinical study results			Central circulatory catheter for trapping embolus	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2024	Jan. 12, 2024/P230023/ GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis	GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (W. L. Gore & Associates G.K.)	Approval	Instrument & apparatus 7	An aortic stent graft system is used for the treatment of patients with thoracoabdominal aortic aneurysms and pararenal abdominal aortic aneurysms who are difficult to treat with conventional surgical repair. It has a branch structure designed to preserve blood flow into the visceral branch vessels while excluding the lesion. It is used as a component of the TAMBE system in combination with the previously approved stent grafts.
	Total review time: 360 days Regulatory review time: 234 days	Foreign clinical study results			Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 28, 2024	No description	Brainsway TMS System (Century Medical, Inc.)	Change	Instrument & apparatus 12	A magnetic stimulator for transcranial treatment that provides treatment for adult patients with Major Depressive Disorder (MDD) (only for the patients who have not benefitted from conventional antidepressant medication), by stimulating neurons with the electric current induced in the local area of the cerebral cortex using a pulsed magnetic field. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 91 days Regulatory review time: 87 days	No clinical study results			Magnetic stimulator for transcranial treatment	
Gastroenterology, Genitourinary and Reproductive Medicine	Nov. 1, 2024	No description	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7	A cytapheresis column to selectively adsorb and remove granulocytes and monocytes in peripheral blood by performing hemoperfusion using an extracorporeal circulation column which is filled with an adsorbent carrier made of cellulose acetate. The application was submitted to add sepsis to the indication of this product. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 318 days Regulatory review time: 253 days	Japanese clinical study results			Cytapheresis column	
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 19, 2024	No description	EC-PDT Probe (Meiji Seika Pharma Co., Ltd.)	Change	Instrument & apparatus 31	A single-use probe to be connected to a PDT semiconductor laser for irradiating a target. It is used for photodynamic therapy for locally residual or recurrent esophageal cancer after chemoradiotherapy or radiotherapy. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 90 days Regulatory review time: 72 days	No clinical study results			Single-use probe for PDT semiconductor laser	
Ophthalmology and Otorhinolaryngology	Nov. 22, 2024	Aug. 11, 2011 P100044/PROPEL SINUS IMPLANT Sep.21, 2012 P100044/S001/PROPEL MINI SINUS IMPLANT Mar. 23, 2016 P100044/S018/PROPEL MINI SINUS IMPLANT Feb. 23, 2017 P100044/S023/PROPEL CONTOUR SINUS IMPLANT	Propel Sinus Implants (Medtronic Japan Co., Ltd.)	Approval	Medical products 4	A bioabsorbable drug-eluting stent for sinus is used for maintaining nasal patency after endoscopic sinus surgery for chronic rhinosinusitis.
	Total review time: 357 days Regulatory review time: 180 days	Clinical evaluation report			Bioabsorbable drug-eluting stent for sinus	

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	May. 2, 2024 Total review time: 293 days Regulatory review time: 213 days	Dec. 13, 2023 Global clinical trial	PulseSelect PFA Loop Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A catheter to conduct pulsed field ablation for cardiac electrophysiological mapping and the treatments of patients with drug refractory recurrent symptomatic paroxysmal atrial fibrillation and drug refractory symptomatic persistent atrial fibrillation. (The original product is in the post-market performance review period.
Cardiopulmonary Circulation	May. 2, 2024 Total review time: 293 days Regulatory review time: 252 days	Dec. 13, 2023 Global clinical trial	PulseSelect PFA Generator (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A pulse generator intended for percutaneous myocardial catheter ablation by the use of pulsed electric fields. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	May. 14, 2024 Total review time: 116 days Regulatory review time: 116 days	- No clinical study results	GORE Cardioform Septal Occluder (W. L. Gore & Associates G.K.)	Change	Medical products 4 Artificial pericardial prosthesis	This product is a percutaneous, transcatheter patent foramen ovale (PFO) closure device. This treatment is intended to close the PFO to reduce the risk of recurrence of ischemic stroke in patients who have had a cryptogenic stroke with possible involvement of a PFO due to a presumed paradoxical embolism. The application was submitted to correct discrepancy in the descriptions of raw materials in the approval document (A "partial change" application).
Cardiopulmonary Circulation	Jul. 24, 2024 Total review time: 254 days Regulatory review time: 128 days	Jun. 1, 2017 Foreign clinical study results	SENTINEL Cerebral Protection System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	A distal embolic protection device designed to temporarily place filters at the aortic bifurcation (brachiocephalic artery and left common carotid artery) for capturing and removing substances causing embolization during transcatheter aortic valve replacement (TAVR).
Cardiopulmonary Circulation	Sep. 26, 2024 Total review time: 321 days Regulatory review time: 262 days	Jan. 30, 2024 Foreign clinical study results	FARASTAR Console (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A pulse generator for pulsed field ablation procedures used for the treatment of arrhythmia. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Sep. 26, 2024 Total review time: 321 days Regulatory review time: 229 days	Jan. 30, 2024 Foreign clinical study results	FARAWAVE Catheter (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A catheter intended to be used for pulsed field ablation procedure of cardiac tissues and cardiac electrophysiological mapping for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Sep. 27, 2024 Total review time: 351 days Regulatory review time: 197 days	Jun. 29, 2023 Global clinical trial	Aveir LP (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode integrated cardiac pacemaker intended to be percutaneously placed in the right heart using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. This product has approved as a ventricular leadless pacemaker. The application was submitted to add an atrial leadless pacemaker in the product, and also to add the indications of atrial pacing or dual-chamber pacing that physiologically synchronizes the atria and ventricles (A "partial change" application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Program	Sep. 19, 2024	-	HemeSight Analysis Program (Otsuka Pharmaceutical Co., Ltd.)	Approval	Program 1	The application was submitted for marketing approval of software for gene variants analysis that outputs genomic profiles summarizing hematological malignancy-related variant information, using, as input information, the base sequence data obtained by the sequence analysis of tumor and normal specimen-derived DNA and tumor specimen-derived RNA from patients with hematological malignancies or similar diseases. The output genomic profiles are used for diagnosis, selection of treatment methods, and investigation of prognosis predictions for hematological malignancies and similar disease, based on the "Guidelines for Genomic Testing of Hematological Malignancies" established by the Japanese Society of Hematology, etc.
	Total review time: 174 days Regulatory review time: 137 days	No clinical study results			Software for gene variants analysis (for cancer genome profiling)	

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Improved Medical Devices (With Clinical Data) Approved from April to December 2024

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Jun. 10, 2024	License date: Jul. 21, 2009 License No.: K091645 License date: Jun. 21, 2016 License No.: K160209 License date: Jun. 11, 2020 License No.: K201117 Brand name: Gold Anchor Number of units shipped: Conventional needle (approved product): 61,894 New needle (proposed product): 36,181	Gold Anchor Marker (GA Japan Company, Inc.)	Change	Medical products 4	A serrated gold wire to be implanted in the body to create an identification maker that can be visualized on film or digital imaging during radiation therapy. It is an implantable lesion identification marker used for locating and delineating malignant tumors in the lung, prostate, liver, pancreas, and breast in the trunk of the body. The application was submitted to add the kidney and uterus to the indications and change the shapes and measurements of the needle components (A “partial change” application).
	Total review time: 180 days Regulatory review time: 109 days	Clinical evaluation report			Implantable lesion identification marker	
Robotics, IoT, and other devices (not classified as other categories)	Aug. 28, 2024	Date of license: May 26, 2017 License No.: K171294 Brand name: da Vinci X Surgical System, Model IS4200 Number of units shipped: --	da Vinci X Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, gynecology, and head and neck surgery (limited to transoral surgery), to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal placement, ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of breast surgery (limited to nipple-sparing mastectomy) and additional concomitant devices (A “partial change” application).
	Total review time: 488 days Regulatory review time: 331 days	Clinical evaluation report			Surgical robot unit	
Robotics, IoT, and other devices (not classified as other categories)	Aug. 28, 2024	Date of license: Mar. 28, 2014 License No.: K131861 Brand name: da Vinci Surgical System, Model IS4000 Number of units shipped: No description	da Vinci Xi Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, gynecology, and head and neck surgery (limited to transoral surgery), to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal placement, ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of breast surgery (limited to nipple-sparing mastectomy) and additional concomitant devices (A “partial change” application).
	Total review time: 485 days Regulatory review time: 328 days	Clinical evaluation report			Surgical robot unit	
Robotics, IoT, and other devices (not classified as other categories)	Sep. 9, 2024	No actual data	Radiopharmaceutical Synthesis Device MPS200Aβ (Sumitomo Heavy Industries, Ltd.)	Change	Instrument & apparatus 10	A radioactive compound synthesizing facility used for the semi-automated preparation of a radioisotope labeled compound, florbetapir (18F) injection used for positron emission tomography. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of florbetapir (18 F) injection (A “partial change” application).
	Total review time: 195 days Regulatory review time: 154 days	Clinical evaluation report			Radioactive compound synthesizing facilities	

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Dec. 17, 2024 Total review time: 270 days Regulatory review time: 217 days	Feb. 2023（510k） Foreign clinical study results	FreeStyle Libre 3 (Abbott Japan LLC)	Change	Instrument & apparatus 20 Glucose monitor system	A glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. The application was submitted mainly to add a sensor that the designed duration has been extended from 14 to 15 days to the components (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Dec. 17, 2024 Total review time: 270 days Regulatory review time: 217 days	Mar. 3, 2023（510K） Foreign clinical study results	FreeStyle Libre 2 (Abbott Japan LLC)	Change	Instrument & apparatus 20 Glucose monitor system	A glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. The application was submitted mainly to add a sensor that the designed duration has been extended from 14 to 15 days to the components (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Dec. 17, 2024 Total review time: 292 days Regulatory review time: 175 days	Jun. 9, 2023 (K223865) Sep. 21, 2023 (K231248) Foreign clinical study results	HemoSphere Advanced Monitoring Platform (Edwards Lifesciences Limited)	Change	Instrument & apparatus 21 Multiparameter monitor with critical parameters	A multiparameter monitor with critical parameters intended to measure thermodilution cardiac output, arterial pressure-based cardiac output, blood pressure, venous oxygen saturation, and tissue oxygen saturation, and to collect and monitor various physiological information. Since this product includes a cerebral oximeter function, it was judged to be non-conforming to the certification standards. Following the judgement, the application was submitted for marketing approval of the product. This application was submitted to add a finger cuff for the measurement of digital arterial pressure to the components and to incorporate a non-invasive function to calculate hemodynamic parameters and hypotension prediction indices (A “partial change” application).
Orthopedic and Plastic Surgery	Jun. 24, 2024 Total review time: 346 days Regulatory review time: 266 days	- Clinical evaluation report	Lymmity (Techno Takatsuki Co., Ltd.)	Approval	Instrument & apparatus 12 Pneumatically-powered sequential device for stimulating lymph flow	A pneumatically-powered sequential device for stimulating lymph flow to reduce edema in patients with lymphedema by applying pneumatic compression to the affected limb and trunk. The product consists of a main unit with a built-in actuator and sleeves that compress the affected limb and trunk. As clinical evaluation data, a clinical evaluation report summarizing the literature research data on a foreign clinical study of intermittent pneumatic compression therapy with a similar product was submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 23, 2024 Total review time: 315 days Regulatory review time: 192 days	Sep. 25, 2000 P990040/TRUFILL n-butyl cyanoacrylate (n-BCA) Liquid Embolic System Clinical evaluation report	TRUFILL n-BCA Liquid Embolic System (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	A central circulatory intravascular embolization prosthesis is used as an embolic agent for vascular embolization in cases where embolization is needed before surgical removal of cerebral arteriovenous malformation refractory to non-surgical approaches or in dural arteriovenous fistula that is difficult to treat sufficiently with transvenous embolization, etc. A clinical evaluation report summarizing the literature research data, etc. on the efficacy and safety of this product was submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 19, 2024 Total review time: 266 days Regulatory review time: 141 days	- Japanese clinical study results	Medilizer AGD System (Bolt Medical, Inc.)	Approval	Instrument & apparatus 51 Cerebrovascular guiding assist device	A cerebrovascular guiding assist device used to deliver an endovascular treatment device to a target lesion. The product is used in cases where the delivery of endovascular treatment devices including catheters is difficult by traditional methods due to vascular tortuosity, etc. The results of clinical studies conducted in Japan were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 29, 2024 Total review time: 391 days Regulatory review time: 197 days	Jan. 20, 2023 K222848/No description Foreign clinical study results	pRESET Stent Retriever (phenox Limited)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy that is intended for use to restore blood flow by removing clots from the intracranial blood vessel in patients with acute ischemic stroke (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with the t-PA therapy. The results of foreign clinical studies were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 8, 2024 Total review time: 146 days Regulatory review time: 126 days	[Type IIIc] Dec. 2022 k222808/Penumbra System (Reperfusion Catheter RED 43) [Type IIb] Nov. 2011 k113163/Penumbra System MAX [Type IIIb] Nov. 2011 k113163/Penumbra System MAX Clinical evaluation report	Penumbra System 4 (Medico's Hirata Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy used for revascularization for patients with acute ischemic stroke (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) therapy or who failed in revascularization with the t-PA therapy. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literature, etc. was submitted to evaluate the efficacy and safety of ADAPT.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 18, 2024 Total review time: 595 days Regulatory review time: 514 days	Jan. 8, 2014 K130681(FDA)/Radial 2ring Fiber Clinical evaluation report	ELVeS Laser 1470 (Integral Corporation)	Change	Instrument & apparatus 31 Diode laser	A diode laser used for the treatment of the truncal saphenous veins and tributary varicose veins in primary varicose veins of the lower extremities (greater saphenous vein with vessel diameter of 20 mm or less or small saphenous vein). The application was submitted to add an indication for the treatment of tributary varicose veins originating from the trunk vein, as long as the procedure is performed concurrently with that for the trunk vein (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 8, 2024 Total review time: 366 days Regulatory review time: 322 days	Feb. 1, 2019 P180025/MANTA Vascular Closure Device Foreign clinical study results	MANTA Vascular Closure Device (Teleflex Medical Japan, Ltd.)	Approval	Medical products 4 Absorbable topical hemostatic material with collagen	An absorbable topical hemostatic material with collagen used for hemostasis at the femoral artery puncture site following percutaneous catheterization.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2024 Total review time: 267 days Regulatory review time: 218 days	Apr. 22, 2024 (PMA Supplement Approval)/GORE® VIABAHN ® VBX Balloon Expandable Endoprosthesis Foreign clinical study results	GORE VIABAHN VBX Balloon Expandable Endoprosthesis (W. L. Gore & Associates G.K.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A heparin-coated stent-graft for a central circulatory system used to treat de novo or restenotic lesions found in the iliac arteries. The application was submitted to add an indication for the implantation of this device in the celiac, superior mesenteric, and renal arteries, when used in combination with the "GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis" (Approval No. 30600BZX00235000) for the treatment of thoracoabdominal and pararenal abdominal aortic aneurysms (A "partial change" application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2024 Total review time: 360 days Regulatory review time: 314 days	- Foreign clinical study results	GORE EXCLUDER AAA Endoprosthesis (W. L. Gore & Associates G.K.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for the intravascular treatment of abdominal aortic aneurysms and aortic aneurysms extending from the abdominal aorta to the iliac artery. The application was submitted to enable its use in combination with the "GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis" (Approval No. 30600BZX00235000) for the treatment of thoracoabdominal and pararenal abdominal aortic aneurysms (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2024 Total review time: 360 days Regulatory review time: 311 days	- Foreign clinical study results	GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates G.K.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for the intravascular treatment of thoracic aortic diseases. The application was submitted to enable its use in combination with the "GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis" (Approval No. 30600BZX00235000) for the treatment of thoracoabdominal aortic aneurysms (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 27, 2024 Total review time: 302 days Regulatory review time: 204 days	May 2022 PMA approval (no number stated)/GORE TAG Thoracic Branch Endoprosthesis Foreign clinical study results	GORE TAG Thoracic Branch Endoprosthesis (W. L. Gore & Associates G.K.)	Approval	Instrument & apparatus 7 Aortic stent graft	A branch aortic stent graft system used for the intravascular treatment of thoracic descending aorta diseases. It has a branched stent graft structure that enables the treatment while preserving blood flow into the left subclavian artery.
Gastroenterology, Genitourinary and Reproductive Medicine	Jun. 24, 2024 Total review time: 312 days Regulatory review time: 169 days	Initial: Sep. 29, 2010/ CryoBalloon Ablation System Proposed product: Jan. 23, 2018 C2 CryoBalloon Ablation System Japanese clinical study results	C2 CryoBalloon Ablation System (HOYA Corporation)	Change	Instrument & apparatus 31 General-purpose cryosurgical unit	A general-purpose cryosurgical unit intended for endoscopic cryoablation of lesion tissue. This product has already been approved for use in patients with "endoscopically-unresectable, recurrent Barrett's esophageal lesion associated with dysplasia or noninvasive adenocarcinoma that has arisen from residual diseased tissue or in/around the scar after endoscopic resection." The application was submitted to add the indication of “endoscopically-unresectable, recurrent esophageal squamous cell carcinoma that has arisen from residual diseased tissue or in/around the scar after endoscopic resection” (A “partial change” application).
Gastroenterology, Genitourinary and Reproductive Medicine	Sep. 2, 2024 Total review time: 242 days Regulatory review time: 122 days	None Japanese clinical study results	Zeostent HG (Zeon Medical Inc.)	Approval	Instrument & apparatus 51 Transgastric biliary drainage stent	A transgastric biliary drainage stent designed to create an anastomotic site between the gastrointestinal wall (stomach) and the bile duct in endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) for use as a drainage pathway. The product consists of a self-expanding stent with a hook-shaped anchor at the gastric wall-side distal end and a delivery system.
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 5, 2024 Total review time: 148 days Regulatory review time: 60 days	Mar. 12, 2012 K113860/Visual-ICE Clinical evaluation report	Visual-ICE Cryoablation System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 31 General-purpose cryosurgical unit	A general-purpose cryosurgical unit that freezes and necrotizes biological tissues. The application was submitted to add the followings to the intended use of this product; "liver tumor" as well as "pulmonary malignant tumor," "malignant bone tumor," "osteoid osteoma," "intrapelvic malignant tumor," and "soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity" that are ineligible for or refractory to standard therapy (A "partial change" application).

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Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 17, 2024 Total review time: 231 days Regulatory review time: 197 days	• (Indication for PPC/WON) Aug. 5, 2015 K150692/AXIOS Stent and Electrocautery-Enhanced Delivery System • (Indication for gallbladder drainage) Aug. 18, 2023 DEN230019/AXIOS Stent and Electrocautery-Enhanced Delivery System Foreign clinical study results	Hot AXIOS System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51 Fistula formation prosthesis for pancreas	A fistula formation prosthesis for pancreas intended to form a fistula by pulling the gastrointestinal walls together or pulling the gastrointestinal and cyst walls through the gastrointestinal tract (stomach or duodenum) with endoscopic ultrasound. The application was submitted to add an indication for use for transgastric or transduodenal endoscopic gallbladder drainage in patients with acute cholecystitis who are at high risk for surgery (A "partial change" application).
Ophthalmology and Otorhinolaryngology	Jun. 3, 2024 Total review time: 270 days Regulatory review time: 138 days	- Japanese clinical study results	SEERS (Menicon Co., Ltd.)	Approval	Medical products 4 Ophthalmic material for maintaining visibility	The application was submitted for marketing approval of an ophthalmic material for maintaining visibility during open surgery to treat glaucoma. The product is a prefilled syringe loaded with synthetic peptide in a clear gel formulation, which is applied to the area of observation or treatment to ensure a clear operative field and help with observation and treatment.
Ophthalmology and Otorhinolaryngology	Jun. 6, 2024 Total review time: 252 days Regulatory review time: 137 days	Aug. 10, 2018 /P170034/Hydrus Microstent Foreign clinical study results	Hydrus Glaucoma Microstent (Alcon Japan Ltd.)	Approval	Medical products 4 Intraocular drain	The application was submitted for marketing approval of a stent and its delivery system used simultaneously during cataract surgery to lower intraocular pressure in patients with mild to moderate open-angle glaucoma.
Ophthalmology and Otorhinolaryngology	Jun. 19, 2024 Total review time: 265 days Regulatory review time: 144 days	- Japanese clinical study results	PODEYE Toric (Beaver-Visitec International Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The application was submitted for marketing approval of a posterior chamber lens with cylindrical refractivity to be implanted in the posterior chamber of the eye to replace a cloudy crystalline lens and restore vision.
Ophthalmology and Otorhinolaryngology	Jul. 11, 2024 Total review time: 265 days Regulatory review time: 119 days	- Clinical evaluation report	iStent inject Trabecular Micro-Bypass System (Glaukos Corporation)	Change	Medical products 4 Heparin-coated drain for intraocular	A stent and the injector used for lowering intraocular pressure in patients with mild to moderate open-angle glaucoma. The application was submitted to expand the indications by adding the use of the product alone to the conventional indications for simultaneous use in cataract surgery, and to add a new type of injector (A "partial change" application).
Ophthalmology and Otorhinolaryngology	Aug. 2, 2024 Total review time: 224 days Regulatory review time: 162 days	- Foreign clinical study results	TECNIS PureSee Extended Depth of Focus IOL Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter.
Ophthalmology and Otorhinolaryngology	Aug. 2, 2024 Total review time: 224 days Regulatory review time: 162 days	- Foreign clinical study results	TECNIS PureSee Toric Extended Depth of Focus IOL Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter.
Ophthalmology and Otorhinolaryngology	Sep. 19, 2024 Total review time: 269 days Regulatory review time: 169 days	- Japanese clinical study results	Acriva Trinova Pro (Wakamoto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	The application was submitted for marketing approval of a multifocal posterior chamber lens which is used to correct near, intermediate and far vision of an aphakic eye and reduce spectacle dependence.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Sep. 30, 2024 Total review time: 854 days Regulatory review time: 353 days	Jul. 3, 2019 K190589/OSI100, Osia SP, (Osia System) Nov. 15, 2019 K191921/OSI200, Osia 2 SP (Osia System/Osia 2 System) Foreign clinical study results	Osia System (Nihon Cochlear Co., Ltd.)	Approval	Instrument & apparatus 73 Implantable bone-conduction hearing aid	The application was submitted for marketing approval of an implantable bone-conduction hearing aid to improve the ability to hear environmental sounds and speech sounds in patients with hearing impairment who have normal bone conduction thresholds or mild impairment at least in one ear.
Ophthalmology and Otorhinolaryngology	Oct. 23, 2024 Total review time: 261 days Regulatory review time: 224 days	- Foreign clinical study results	PV 1DAY SiHY (Pegavision Corporation)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens and single-use colored vision non-corrective contact lens. The lens is composed of silicone hydrogel with a water content of 60% and oxygen permeability (Dk) of 50×10^{-11} $(cm^2/sec)\cdot(mLO_2/[mL \times mmHg])$.
Ophthalmology and Otorhinolaryngology	Nov. 18, 2024 Total review time: 262 days Regulatory review time: 212 days	No description Foreign clinical study results	Vivinex Gemetric Plus (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of an aphakic eye.
Ophthalmology and Otorhinolaryngology	Nov. 18, 2024 Total review time: 262 days Regulatory review time: 206 days	No description Foreign clinical study results	Vivinex Gemetric Plus Toric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of aphakic eyes with corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Nov. 22, 2024 Total review time: 267 days Regulatory review time: 170 days	- Foreign clinical study results	WaveLight EX500 (Alcon Japan Ltd.)	Change	Instrument & apparatus 31 Ophthalmic corneal surgery laser system	An ophthalmic corneal surgery laser system with a wavelength of 193 nm using argon-fluorine gas as an oscillation medium for correction of refractive error or resection of corneal lesions by removing corneal tissues using laser irradiation. The application was submitted to broaden the target of myopia and myopic astigmatism correction by LASIK (laser in situ keratomileusis) to include myopia of -10.0 D or less, and to add hyperopia and hyperopic astigmatism correction by LASIK, in the intended use or indications (A "partial change" application).
Ophthalmology and Otorhinolaryngology	Dec. 17, 2024 Total review time: 265 days Regulatory review time: 252 days	Dec. 20, 2023 Foreign clinical study results	Hydron 1 Day PurePlus (Yung Sheng Optical Japan Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens and single-use colored vision non-corrective contact lens. The lens is composed of silicone hydrogel with a water content of 44% and oxygen permeability (Dk) of 120 × 10-11 $(cm^2/sec)\cdot(mLO_2)/[mL \times mmHg])$.
Ophthalmology and Otorhinolaryngology	Dec. 24, 2024 Total review time: 264 days Regulatory review time: 237 days	Dec. 2, 2020 P960058/S149/Naida CI M90, Sky CI M90 Foreign clinical study results	Naida CI M90 Sound Processor (Nihon Bionics Co., Ltd.)	Approval	Medical products 4 Auditory electrical stimulator	The application was submitted for marketing approval of an auditory electrical stimulator used in patients with bilateral severe hearing loss who have not responded sufficiently to wearing hearing aids.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Apr. 22, 2024 Total review time: 130 days Regulatory review time: 111 days	May 2, 2017 Clinical evaluation report	RESONATE ICD Series (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an automatic implantable defibrillator. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a model with a function to provide indicators related to the changes in the patient's biological information (HeartLogic function) as per the section 3 in the "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1 and PSEHB/SD Notification No. 1117-1 dated on November 17, 2017)" (A "partial change" application).
Cardiopulmonary Circulation	Jun. 12, 2024 Total review time: 160 days Regulatory review time: 145 days	- Japanese clinical study results	Kaneka Cutting Balloon Catheter CO-R1 (Kaneka Corporation)	Approval	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A balloon catheter used to dilate coronary stenosis that is difficult to dilate with a conventional balloon catheter. The balloon has integrated blades along its surface.
Cardiopulmonary Circulation	Jun. 18, 2024 Total review time: 82 days Regulatory review time: 44 days	- Clinical evaluation report	POLARx Cryoablation Balloon Catheter (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon catheter used for cryoablation of cardiac tissue. The application was submitted to add "the treatment of drug-resistant, symptomatic, persistent atrial fibrillation" to the existing intended use (the treatment of drug-refractory, recurrent, symptomatic, paroxysmal arterial fibrillation) and "compatibility with electric powered injectors" to the specifications related to performance and safety (A "partial change" application).
Cardiopulmonary Circulation	Jun. 18, 2024 Total review time: 230 days Regulatory review time: 182 days	Oct. 1, 2022 Foreign registry	SelectSecure Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable endocardial pacemaker electrode/lead	The device is an implantable endocardial pacemaker electrode/lead. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add left bundle branch area pacing to its intended use (A "partial change" application).
Cardiopulmonary Circulation	Jun. 19, 2024 Total review time: 257 days Regulatory review time: 180 days	- Performance evaluation study results using existing medical information in Japan	CardiMax FCP-9900Ai System (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 21 Multi-function electrocardiograph	A multi-functional electrocardiograph intended for ECG with at least 12 leads including limb leads and chest leads. The device was developed based on "CardiMax FCP-9900 System" (Certification No.: 301ADBZX00034000). The change is addition of a function that estimates the possibility of paroxysmal atrial fibrillation occurring in the past 2 years.
Cardiopulmonary Circulation	Aug. 2, 2024 Total review time: 219 days Regulatory review time: 140 days	- Foreign registry	COMBO Plus Coronary Stent (Orbusneich Medical K. K.)	Change	Instrument & apparatus 7 Murine antibody-coated coronary stent	A coronary stent system consists of a drug-eluting stent used to treat patients with ischemic heart disease and a delivery catheter to deploy a stent to the stenosed lesion. A murine-derived anti-CD34 antibody and sirolimus are coated on the stent surface of the device. The application was submitted to add stent sizes (A "partial change" application).
Cardiopulmonary Circulation	Aug. 26, 2024 Total review time: 242 days Regulatory review time: 196 days	- Performance evaluation study results using existing medical information in Japan	CardiMax FCP-9800Ai (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 21 Multi-function electrocardiograph	A multi-functional electrocardiograph intended for ECG with 12 leads including limb leads and chest leads. The device was developed based on the "CardiMax FCP-9800" (Certification No.: 303ADBZX00038000). The change is addition of a function that estimates the possibility of paroxysmal atrial fibrillation occurring in the past 2 years.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 15, 2024 Total review time: 267 days Regulatory review time: 201 days	Aug. 14, 2021 Foreign clinical study results	Amulet Left Atrial Appendage Occluder (Abbott Medical Japan LLC)	Approval	Instrument & apparatus 51 Intracardiac prosthesis	The device is an intracardiac prosthesis intended to reduce a risk of thromboembolism attributed to the left atrial appendage in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism. The device consists of a closure device, a delivery catheter, and an access system.
Cardiopulmonary Circulation	Oct. 22, 2024 Total review time: 265 days Regulatory review time: 133 days	Oct. 20, 2023 Foreign clinical study results	Aurora EV ICD MRI Device (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator intended to treat ventricular tachycardia that performs sensing, cardioversion, anti-tachycardia pacing therapy, and defibrillation by being implanted in the body and used in combination with a substernal implantable lead. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements.
Cardiopulmonary Circulation	Oct. 22, 2024 Total review time: 265 days Regulatory review time: 129 days	Oct. 20, 2023 Foreign clinical study results	Epsila EV MRI Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker electrode/lead	A substernal implantable lead to be connected to an implantable cardioverter defibrillator used for sensing, cardioversion, anti-tachycardia pacing therapy, and defibrillation for ventricular tachycardia. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements.
Cardiopulmonary Circulation	Oct. 28, 2024 Total review time: 245 days Regulatory review time: 38 days	- Foreign clinical study results	EXCOR Pediatric Ventricular Assist Device (Cardio Incorporated)	Change	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	This device is a single-use extracorporeal ventricular assist device. It is used for severe pediatric heart failure patients who cannot expect improvement of symptoms in conventional medication, surgery and circulation support. If the system is judged as best for the patients, it is used for the patients to improve circulation until reaching heart transplantation or recovery of cardiac function. The application was submitted to add an Active driving unit that is smaller and lighter than the existing ventricular assist device (A "partial change" application).
Cardiopulmonary Circulation	Nov. 19, 2024 Total review time: 264 days Regulatory review time: 156 days	Aug. 30, 2024 Foreign clinical study results	Solia S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable endocardial pacemaker electrode/lead	The device is an implantable endocardial pacemaker electrode/lead. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add left bundle branch area pacing to its intended use (A "partial change" application).
Program	May 8, 2024 Total review time: 398 days Regulatory review time: 320 days	License date: Jun. 3, 2022 License number: K213971 Brand name: Atrial Fibrillation History Feature Foreign clinical study results	Apple's Atrial Fibrillation History Feature (Apple Inc.)	Approval	Program 1 Software for home use heart rate monitor	The application was submitted for marketing approval of a software for home use heart rate monitor. The device is used to analyze pulse rate data to identify episodes suggestive of atrial fibrillation, and to provide users with the estimated percentage of time that the heart showed the signs of atrial fibrillation in the past relative to the time wearing the Apple Watch.
Program	Aug. 2, 2024 Total review time: 368 days Regulatory review time: 149 days	- Performance evaluation study results using existing medical information in Japan	Endoscopic Surgery Support Program SurVis-Hys (Jmees Inc.)	Approval	Program 1 Supporting software for surgical image recognition	The application was submitted for marketing approval of supporting software for surgical image recognition. This software assists surgeons with image recognition by processing image data obtained from an endoscopy system and highlighting candidate areas of the ureter and bladder during surgery.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Program	Aug. 23, 2024 Total review time: 333 days Regulatory review time: 196 days	None Japanese clinical study	RST Calculation Program (HeartLab, Inc.)	Approval	Program 1 Software for analysis of body motion information	Software for analysis of body motion information used to provide an index related to respiratory stability by analyzing nocturnal body motion data. The present application for marketing approval of the product was submitted based on the "Concept of two-step approval of Software as a Medical Device for disease diagnosis" described in the "Handling of two-step approval based on the characteristics of Software as a Medical Device" (PSB/MDED Notification No. 1116-2 dated November 16, 2023).
Program	Aug. 26, 2024 Total review time: 270 days Regulatory review time: 167 days	Sep. 13, 2024 Foreign clinical study results	Apple's Sleep Apnea Notification Feature (Apple Inc.)	Approval	Program 1 Software for analysis of home use body motion information	The application was submitted for marketing approval of software for analysis of home use body motion information that analyzes wrist motion data from the built-in accelerometer of the Apple Watch to detect any irregular breathing suggestive of sleep apnea and notifies the user of it.
Program	Sep. 30, 2024 Total review time: 241 days Regulatory review time: 99 days	Sep. 12, 2024 Foreign clinical study results	Apple's hearing assist Feature (Apple Inc.)	Approval	Program 1 Software for home use hearing assist fitting	The application was submitted for marketing approval of software for home use hearing assist fitting that allows the user to configure the sound amplification-related settings for hearing aid based on the input audiogram results.
Program	Sep. 30, 2024 Total review time: 122 days Regulatory review time: 61 days	- Clinical evaluation report	Apple's hearing check feature (Apple Inc.)	Approval	Program 1 Software for home use audiometry device	The application was submitted for marketing approval of software for home use audiometry device used to notify the user of the possibility of hearing loss by performing air conduction audiometry.
Program	Nov. 27, 2024 Total review time: 541 days Regulatory review time: 270 days	- Performance evaluation study results using existing medical information in Japan	AI-Powered Software for Bacterial Infection Species Identification Assistance BiTTE-Urine (NextGeM Inc.)	Approval	Program 1 Supporting software for microbial classification	The application was submitted for marketing approval of supporting software for microbial classification. This software assists physicians in diagnosis by detecting and analyzing the characteristics of each bacterial cell based on urinary gram-stained images, and displaying the results of estimated bacterial species on the screen.
Program	Dec. 17, 2024 Total review time: 484 days Regulatory review time: 205 days	- Clinical evaluation report	HUAWEI ECG Application (Huawei Device Co., Ltd.)	Approval	Program 1 Software for home use electrocardiograph	The application was submitted for marketing approval of a software for home use electrocardiograph with functions of creating, recording, storing, transferring, and displaying a single-channel ECG similar to Lead-I ECG, as well as functions of analyzing the generated ECG, classifying the wave form suggesting sinus rhythm or atrial fibrillation, and notifying the results to the user.
Program	Dec. 24, 2024 Total review time: 420 days Regulatory review time: 306 days	- Japanese clinical study results	Paroxysmal Atrial Fibrillation Feature Detection Software SmartPAFin Series (Cardio Intelligence Inc.)	Approval	Program 1 Software for general-purpose electrocardiograph	The application was submitted for marketing approval of a software for general-purpose electrocardiograph (ECG) that analyzes electrocardiographic data obtained from a general-purpose ECG, etc. and detects features of paroxysmal atrial fibrillation. The product is used to detect features of paroxysmal atrial fibrillation and examine whether additional ECGs are required.

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New Medical Devices Approved in FY2023

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Nov. 2, 2023 Total review time: 335 days Regulatory review time: 310 days	— No clinical study results	1	EpiFix (MiMedx Group, Inc.)	Change	Medical products 4 Healing promoting material using human amnion	A tissue-healing promoting material composed of human amniotic membranes intended to promote wound healing in patients with refractory ulcers who have not responded to conventional therapies. The product is made of dried human amniotic/chorionic membranes obtained from the human placenta, prepared by cleaning, drying, and sterilizing, and contains multiple types of amniotic/chorionic membrane-derived extracellular matrix proteins, growth factors, cytokines, etc. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 29, 2023 Total review time: 53 days Regulatory review time: 39 days	- No clinical study results	2	Jetstream Atherectomy System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 51 Atherectomy ablative angioplasty catheter	An atherectomy ablative angioplasty catheter that is percutaneously inserted into the peripheral blood vessel to cut, crush, and suck the lesion by rotating the tip of the catheter. The application was submitted to add a raw material of the catheter (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 7, 2023 Total review time: 261 days Regulatory review time: 116 days	Jun. 24, 2020 P960009/S361/Percept PC Clinical evaluation report	3	Medtronic Percept PC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Tremor brain electrical stimulator	An implantable stimulator for deep brain stimulation (DBS) used to improve motor disorders by applying an electrical stimulation to the deep brain. The application was submitted to add an indication for the reduction of focal epileptic seizures in drug-resistant epilepsy by stimulating the anterior nucleus of thalamus (ANT) (A “partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 11, 2023 Total review time: 116 days Regulatory review time: 52 days	Dec. 2019 No description/Flow Re-Direction Endoluminal Device (FRED) system No clinical study results	4	FRED System (Terumo Corporation)	Change	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	FRED System is a flow diverter system intended to be used to occlude intracranial aneurysms (including fusiform aneurysm) that are difficult to treat surgically or by coil embolization with a maximum diameter of 5 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment of the internal carotid artery to the proximal regions of the middle cerebral artery and anterior cerebral artery, and in basilar and vertebral arteries, except for acute phase ruptured aneurysms. The application was submitted to add the fixation points of the inner layer and outer layer to the edge of the stent (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 16, 2023 Total review time: 33 days Regulatory review time: 28 days	— No clinical study results	5	Woven EndoBridge Device (Terumo Corporation)	Change	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	A central circulatory intravascular embolization device intended to be used for endovascular treatment of wide-necked (defined the size as neck width 4 mm or greater or dome-to-neck ratio less than 2) bifurcation intracranial aneurysms located in anterior or posterior circulation. The application was submitted to add electron beam sterilization method (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 4, 2023 Total review time: 350 days Regulatory review time: 126 days	Feb. 16, 2017 original 510k: K163549/ClotTriever Thrombectomy System Sep. 9, 2020 K193462/ClotTriever Thrombectomy System Foreign clinical study results	6	ClotTriever Thrombectomy System (Inari Medical, Inc.)	Approval	Instrument & apparatus 51 Catheter for non-central circulatory embolectomy	A catheter for non-central circulatory embolectomy used to restart blood flow in patients with deep vein thrombosis with severe acute symptoms excluding post-thrombotic syndrome. The results of foreign clinical studies were submitted.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 5, 2023	[Type 1] Dec. 2019 No description/Flow Re-Direction Endoluminal Device (FRED) system [Type 2] Sep. 2021 No description/Flow Re-Direction Endoluminal Device (FRED) system	7	FRED System (Terumo Corporation)	Change	Instrument & apparatus 51	FRED System is a flow diverter system intended to be used to occlude intracranial aneurysms (including fusiform aneurysm) that are difficult to treat surgically or by coil embolization with a maximum diameter of 5 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment of the internal carotid artery to the proximal regions of the middle cerebral artery and anterior cerebral artery, and in basilar and vertebral arteries, except for acute phase ruptured aneurysms. The application was submitted to add a product type treated with surface processing using hemocompatible poly(2-methoxyethylacrylate) to the surface of the stent to improve operability (A “partial change” application).
	Total review time: 146 days Regulatory review time: 76 days	No clinical study results				Central circulatory intravascular embolization prosthesis	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 21, 2023	—	8	Toraymyxin (Toray Industries, Inc.)	Change	Instrument & apparatus 7	An endotoxin removal adsorption hemoperfusion column intended to selectively adsorb and remove disease agents, primarily blood endotoxins, by whole blood perfusion. This product has been approved as a device to improve disease state in patients with severe conditions caused by endotoxemia or suspected gram-negative bacterial infection (Approval No. 20500BZZ00926000). The application was submitted to add the indication for acute exacerbation of idiopathic pulmonary fibrosis utilizing the Conditional Early Approval System for Medical Devices (A “partial change” application).
	Total review time: 262 days Regulatory review time: 117 days	Clinical evaluation report				Endotoxin removal adsorption hemoperfusion column	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 22, 2023	Feb. 16, 2021	9	Relivion (Sawai Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 12	A transcutaneous electrical nerve stimulator for the head intended for the acute treatment of migraine with or without aura. The results of foreign clinical studies were submitted.
	Total review time: 360 days Regulatory review time: 208 days	Foreign clinical study results				Transcutaneous electrical nerve stimulator for the head	
Gastroenterology, Genitourinary and Reproductive Medicine	Jul. 7, 2023	Feb. 25, 2022	10	Cool-tip RFA System E Series (Covidien Japan Inc.)	Change	Instrument & apparatus 29	A radio-frequency ablation system used for coagulating and ablating tissues. The product has already been approved for the indications of "hepatic tumors and small-diameter renal malignant tumor," "blood flow blockage to an acardiac fetus of acardiac twins," and "pulmonary malignant tumor, malignant bone tumors, osteoid osteomas, pelvic malignant tumor, and soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity that are ineligible for or refractory to standard therapy." The application was submitted to add an indication of mammary tumors (single, localized, early breast cancer with a tumor diameter of 1.5 cm or less, free of axillary lymph node metastasis and distant metastasis by palpation and diagnostic imaging) (A “partial change” application).
	Total review time: 219 days Regulatory review time: 166 days	Japanese clinical study results				Radio-frequency ablation system	

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 30, 2023 Total review time: 125 days Regulatory review time: 92 days	- Clinical evaluation report	11	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Cytapheresis column	A cytapheresis column to adsorb and remove leukocytes (mainly granulocytes) from the blood by extracorporeal circulation. The product has already been approved for indications for "remission induction in severe ulcerative colitis," etc. The application was submitted to add patients with refractory moderate ulcerative colitis to the indication for remission induction in ulcerative colitis. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Mar. 29, 2024 Total review time: 99 days Regulatory review time: 81 days	Dec. 21, 2017 No clinical study results	12	AQUABEAM Robotic System (PROCEPT BioRobotics Corporation)	Change	Instrument & apparatus 12 Surgical robot unit	A device to resect and remove prostate tissues of male patients with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	May 8, 2023 Total review time: 199 days Regulatory review time: 148 days	Sep. 19, 2019 Foreign and Japanese clinical study results	13	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the position of the aortic valve. The device has been approved for the indication of severe symptomatic native aortic stenosis or treatment in patients with symptomatic valvular disease due to dysfunction of a surgically placed bioprosthetic aortic valve who are not receiving chronic dialysis. The application was submitted to expand the indication for patients on chronic dialysis with these findings for whom surgery cannot be performed (A “partial change” application).
Cardiopulmonary Circulation	May 11, 2023 Total review time: 867 days Regulatory review time: 510 days	- Japanese clinical study results	14	Paravalvular Leak Closure Set (Japan Lifeline Co., Ltd.)	Approval	Medical products 4 Artificial pericardial prosthesis	A set consisting of an occluder, pusher, and loader intended to be used for percutaneous closure of a defect hole for prosthetic paravalvular regurgitation.
Cardiopulmonary Circulation	Jun. 12, 2023 Total review time: 56 days Regulatory review time: 56 days	- No clinical study results	15	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted to add a raw material, falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No. 1110001 dated on November 10, 2008). (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jul. 11, 2023 Total review time: 169 days Regulatory review time: 142 days	- Japanese clinical study results	16	SYNFOLIUM (TEIJIN MEDICAL TECHNOLOGIES CO.,LTD.)	Approval	Instrument & apparatus 7 Synthetic cardiovascular patch	A synthetic cardiovascular patch used for correction of blood flow, securing blood flow paths, and generation/reconstruction of surrounding tissues in congenital cardiac surgery. The product has an integrated structure in which a knitted fabric composed of biodegradable synthetic polymer (poly-L-lactic acid yarn) and a non-biodegradable synthetic polymer (polyethylene terephthalate yarn) is coated with a crosslinked gelatin membrane.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 18, 2023 Total review time: 322 days Regulatory review time: 173 days	Sep. 14, 2022 Foreign clinical study results	17	PASCAL Precision System (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The device is indicated for degenerative mitral regurgitation (DMR). The device consists of an implant system equipped with a clip and a guide sheath set that is used to deliver the implant system to the left atrium. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Nov. 2, 2023 Total review time: 363 days Regulatory review time: 59 days	Oct. 16, 2020 No clinical study results	18	Perceval Bioprosthetic Valve (Corcym Canada Corp,)	Change	Instrument & apparatus 7 Bovine pericardium valve	A bioprosthetic valve primarily consisting of a bovine pericardium and a self-expandable metallic stent is used for replacing a diseased native aortic valve or malfunctioning prosthetic aortic valve. The application was submitted mainly to change dimensions of the XL size of the valve as well as treatment processes for phospholipid reduction and calcification inhibition of the valve and add accessory kits. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Dec. 22, 2023 Total review time: 322 days Regulatory review time: 229 days	— Foreign clinical study results	19	VARIPULSE Pulsed Field Ablation Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A multielectrode catheter is used for conducting pulsed field ablation and cardiac electrophysiological mapping for the treatment of patients with drug-refractory symptomatic paroxysmal atrial fibrillation.
Cardiopulmonary Circulation	Dec. 22, 2023 Total review time: 322 days Regulatory review time: 231 days	— Foreign clinical study results	20	TRUPULSE Generator (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A generator that delivers pulsed field ablation energy for percutaneous myocardial catheter ablation is used for the treatment of patients with tachyarrhythmia.
Cardiopulmonary Circulation	Feb. 6, 2024 Total review time: 221 days Regulatory review time: 182 days	— No clinical study results	21	Paravalvular Leak Closure Set (Japan Lifeline Co., Ltd.)	Change	Medical products 4 Artificial pericardial prosthesis	A device consisting of an occluder, pusher, and loader intended to be used for percutaneous closure of a defect hole for prosthetic paravalvular regurgitation. This application was submitted mainly to add a pistol pusher. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Feb. 13, 2024 Total review time: 231 days Regulatory review time: 179 days	Jun. 17, 2015 Clinical evaluation report	22	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a method to deliver a prosthetic valve via the common carotid artery, which is a route to be considered for patients for whom the valve cannot be delivered safely via the femoral artery. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 5, 2024 Total review time: 151 days Regulatory review time: 118 days	— No clinical study results	23	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add ISO80369-7 to the applicable standards of plural connectors included in the components of this product and to add raw materials for the introducer and loader. (A "partial change" application submitted during the post-market performance review period)

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Improved Medical Devices (With Clinical Data) Approved in FY 2023

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Aug. 25, 2023 Total review time: 120 days Regulatory review time: 70 days	- Clinical evaluation report	1	Automated Synthesizer for Radiopharmaceuticals Synthera+ (CMI Inc.)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound, fluorodeoxyglucose (18F) injection and florbetaben (18F) injection used for positron emission tomography, by remote control system. This application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease to the indications of florbetaben (18 F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Sep. 28, 2023 Total review time: 300 days Regulatory review time: 227 days	- Foreign clinical study results	2	Dexcom G7 CGM System (Dexcom, Inc.)	Approval	Instrument & apparatus 20 Glucose monitor system	The application was submitted for marketing approval of a continuous glucose monitoring system that continuously measures glucose levels in the interstitial fluid in people with diabetes mellitus and displays the trends and the patterns of glucose fluctuation. The product is used for assisting the detection of hyperglycemia and hypoglycemia and daily self-management by people with diabetes mellitus.
Robotics, IoT, and other devices (not classified as other categories)	Oct. 30, 2023 Total review time: 168 days Regulatory review time: 131 days	- Clinical evaluation report	3	Radioactive Pharmaceutical Synthesizer FASTlab (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound injection by remote control system. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of flutemetamol (18F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 30, 2023 Total review time: 168 days Regulatory review time: 131 days	- Clinical evaluation report	4	Radioactive Pharmaceutical Synthesizer FASTlab 2 (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound injection by remote control system. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of flutemetamol (18F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Jan. 22, 2024 Total review time: 270 days Regulatory review time: 204 days	License date: May 2022 License No.: - Brand Name: FreeStyle Libre 3 Continuous Glucose Monitoring System Foreign clinical study results	5	FreeStyle Libre 3 (Abbott Japan LLC)	Approval	Instrument & apparatus 20 Glucose monitor system	The application was submitted for marketing approval of a glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen.
Robotics, IoT, and other devices (not classified as other categories)	Feb. 6, 2024 Total review time: 364 days Regulatory review time: 177 days	License date: Oct. 2017 License No.: K170840 Brand name: MAGNETOM Terra Clinical evaluation report	6	MAGNETOM Terra (Siemens Healthcare K.K.)	Approval	Instrument & apparatus 21 Superconducting magnet head/extremity imaging MRI system	The application was submitted for marketing approval of a superconducting magnet head/extremity imaging MRI system with a static magnetic field strength of 7T that performs computer processing magnetic resonance signals related to the patient's head or extremity and presents the reconstructed imaging for medical care purposes.
Orthopedic and Plastic Surgery	Jun. 12, 2023 Total review time: 252 days Regulatory review time: 175 days	Apr. --, 2004 K033801/KyphX HV-R Jul. --, 2004 K041584/KyphX HV-R Aug. --, 2010 K093828/KyphX HV-R Apr. --, 2015 K150460/KYPHON HV-R Aug. --, 2016 K160983/KYPHON HV-R May --, 2018 K180700/KYPHON HV-R Clinical evaluation report	7	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	An orthopedic bone cement used to restore the vertebral height of the fractured vertebral body and to relieve pain in patients with vertebral fracture due to osteoporosis, multiple myeloma, or metastatic bone tumor. The application was submitted to add the indication of simultaneous treatment of multiple vertebral bodies, to delete the indications restricted to primary osteoporosis and acute spinal compression fracture, and to add the indication for patients who are considered unlikely to respond to conservative therapy, in the case to use the medical device for vertebral fracture due to osteoporosis (A “partial change” application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Oct. 12, 2023 Total review time: 261 days Regulatory review time: 184 days	Jun. 9, 2005 Clinical evaluation report	8	Mendec Spine Bone Cement Kit (J-Sol Medical Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	An orthopedic bone cement used for percutaneous vertebroplasty and balloon kyphoplasty. The application was submitted to add the indication of simultaneous treatment of multiple vertebral bodies, to delate the indications restricted to primary osteoporosis and acute vertebral compression fractures, and to add the indication for patients who are considered unlikely to respond to conservative therapy, in the indications for osteoporosis for use in balloon kyphoplasty (A “partial change” approval application).
Orthopedic and Plastic Surgery	Feb. 15, 2024 Total review time: 290 days Regulatory review time: 252 days	Jul. 15, 2015 K150907/Ellipse Nordlys (with IPL and Nd: YAG hand pieces/applicators) Clinical evaluation report	9	Phototherapy Device for Skin Disease/Long-term Hair Reduction Nordlys (Syneron Candela K.K.)	Change	Instrument & apparatus 12 Phototherapy device for skin disease	A phototherapy device for skin diseases used to treat superficial skin benign pigmentary diseases, improve superficial telangiectasia symptoms in benign cutaneous vascular lesions, and achieve long-term hair reduction by thermal action of continuous spectral light from visible to infrared rays contained in intense pulse light. The application was submitted to add the long-term hair reduction to the indication of the product (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 3, 2023 Total review time: 264 days Regulatory review time: 116 days	Nov. 27, 2018 —/VASCADE MVP® Venous Vascular Closure System Foreign clinical study results	10	VASCADE MVP (Haemonetics Japan G.K.)	Approval	Medical products 4 Absorbable topical hemostatic material with collagen	The application was submitted for marketing approval of an absorbable topical hemostatic material with collagen used for hemostasis at the femoral venous access site following percutaneous catheterization. As clinical evaluation data, the results of foreign clinical studies were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 20, 2023 Total review time: 115 days Regulatory review time: 50 days	Sep. 2012 K121917/CAT/SEP 3 & 5 May 2015 K142870/CAT/SEP 6 & 8 Jul. 2016 K161523/CAT/SEP 6 & 8 May 2018 K180939/Aspiration Tubing Clinical evaluation report	11	INDIGO System (Penumbra, Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	The application was submitted for marketing approval of catheter for central circulatory embolectomy used to aspirate thrombus from a peripheral artery or vein. A clinical evaluation report summarizing foreign clinical studies and the contents of foreign literatures was submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2023 Total review time: 207 days Regulatory review time: 119 days	- Japanese clinical study results	12	Envi-SR Retriever for Mechanical Thrombectomy (NeuroVasc Technologies, Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy intended for use to restore blood flow in patients with acute ischemic stroke in whom intravenous tissue plasminogen activator (tPA) therapy is not indicated or fails to achieve reperfusion. As clinical evaluation data, the results of clinical studies conducted in Japan were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 8, 2023 Total review time: 269 days Regulatory review time: 156 days	Jun. 15, 2004 K040835/XenoSure Bioligic Patch Clinical evaluation report	13	Bovine Pericardium Patch XenoSure (LeMaitre Vascular G.K.)	Change	Instrument & apparatus 7 Bovine pericardial patch	A bovine pericardial patch used for repair or procedure of femoral artery, femoral vein, and carotid artery. The application was submitted to add an indication for carotid artery (A “partial change” application). The clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 29, 2023 Total review time: 320 days Regulatory review time: 194 days	Apr. 2022 —/Thoraflex Hybrid Foreign clinical study results	14	Thoraflex Hybrid (Terumo Corporation)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft and gelatin coated vascular graft used for surgical repair in patients with aneurysms or dissections of the aortic arch and descending aorta. The aortic stent graft and gelatin coated vascular graft are sutured and integrated in advance for the purpose of simplifying the procedure. The results of foreign clinical studies were submitted as clinical evaluation data.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 25, 2023 Total review time: 277 days Regulatory review time: 81 days	Mar. 23, 2021 K203592/Tigertriever Mar. 23, 2021 K203592/Tigertriever 17 Foreign clinical study results	15	Tigertriever Thrombectomy Device (Rapid Medical Ltd.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy that is intended for use to restore blood flow by removing clots from the intracranial blood vessel in patients with acute ischemic stroke (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with the t-PA therapy. The results of foreign clinical studies were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 10, 2023 Total review time: 221 days Regulatory review time: 78 days	Jul. 13, 2018 P170024/Surpass Evolve Flow Diverter Foreign clinical study results	16	Surpass Evolve Flow Diverter System (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	The application was submitted for marketing approval of a flow diverter system intended to be used for endovascular therapy for intracranial aneurysms that are difficult to treat surgically or by coil embolization with a maximum diameter of 10 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment to the supraclinoid segment of the internal carotid artery (except for the acute ruptured aneurysms).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 15, 2023 Total review time: 259 days Regulatory review time: 137 days	Sep. 11, 2016 K161519/NeuroStar TMS Therapy System Clinical evaluation report	17	NeuroStar TMS Therapy System (Neuronetics, Inc.)	Change	Instrument & apparatus 12 Magnetic stimulator for transcranial treatment	A repetitive transcranical magnetic stimulator that provides treatment for adult patients with Major Depressive Disorder (MDD) (only for the patients who have not benefitted from conventional antidepressant medication). The application was submitted to (1) enable to set the short intertrain interval (off-time) in the treatment protocol, (2) add the new model (Model 3) with a mechanism for cooling treatment coils, wide monitor and fingerprint recognition module, and (3) add the MT-cap and D-Tect as new accessories (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2023 Total review time: 907 days Regulatory review time: 215 days	— Clinical evaluation report	18	Thymatron (Koden Medical Co., Ltd.)	Change	Instrument & apparatus 12 Convulsive therapy brain electrical stimulator	An electrical stimulator for electroconvulsive therapy in patients with severe drug-resistant depression, manic depression, or schizophrenia who have strong suicidal tendency or rejection symptoms and require imminent treatment for life support. The application was submitted to add a model (Model 200) whose maximum output power was raised from 504 mC to 1,008 mC (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 13, 2024 Total review time: 270 days Regulatory review time: 179 days	Sep. 2014 PMA approved/GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface Foreign clinical study results and clinical evaluation report	19	Gore Viabahn Stent Graft (W. L. Gore & Associates, G.K.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft with nitinol stent wires wound around the outside of the graft (external stent structure type) and a delivery catheter. The application was submitted for an additional indication of in-stent restenosis lesions among symptomatic peripheral arterial diseases in the superficial femoral artery (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 27, 2024 Total review time: 271 days Regulatory review time: 105 days	May 25, 2018 No description/IN.PACT Admiral Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter Foreign clinical study results	20	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for balloon dilatation angioplasty	A paclitaxel-coated balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the superficial femoral and popliteal arteries. The application was submitted to add a balloon length of 250 mm and change the target maximum lesion length from 200 mm to 350 mm (A "partial change" application).
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 31, 2023 Total review time: 251 days Regulatory review time: 179 days	May 7, 2018 De Novo: DEN170015/Hemospray Endoscopic Hemostat Foreign clinical study results and clinical evaluation report	21	COOK Hemospray Endoscopic Non-absorbable Hemostatic Material (Cook Medical Japan G.K.)	Approval	Medical products 4 Non-absorbable topical hemostatic material	A non-absorbable hemostatic material is used to stop non-variceal gastrointestinal bleeding by endoscopically inserted into the gastrointestinal tract. The product is composed of hemostatic material and the delivery system.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary, and Reproductive Medicine	Jan. 26, 2024 Total review time: 217 days Regulatory review time: 116 days	Generator: Not licensed Electrode: Mar. 14, 2018 Clinical evaluation report	22	RFA Lesion System (Century Medical, Inc.)	Change	Instrument & apparatus 29 Radio-frequency ablation system	A radio-frequency ablation system used for coagulating and ablating tissues. The application was submitted to add the followings to the intended use of this product; "small malignant renal mass" as well as "pulmonary malignant tumor," "malignant bone tumor," "osteoid osteoma," "intrapelvic malignant tumor," and "soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity" that are ineligible for or refractory to standard therapy (A “partial change” application).
Dentistry and Oral Medicine	Jul. 11, 2023 Total review time: 476 days Regulatory review time: 276 days	- Japanese clinical study results	23	Blue Radical P-01 (Luke Co., Ltd.)	Approval	Instrument & apparatus 62 Ultrasonic periodontal scaler in combination with drugs	An ultrasonic periodontal scaler in combination with drugs is used for removing dental calculus and other deposits and sterilizing the base of periodontal pockets in the treatment of patients with periodontitis at stage III or IV. The product consists of a scaler tip attached handpiece, dedicated hydrogen peroxide solution, and laser unit.
Ophthalmology and Otorhinolaryngology	Aug. 18, 2023 Total review time: 233 days Regulatory review time: 190 days	- Clinical evaluation report	24	MED-EL Cochlear Implant System Mi1250 SYNCHRONY2 FLEX (MED-EL Elektro-Medizinische Ger äte GmbH)	Change	Medical products 4 Auditory electrical stimulator	An implant that constitutes cochlear implant system for severe hearing disabilities (CI) or patients with ski-slope hearing loss, in which there is good hearing for lower frequencies (EAS), who have not responded sufficiently to wearing hearing aids. The application was submitted to add the FLEX electrode included in the company's approved implant "MED-EL Cochlear Implant SYNCHRONY2" (Approval No.: 30400BZI00025000) used only for CI indicated patients to this product so that it can be used for EAS indicated patients (A “partial change” application).
Ophthalmology and Otorhinolaryngology	Nov. 21, 2023 Total review time: 265 days Regulatory review time: 156 days	- Japanese clinical study results	25	Vivinex Gemetric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of an aphakic eye.
Ophthalmology and Otorhinolaryngology	Nov. 21, 2023 Total review time: 265 days Regulatory review time: 192 days	- Japanese clinical study results	26	Vivinex Gemetric Toric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of aphakic eyes with corneal astigmatism.
Cardiopulmonary Circulation	Apr. 25, 2023 Total review time: 827 days Regulatory review time: 485 days	- Clinical evaluation report	27	Filtrap (Nipro Corporation)	Change	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	A basket catheter set that is temporarily placed in the blood vessel to capture or remove intravascular foreign matters such as floating thrombus and blood clots. The application was submitted to add the intended use of capture or removal of substances causing embolization during percutaneous coronary intervention in patients with acute coronary syndrome in whom a large amount of plaque at a high risk for distal embolization was found in the native coronary lesions on intravascular imaging (A “partial change” application).
Cardiopulmonary Circulation	Apr. 26, 2023 Total review time: 295 days Regulatory review time: 181 days	- Clinical evaluation report	28	OSYPKA TMA (Heiwa Bussan Co., Ltd.)	Approval	Instrument & apparatus 7 Extracorporeal pacemaker electrode wire	A wire-type cardiac electrode that is connected to the external pacemaker "OSYPKA DefiPace" (Approval No.: 30500BZX00068000) for temporary cardiac pacing after open heart surgery. When the product is placed in both atria, biatrial pacing and cardioversion for atrial fibrillation can be performed.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	May 29, 2023 Total review time: 935 days Regulatory review time: 240 days	- Clinical evaluation report	29	External Ventricular Assist Device EVAD (Sun Medical Technology Research Corp.)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	A single-use extracorporeal assistant artificial cardiac pump used to maintain normal systemic circulation including the heart itself and improve cardiac insufficiency in patients with severe heart failure exceeding the limit of treating with conventional medication or existing assisted circulation (such as intra-aortic balloon pumping or venoarterial bypass) due to severe heart failure or cardiogenic shock. The device consists of the internal components of the inflow cuff and outflow graft, external components such as the cannula carrying blood into and from the body, blood pump, and controller, and accessories. They are identical to those of the company's approved product "implantable Ventricular Assist System EVAHEART" (Approval No.: 22200BZX00939000) except for the cannula and tunneler.
Cardiopulmonary Circulation	Jul. 27, 2023 Total review time: 269 days Regulatory review time: 92 days	– Japanese clinical study results	30	Soft Life-size 3D Cardiac Model (crossMedical, Inc.)	Approval	Instrument & apparatus 21 Heart model supporting surgical plan	A 3D life-size cardiac model created based on multi-slice CT image information for patients with complex congenital heart disease for which diagnosis and surgical procedure are difficult to be determined with conventional diagnostic imaging. The product is provided in order to diagnose the cardiac structure of complex congenital heart diseases for which it is difficult to diagnose or determine surgical procedures with conventional diagnostic imaging, and it is used with other medical information to support the planning of surgery.
Cardiopulmonary Circulation	Aug. 8, 2023 Total review time: 246 days Regulatory review time: 105 days	– Japanese clinical study results and clinical evaluation report	31	SeQuent Please Neo Drug Eluting Balloon Catheter (Nipro Corporation)	Change	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A catheter for coronary balloon dilatation angioplasty with a paclitaxel-coated balloon to inhibit restenosis in revascularization. The product is used for coronary in-stent restenosis lesions and de novo coronary lesions. The application was submitted to expand the indication of de novo coronary artery lesions with a reference vessel diameter of 3.0 mm or greater and add a balloon size (A "partial change" application).
Cardiopulmonary Circulation	Sep. 28, 2023 Total review time: 189 days Regulatory review time: 121 days	Jan. 22, 2021 Foreign clinical study results	32	Synergy Megatron Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consists of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo coronary artery lesions at the length of 28 mm or less with a reference vessel diameter of 3.50-5.00 mm, and a delivery catheter to implant a stent to the target lesion.
Cardiopulmonary Circulation	Nov. 29, 2023 Total review time: 61 days Regulatory review time: 55 days	- Clinical evaluation report	33	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon-type laser ablation catheter with an endoscope. The application was submitted to add the treatment of drug-resistant recurrent symptomatic persistent atrial fibrillation to the conventional intended use (treatment of drug-resistant recurrent symptomatic paroxysmal arterial fibrillation) (A "partial change" application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Program	May 23, 2023	1) IRNF Version 2.0 License date: Oct. 22, 2021 License No.: K212516 Brand name: IRNF App Number of units shipped: -- 2) IRNF Version 1.0 License date: Sep. 11, 2020 License No.: DEN180042 Brand name: Irregular Rhythm Notification Feature Number of units shipped: 397,800 (2018), 4499,700 (2019), 3922,500 (2020)	34	Apple's Irregular Rhythm Notification Feature (Apple Inc.)	Change	Program 1	A home-use program that analyzes pulse rate data, detects irregular heartbeats suggestive of atrial fibrillation and notifies the user. The application was submitted to change the requirements for the platform to install the product and the classification algorithms to classify irregular heartbeats (A “partial change” application). Data on the platform study under the changed platform requirements and data on validation of the algorithm were submitted. Also, a clinical evaluation report summarizing the contents of foreign clinical literatures, etc. was submitted as data related to results of clinical study results.
	Total review time: 323 days Regulatory review time: 84 days	Clinical evaluation report				Software for home use heart rate monitor	
Program	Aug. 8, 2023	May 30, 2019	35	Medis QFR (Medis medical imaging systems)	Approval	Program 1	Software that calculates QFR (Quantitative Flow Ratio) and supports the diagnosis of patients suspected of having coronary artery disease by reconstructing a three-dimensional model of the coronary artery from angiographic projections and performing numerical analyses.
	Total review time: 252 days Regulatory review time: 161 days	Japanese clinical study results				Analyzing software for hemodynamics or cardiac function	
Program	Oct. 5, 2023	—	36	MIREVO (Ai-BrainScience Inc.)	Approval	Program 1	The application was submitted for marketing approval of a program to continuously collect information on patient’s gaze for use in neuropsychological assessment in order to support medical care for patients with dementia.
	Total review time: 646 days Regulatory review time: 502 days	Japanese clinical study results				Neuropsychological assessment application program	

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Reprocessed Single-Use Medical Devices Approved in FY2023

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company))	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 31, 2023	—	1	Reprocessed Stabilizer G (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 42	A reprocessed single-use medical device originated from the existing certified device "ACROBAT-i stabilizer" (Certification No.: 224AABZX00035000), which is an organ fixation pelotte used to partially immobilize areas around the blood vessel undergoing surgery for stabilizing the anastomotic site under pulsatile conditions during cardiac surgery using sternotomy.
	Total review time: 456 days Regulatory review time: 308 days	No clinical study results				Reprocessed single-use organ fixation pelotte	
Cardiopulmonary Circulation	Mar. 14, 2024	-	2	Reprocessed Loop Electrode Catheter (Stryker Japan) (Stryker Japan K.K.)	Change	Instrument & apparatus 51	A reprocessed single-use medical device originating from “LASSO 2515” (Approval No. 21600BZY00209000) and “LASSO 2515 Navi” (Approval No. 22200BZX00740000), which is a cardiac catheter-tip electrode and is used percutaneously and transluminally placed in the heart to perform a cardiac electrophysiological study and temporary pacing. The application was submitted to change the manufacturing process (A "partial change" application).
	Total review time: 87 days Regulatory review time: 45 days	No clinical study results				Reprocessed cardiac catheter-tip electrode	

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New Medical Devices Approved in FY2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Apr. 26, 2022	-	1	nodoca (Aillis, Inc.)	Approval	Instrument & apparatus 25	A system used as an aid in the diagnosis of influenza virus infection by photographing pharynx and analyzing findings of pharynx such as lymph tissue on the images (including the tonsils and lymph follicles) and clinical data to detect findings, symptoms, etc. characteristic to influenza virus infection. It is not intended to make a definitive diagnosis based only on the analysis results of this product.
	Total review time: 322 days Regulatory review time: 206 days	Japanese clinical study results				Endoscopic telescope	
Orthopedic and Plastic Surgery	Nov. 28, 2022	-	2	AutoloGel System (Rohto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 7	A kit used to prepare autologous platelet-rich plasma (PRP) gel for promoting healing or covering of wounds that have not responded to conventional treatments. PRP is obtained by centrifugation of patient's own blood, and it changes from liquid to gel by mixing the drugs as components of the product. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 363 days Regulatory review time: 197 days	Japanese clinical study results				Platelet-rich plasma gel preparation kit	
Orthopedic and Plastic Surgery	Dec. 22, 2022	Feb. 2021 K202112/DUOLITH SD1 T-Top&Tower System with C-ACTOR Sepia Handpiece *Obtained 510(k) clearance as a treatment device for diabetic foot ulcer	3	DUOLITH SD1 Ultra (Karl Storz Endoscopy Japan K.K.)	Change	Instrument & apparatus 12	An extracorporeal shockwave pain treatment device designed to enable adjustment of output by the conventional electromagnetic induction-type extracorporeal shock wave lithotripter to the low power output. The application was submitted to add the indication of “refractory ulcer in patients with systemic scleroderma” as the “intended use or indication” of the product (A “partial change” application). The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 420 days Regulatory review time: 197 days	Japanese clinical study results				Extracorporeal shockwave pain treatment device	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 14, 2022	Turbo Power series Nov. 12, 2015 K152181/Turbo Power Laser Atherectomy Catheter Turbo Elite series Jul. 23, 2014 K140775/Turbo Elite Atherectomy Catheter	4	Excimer Laser Turbo Power Catheter (Philips Japan Ltd.)	Approval	Instrument & apparatus 51	A laser angioplasty catheter used in percutaneous endovascular treatment for lesions of restenosis or reocclusion that occur within a stent placed in the femoropopliteal artery. The product is used with an exclusive laser console, “Excimer Laser Angioplasty Device” (Approval No. 21300BZY00528000), and is used an atherectomy device used to treat stenosis of lesions by vaporizing the tissue with limited heat damage to the surroundings using an excimer laser at a wavelength of around 308 nm.
	Total review time: 363 days Regulatory review time: 71 days	No clinical study results				Laser angioplasty catheter	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2022	Apr. 1, 2011 P100040 /Valiant Thoracic Stent Graft System with the Captivia Delivery System	5	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A stent graft system used for treatment of thoracic aorta. The application was submitted to add the indication for "chronic complicated Stanford type B aortic dissections (including dissecting aortic aneurysm)" to the intended use. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 160 days Regulatory review time: 58 days	Clinical evaluation report				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 8, 2022	Apr. 30, 2014 P130008/INSPIRE II UPPER AIRWAY STIMULATOR May 5, 2017 P130008/S016/INSPIRE UPPER AIRWAY STIMULATOR MODEL 3028 [Additional type in this application] Lead: Approved Programmer for patients: Approved	6	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure therapy (CPAP). The application was submitted to add a new model aiming at improving the convenience of a programmer for patients, stimulation lead, and sensor lead. (A “partial change” application submitted during the post-market performance review period)
	Total review time: 171 days Regulatory review time: 121 days	No clinical study results				Hypoglossal nerve stimulator	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022	Mar. 10, 2016 K153485/ENROUTE Transcarotid Neuroprotection System	7	ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 51	A device used to prevent embolization by transcarotid vascular access during carotid angioplasty and stent placement in patients with carotis stenosis. The results of foreign clinical study were submitted.
	Total review time: 512 days Regulatory review time: 259 days	Foreign clinical study results				Central circulatory catheter for trapping embolus	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 28, 2022	Jun. 29, 2018 P180002/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM Jul. 30, 2019 P180002/S005/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM Nov. 13, 2019 P180002/S010/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	8	Zephyr Endobronchial Valve System (Pulmonx Corporation)	Approval	Instrument & apparatus 7	An endobronchial valve used in patients who have severe chronic obstructive pulmonary disease with severe emphysema and hyperinflation and are receiving optimal non-invasive treatment and also whose physiological examination shows little to no collateral ventilation between adjacent pulmonary lobes. The results of foreign clinical studies were submitted.
	Total review time: 347 days Regulatory review time: 204 days	Foreign clinical study results				Endobronchial valve	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 22, 2022	Oct. 9, 2020 P200023/Zilver Vena Venous Self-Expanding Stent	9	Zilver Vena Venous Stent (Cook Medical Japan G.K.)	Approval	Instrument & apparatus 7	A venous stent used to maintain the lumen of the iliofemoral vein for symptomatic iliofemoral venous outflow obstruction that is difficult to treat with conventional therapies. The results of foreign clinical study were submitted.
	Total review time: 261 days Regulatory review time: 88 days	Foreign clinical study results				Venous stent	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 27, 2023	Mar. 13, 2019 P180037/Venovo Venous Stent System	10	VENOVO Venous Stent System (Medicon, Inc.)	Approval	Instrument & apparatus 7	A venous stent used to maintain the lumen of the iliofemoral vein for symptomatic iliofemoral venous outflow obstruction that is difficult to be treated with conventional therapies. The results of foreign clinical studies were submitted.
	Total review time: 266 days Regulatory review time: 50 days	Foreign clinical study results				Venous stent	
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 10, 2022	-	11	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7	A cytapheresis column to selectively adsorb and remove granulocytes and monocytes in peripheral blood by performing direct hemoperfusion using an extracorporeal circulation column which is filled with an adsorbent carrier made of cellulose acetate. The application was submitted to mainly extend the shelf life and revise the approved items (specifications related to performance and safety). (A "partial change" application submitted during the post-market performance review period)
	Total review time: 133 days Regulatory review time: 101 days	No clinical study results				Cytapheresis column	
Cardiopulmonary Circulation	May 18, 2022	Mar. 30, 2018 P050006/S60/GORE CARDIOFORM SEPTAL OCCLUDER	12	GORE Cardioform Septal Occluder (W. L. Gore & Associates G.K.)	Approval	Medical products 4	This product is a percutaneous, transcatheter patent foramen ovale (PFO) closure device. This treatment is intended to close the PFO to reduce the risk of recurrence of ischemic stroke in patients who have had a cryptogenic stroke with possible involvement of a PFO due to a presumed paradoxical embolism. Data from the results of foreign clinical studies were submitted.
	Total review time: 359 days Regulatory review time: 134 days	Foreign clinical study results				Artifitial pericardial prosthesis	
Cardiopulmonary Circulation	Aug. 2, 2022	Jul. 28, 2022 P140031 S141/SAPIEN 3 Ultra RESILIA	13	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add RESILIA-treated bioprosthetic valve models and a loader for 29-mm valve and a new introducer sheath set for the transfemoral/trans-subclavian/axillary approach. (A “partial change” application submitted during the post-market performance review period)
	Total review time: 165 days Regulatory review time: 100 days	No clinical study results				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Aug. 17, 2022	Aug. 23, 2017 P160054/Heart Mate3 Left Ventricular Assist System Nov. 24, 2021 P160054/S040 Alternative Apical felt material supplier addition	14	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7	The device is an implantable ventricular assist device system used to assist the blood circulation for severe cardiac failure in patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system. The application was submitted to add a raw material for an apical cuff and coring tool as a surgical accessory. (A “partial change” application submitted during the post-market performance review period)
	Total review time: 111 days Regulatory review time: 104 days	No clinical study results				Implantable assistant artificial heart system	

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Cardiopulmonary Circulation	Sep. 27, 2022 Total review time: 363 days Regulatory review time: 220 days	Sep. 9, 2020 P140031 S112/TAV in TAV Foreign registry	15	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add an indication of symptomatic valvular disease attributed to dysfunction of implanted transcatheter aortic bioprosthesis in patients who are not eligible for surgery. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Oct. 31, 2022 Total review time: 137 days Regulatory review time: 84 days	Sep. 19, 2019 No clinical study results	16	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This device has been approved for the indication in patients with symptomatic valvular disease due to dysfunction of a surgically placed bioprosthetic aortic valve, and who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option. The application was submitted for an additional type of surgical valve designed for the indication. (A “partial change” application).
Cardiopulmonary Circulation	Jan. 17, 2023 Total review time: 158 days Regulatory review time: 133 days	Aug. 12, 2021 No clinical study results	17	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a bioprosthetic valve with a frame to which 3 gold markers were added to improve visibility and a delivery catheter system specific to the model (A “partial change” application).
Cardiopulmonary Circulation	Feb. 7, 2023 Total review time: 119 days Regulatory review time: 118 days	- No clinical study results	18	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a manufacturing site. (A “partial change” application submitted during the post-market performance review period)
Program	Apr. 26, 2022 Total review time: 334 days Regulatory review time: 143 days	- Japanese clinical study results	19	CureApp HT Digital Therapeutic App for Hypertension Adjunctive Treatment (CureApp Inc.)	Approval	Program 2 Supporting software for hypertension treatment	The application was submitted for marketing approval of a supporting software for hypertension treatment used to support the treatment of hypertension by helping to modify lifestyle in the treatment of hypertension in patients with essential hypertension.
Program	Sep. 29, 2022 Total review time: 363 days Regulatory review time: 260 days	- Japanese clinical study results	20	Syringe Pump Control Software for Assisting Total Intravenous Anesthesia (Nihon Kohden Corporation)	Approval	Program 2 Software for automated drug delivery for general anesthesia	The application was submitted for marketing approval of a software that controls the dose of sedatives, analgesics, and muscle relaxants by controlling the concomitantly used syringe pumps under the supervision of anesthesiologists in surgeries in which general anesthesia is provided with intravenous anesthetics.
Program	Feb. 15, 2023 Total review time: 378 days Regulatory review time: 213 days	- Japanese clinical study results	21	SUSMED Med CBT-i App for Insomnia (Susmed, Inc.)	Approval	Program 2 Software for insomnia	The application was submitted for marketing approval of a software for insomnia that supports cognitive behavioral therapy provided by physicians for the treatment of insomnia.

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Improved Medical Devices (With Clinical Data) Approved in FY2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	May 10, 2022 Total review time: 327 days Regulatory review time: 266 days	Date of license: Mar. 27, 2018 License No.: DEN170088 Foreign clinical study results	1	Dexcom G6 CGM System (Dexcom. Inc.)	Change	Instrument & apparatus 20 Glucose monitor system	The device is a glucose monitor system which is intended to measure, record and display fluctuation patterns continuously. The application was submitted to change the intended use in association with the clinical standpoint of the product as management of daily blood glucose based on information regarding glucose levels in the interstitial fluid obtained from the product (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 24, 2022 Total review time: 423 days Regulatory review time: 255 days	Progressive incurable neuromuscular diseases (8 diseases) Date of license: Oct. 2, 2020, 510k (License No. K201559) Japanese clinical study results	2	HAL for Medical USE (Lower Limb Type) (CYBERDYNE Inc.)	Change	Instrument & apparatus 58 Physiological signal use motion function improvement supporting system	The device is used to improve the gait function through repeated gait exercise with assistance for the movement of the lower limbs based on biological signals by wearing the device intermittently. This application was submitted to add patients with declined gait instability due to HTLV-1 associated myelopathy or spastic paraplegia resulting from hereditary spastic paraplegia to the indication for this device (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 27, 2022 Total review time: 268 days Regulatory review time: 162 days	- Clinical evaluation report	3	NanoZoomer S360MD Slide scanner system (Hamamatsu Photonics K.K.)	Approval	Instrument & apparatus 21 Diagnostic assistant device for pathological whole slide image	The application was submitted for marketing approval of a diagnostic assistant device for pathological whole slide image, which is intended to assist pathologists to evaluate and diagnose high magnification digital images of whole pathological slide samples. This product automatically creates, displays, and stores pathological whole slide images.
Robotics, IoT, and other devices (not classified as other categories)	Feb. 24, 2023 Total review time: 270 days Regulatory review time: 219 days	- Foreign clinical study results	4	Medtronic Guardian Connect (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 20 Glucose monitor system	The device is a glucose monitor system that continuously measures glucose levels in the interstitial fluid under the skin in persons with diabetes mellitus. The application was submitted to add a new transmitter and sensor to the component in order to reduce the number of calibrations by self-monitoring of blood glucose levels and improve the reliability of sensor glucose value obtained by using the product, and to change the clinical positioning of the product in daily blood glucose management when using the component (A “partial change” application). The results of foreign clinical studies showing that the product or its equivalent can similarly make the blood glucose management to using a blood glucose self-monitoring device were submitted. In addition, the results of foreign clinical studies demonstrating that the accuracy of the glucose levels measured by the product was acceptable to be used as an aid for management of self-monitoring blood glucose level for patients with diabetes mellitus were submitted.
Robotics, IoT, and other devices (not classified as other categories)	Feb. 24, 2023 Total review time: 270 days Regulatory review time: 236 days	Date of license: Under review License No.: - Brand name: MiniMed 780G System Number of units shipped: - Foreign clinical study results	5	Medtronic MiniMed 700 Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 74 Portable insulin infusion pump	An insulin pump used for continuous subcutaneous infusion of basal insulin at a selected rate and bolus infusion of insulin at a selected dose. The application was submitted mainly to add a new model of portable insulin infusion pump, in which a function to automatically inject correction bolus insulin based on glucose concentration in interstitial fluid obtained from the product was added to the AutoMode automatically injecting basal insulin, and a transmitter and sensor that can be used with the pump to the component (A “partial change” application). The results of foreign clinical studies evaluating the efficacy and safety of the product using the automatic mode were submitted.

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Orthopedic and Plastic Surgery	Apr. 7, 2022 Total review time: 765 days Regulatory review time: 701 days	- Japanese clinical study results	6	Medicarbo Hip Nail (B.I.TEC Co., Ltd.)	Approval	Medical products 4 Implantable femur intramedullary fixation nail	An implantable femur intramedullary fixation nail that is inserted into the medullary cavity of the femur for fixation or stabilization of fracture of the base of the femoral neck or trochanteric femoral fracture. Carbon fiber reinforced PEEK resin is used as the raw material for the nail and lag screw body contained in the component. The results of a Japanese clinical study conducted as a multicenter, single-arm, open-label design were submitted to evaluate the performance of this product for bone union as well as malfunctions and adverse events.
Orthopedic and Plastic Surgery	Sep. 6, 2022 Total review time: 258 days Regulatory review time: 175 days	Jun. 8, 2007 K062937X/COOLIEF* Cooled Radiofrequency Sterile Tube Kit Dec. 16, 2016 K163236/COOLIEF* Radiofrequency Fluid Delivery Introducer Apr. 13, 2017 K163461/COOLIEF* Cooled Radiofrequency Probe Feb. 21, 2020 K192491/COOLIEF* Pain Management RF Generator System Dec. 22, 2020 K203066 COOLIEF* Cooled Radiofrequency Kit Advanced Foreign clinical study results	7	Coolief Radiofrequency Pain Management System (Avanos Medical Japan Inc.)	Approval	Instrument & apparatus 29 Electrosurgical unit for cardiac ablation	An electrosurgical unit for ablation to treat pain by supplying a high-frequency current to the peripheral nerve to warm and coagulate (cauterize) the nerve in patients with chronic pain associated with knee osteoarthritis who are not candidates for orthopedic surgery and do not respond to conventional conservative therapy. The product can also be used to treat chronic pain of the face, neck, and back. The results of foreign clinical studies in which the effectiveness of product was compared with that of adrenocorticosteroid injection for pain relief in patients with chronic knee pain due to knee osteoarthritis were submitted.
Orthopedic and Plastic Surgery	Oct. 14, 2022 Total review time: 261 days Regulatory review time: 139 days	2012 Classification I *510(k) exemption/overseas brand name: StrataXRT Clinical evaluation report	8	Radiation Dermatitis Film-forming Material StrataXRT (Toyo Medic Co., Ltd.)	Approval	Medical products 4 Local control hydrogel dressing	A local control hydrogel dressing made of silicone gel used to reduce skin disorders caused by irradiation and promote healing. The product was developed to cover the inflammatory area and maintain a moist environment for the purpose of promoting healing of radiation dermatitis. A clinical evaluation report summarizing foreign clinical literatures, etc. was submitted to evaluate that this product is effective in suppressing or improving the severity of radiation dermatitis and that there are no risks of adverse events specific to this product.
Orthopedic and Plastic Surgery	Jan. 13, 2023 Total review time: 276 days Regulatory review time: 191 days	Jun. 9, 2005 K042415/Mendec Spine Clinical evaluation report	9	Conamon PVP Kit (J-Sol Medical Co., Ltd.)	Approval	Medical products 4 Orthopedic bone cement	An orthopedic bone cement used for percutaneous vertebroplasty. It mainly consists of a polymethyl methacrylate bone cement and instruments used for preparation (mixer, injector, and needle). The bone cement of the product is identical with the company's approved product "Mendec Spine Bone Cement Kit" (22800BZX00185000), which has approval for the indication of painful vertebral fracture due to malignant spinal tumor. The difference from the approved product is that the indication of vertebral fracture due to osteoporosis is included in addition to the indication of the approved product.
Orthopedic and Plastic Surgery	Mar. 3, 2023 Total review time: 150 days Regulatory review time: 67 days	Jul. 15, 2015 K150907/Ellipse Nordlys (with IPL and Nd: YAG hand pieces/applicators) Clinical evaluation report	10	Phototherapy Device for Skin Disease Nordlys (Syneron Candela K.K.)	Change	Instrument & apparatus 12 Phototherapy device for skin diseases	A phototherapy device for skin diseases used to treat superficial skin benign pigmentary diseases and superficial telangiectasia symptoms in benign cutaneous vascular lesions by thermal action of continuous spectral light from visible to infrared rays contained in intense pulse light. The application was submitted to add the treatment of superficial telangiectatic symptoms to the indication of the product (A "partial change" application).

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 28, 2022 Total review time: 260 days Regulatory review time: 77 days	- Clinical evaluation report	11	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51 Catheter for balloon dilatation angioplasty	A catheter for balloon dilatation angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery. The balloon surface of this product is coated with a drug primarily composed of paclitaxel. The application was submitted for additional indications of in-stent restenotic lesions and long lesions up to 30 cm in length and the addition of the balloon length associated with the additional indication (A "partial change" application). A clinical evaluation report summarizing the results of foreign clinical studies, etc. evaluating the efficacy and safety of the product for in-stent restenotic lesions and long lesions were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 26, 2022 Total review time: 268 days Regulatory review time: 124 days	- Japanese clinical trial results	12	PENTAS Stent (PENTAS Inc.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	A self-expandable assist stent used to prevent a coil mass from protruding into and dropout from the parent artery during the coil embolization treatment in patients with a parent artery with a diameter of 2.5-4.6 mm among patients with unruptured cerebral aneurysm (the maximum diameter of 5 mm or greater) that are difficult to be treated with surgery or coil embolization with embolic coil alone and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2). The product was developed as a stent expected to have the maximum blood flow suppression effect with the minimum metal area. An available treatment planning program is included to supplementally support the stent placement. The results of Japanese clinical studies were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 29, 2022 Total review time: 154 days Regulatory review time: 131 days	(Approved size) Mar, 2014 P120020/Supera Peripheral Stent System (LV size) May 2021 P120020, S026/Supera Peripheral Stent System Clinical evaluation report	13	Supera Stent (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 7 Vascular stent	A self-expanding vascular stent used for the treatment of symptomatic vascular disease with a reference vessel diameter of 4.0-7.5mm and a lesion length up to 140 mm in the superficial femoral artery and proximal popliteal artery, and for the treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The application was submitted for an additional stent size of 7.0 mm and 7.5 mm in diameter (reference vessel diameter 6.5-7.5 mm) (A "partial change" application). As clinical evaluation data, a clinical evaluation report summarizing the results of additional analysis of foreign clinical studies using the approved size, foreign literature on the additional size and approved size, and the clinical usage in Japan and foreign countries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 27, 2022 Total review time: 179 days Regulatory review time: 100 days	Aug. 2021 Not described/RelayPro Thoracic Stent Graft System Foreign clinical study results	14	RelayPro Thoracic Stent Graft System (Terumo Corporation)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for endovascular treatment of descending thoracic aorta. The application was submitted to add “acute complicated Stanford type B aortic dissection” as the “intended use or indication” of the product (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022 Total review time: 512 days Regulatory review time: 215 days	May 18, 2015 P140026/ENROUTE Transcarotid Stent System Foreign clinical study results	15	ENROUTE Transcarotid Stent System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 7 Carotid artery stent	A stent system is used for extending and maintaining the vascular lumen through a transcarotid approach to be inserted and placed in the site of stenosis in the cervical carotid artery (common carotid artery, internal carotid artery). The results of foreign clinical study were submitted.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 8, 2023 Total review time: 188 days Regulatory review time: 76 days	- Foreign clinical study results	16	Medtronic Inceptiv (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief used to relieve chronic intractable pain by applying an electrical stimulation to the spinal epidural space. A function to sense evoked compound action potentials (ECAPs) from the spinal cord (ECAP sensing) and automatically optimize the stimulus strength (neurosensing function) were installed based on the company's approved product "Intellis" (Approval No. 22900BZX00255000). ECAP sensing and neurosensing function reduce hyperstimulation and discomfort caused by the momentary approach of the distance between the spinal cord and lead, such as coughing and sneezing. The results of foreign clinical studies to evaluate the efficacy and safety of ECAP sensing and neurosensing function were submitted.
Gastroenterology, Genitourinary, and Reproductive Medicine	Jul. 4, 2022 Total review time: 193 days Regulatory review time: 144 days	- Clinical evaluation report	17	Niti-S EUS-BD System (Century Medical, Inc.)	Approval	Instrument & apparatus 51 Transgastric biliary drainage stent	The product is a stent for maintaining the drainage route between the punctured gastrointestinal tract and bile duct in endoscopic ultrasound-guided biliary drainage (EUS-BD). The application was submitted to expand the indication of the company's approved product "Niti-S Biliary Silicone Covered Stent (Approval No.: 22200BZX00699000)" to EUS-BD. The clinical evaluation report on the treatment outcome of EUS-BD using the product was submitted.
Gastroenterology, Genitourinary, and Reproductive Medicine	Sep. 9, 2022 Total review time: 528 days Regulatory review time: 135 days	Sep. 29, 2010 (Proposed product: Jan. 23, 2018)/ Not described/C2 Cryo Ballon Ablation System Clinical evaluation report	18	C2 CryoBalloon Ablation System (HOYA Corporation)	Approval	Instrument & apparatus 31 General-purpose cryosurgical unit	A general-purpose cryosurgical unit for endoscopic cryoablation of lesion tissue in patients with Barrett's esophageal lesion associated with dysplasia or non-invasive adenocarcinoma. The product consists of a balloon catheter and a controller that sprays and exhausts nitrous oxide gas. By spraying nitrous oxide gas into the balloon, cryoablation can be provided to the lesion based on the principle of adiabatic expansion. A clinical evaluation report was submitted to evaluate the clinical efficacy and safety of cryoablation of lesions.
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 30, 2023 Total review time: 113 days Regulatory review time: 81 days	- Clinical evaluation report	19	EBL Device (SB-Kawasumi Laboratories, Inc.)	Change	Instrument & apparatus 30 Endoscopic loop ligator	An endoscopic loop ligator to be mounted on the tip of an endoscope and to be used to ligate internal hemorrhoid, colonic diverticula bleeding points, or neuroendocrine tumor (rectal NET) with a diameter of less than 10 mm developed in the rectum with an O-ring by drawing them into the device. The application was submitted to expand the indication of the device to draw and ligate rectal NET using the product in the ESMR-L method (A "partial change" application). The clinical evaluation reports were attached for the clinical efficacy and safety evaluation of the ESMR-L method using this product.
Dentistry and Oral Medicine	Sep. 9, 2022 Total review time: 247 days Regulatory review time: 193 days	- Japanese clinical study results	20	Apajet (Sangi Co., Ltd.)	Approval	Instrument & apparatus 60 Tooth surface coating spray device	A tooth surface coating spray device with which the tooth surface is coated with hydroxyapatite layer to suppress hypersensitivity of dentin or formed dentin and reline the cavity containing dentin. The results of Japanese clinical studies conducted to verify the efficacy and safety based on novelty of the principle of coating the tooth surface by spraying the dedicated powder were submitted.
Ophthalmology and Otorhinolaryngology	Jun. 2, 2022 Total review time: 269 days Regulatory review time: 191 days	Nov. 21, 2016 Foreign clinical study results	21	WaveLight EX 500 (Alcon Japan Ltd.)	Change	Instrument & apparatus 31 Ophthalmic corneal surgery laser system	An ophthalmic corneal surgery laser system for correction of refractive error or resection of corneal lesions by removing corneal tissues using laser irradiation. The application was submitted to mainly add photorefractive keratectomy (PRK) to the intended use (A "partial change" application).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Sep. 6, 2022 Total review time: 253 days Regulatory review time: 157 days	- Foreign and Japanese clinical study results	22	FINEVISION HP (Beaver-Visitec International Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	The application was submitted for marketing approval of a multifocal posterior chamber lens to be inserted as a substitute for the crystalline lens in the posterior chamber to correct near, intermediate, and far vision of an aphakia eye.
Ophthalmology and Otorhinolaryngology	Sep. 20, 2022 Total review time: 267 days Regulatory review time: 192 days	- Japanese clinical study results	23	Avansee Preload1P Toric (Kowa Company, Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of posterior chamber lens with inserter having cylindrical refractivity, which is intended to be used for visual correction of corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022 Total review time: 224 days Regulatory review time: 169 days	- Foreign clinical study results	24	Airy One Day (HOYA Corporation)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel with a water content of 48% and an oxygen permeability (Dk) of 112 × 10^{-11} (cm^2/sec)·(mLO_2/[mL × mmHg]).
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022 Total review time: 224 days Regulatory review time: 169 days	- No clinical study results	25	hoyaONE treasured (HOYA Corporation)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	A product with multiple brand name of "Airy One Day."
Ophthalmology and Otorhinolaryngology	Dec. 21, 2022 Total review time: 337 days Regulatory review time: 177 days	Jul. 26, 2021 510(k) LTF K193500 and DEN200028/OptiLight System Foreign clinical study results	26	OptiLight M22 IPL model (Lumenis Be Japan K.K.)	Approval	Instrument & apparatus 12 Xenon beam light therapy unit	The application was submitted for marketing approval of a xenon beam light therapy unit used to improve blood flow and relieve pain and inflammation by hyperthermia effect and for providing localized heat to the eyelids in patients with meibomian gland dysfunction.
Ophthalmology and Otorhinolaryngology	Feb. 8, 2023 Total review time: 267 days Regulatory review time: 104 days	- Japanese clinical study results	27	Clareon Aspheric PanOptix TORIC Trifocal Hydrophobic Acrylic IOL (Alcon Japan Ltd.)	Change	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens in the posterior chamber to correct near, intermediate, and far vision of an aphakic eyes with corneal astigmatism. The application was submitted to add a model with a cylindrical power of 1.00 D to deal with correction of lower power of astigmatism (A “partial change” application).
Ophthalmology and Otorhinolaryngology	Feb. 24, 2023 Total review time: 275 days Regulatory review time: 202 days	Jan. 26, 2022 Unlisted/Clareon Vivity Extended Vision Hydrophobic IOL with the AutonoMe Automated Pre-loaded Delivery System (CNAET0) Foreign clinical study results	28	Clareon Vivity Extended Vision IOL AutonoMe Automated Preload Delivery System (Alcon Japan Ltd)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of posterior chamber lenses with inserter preloaded with a multifocal intraocular lens which is used to correct near, intermediate, and far vision of an aphakic eye and reduce spectacle dependence.
Ophthalmology and Otorhinolaryngology	Mar. 22, 2023 Total review time: 295 days Regulatory review time: 254 days	Sep. 13, 2016 Foreign clinical study results	29	VisuMax Femtosecond Laser (Carl Zeiss Meditec Co., Ltd.)	Change	Instrument & apparatus 31 Ophthalmic corneal surgery laser system	An ophthalmic corneal surgery laser system used for incision and resection of corneal tissue by focusing and irradiating ultra-short pulse laser light to corneal tissue. The application was submitted mainly to add refractive correction by small incision lenticule extraction (SMILE) to the intended use (A “partial change” application).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Mar. 28, 2023 Total review time: 270 days Regulatory review time: 158 days	- Foreign clinical study results	30	Kao Steam Eye Care Mask (Kao Corporation)	Approval	Medical products 4 Home-use eyelid warming pack	The application was submitted for marketing approval of a single-use pack to alleviate symptoms such as dry eyes and tired eyes by applying heat with steam generated by oxidation reaction of iron to the skin around the eyes.
Cardiopulmonary Circulation	May 30, 2022 Total review time: 161 days Regulatory review time: 105 days	Jun. 18, 2021 Foreign clinical study results	31	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is used for cryoablation for cardiac tissue. The application was submitted to mainly remove "drug-refractory" from the indication of the catheter for paroxysmal atrial fibrillation (drug-refractory recurrent symptomatic paroxysmal atrial fibrillation), change the raw material of the guide wire luer, and change the requirements for performance and safety related to tensile strength and leakage (A “partial change” application). Results of foreign clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	May 30, 2022 Total review time: 161 days Regulatory review time: 105 days	Dec. 17, 2010 Foreign clinical study results	32	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	An ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is intended to be used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites for the treatment of atrial fibrillation, or creation of an ablation line between the inferior vena cava and the tricuspid valve when performing the procedure of cryoablation for cardiac tissue. The application was submitted to mainly remove "drug-refractory" from the indication of the catheter for paroxysmal atrial fibrillation (drug-refractory recurrent symptomatic paroxysmal atrial fibrillation) (A "partial change" application). Results of foreign clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Jun. 9, 2022 Total review time: 224 days Regulatory review time: 135 days	Aug. 2015 ReDS Wearable System/K150095 Feb. 2019 ReDS System/K180479 Clinical evaluation report	33	ReDS Pro System (Century Medical, Inc.)	Approval	Instrument & apparatus 21 Electromagnetic component analyzer	A device to provide the lung fluid composition ratio by measuring the lung fluid content using electromagnetic waves, consisting of a console, a sensor unit, etc. The device was developed for the intention of the use as an auxiliary positioning in the treatment of heart failure by monitoring the lung fluid composition ratio quantitatively measured with this device. As the clinical evaluation data, the clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted.
Cardiopulmonary Circulation	Aug. 2, 2022 Total review time: 260 days Regulatory review time: 86 days	- Japanese clinical study results	34	M-DES Coronary Stent (Nipro Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.5-4.25 mm and a delivery catheter used to implant the stent to the site of stenosis. The results of a Japanese clinical study were submitted for evaluation of the efficacy and safety of the product.
Cardiopulmonary Circulation	Aug. 19, 2022 Total review time: 435 days Regulatory review time: 166 days	Apr. 12, 2019 510(k):K183599/Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter, TVC-C195-42 Foreign clinical study results	35	TVC NIRS Catheter (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system intravascular near-infrared catheter	A catheter with a near-infrared spectroscopy (NIRS) function using NIRS to detect lipid core plaque in the vascular wall. This device provides imaging information for diagnosis. NIRS function presents one of the risk factors associated with major cardiovascular events. At the same time, the shape and characteristics of the central circulatory vascular lumen and vascular wall are visualized with ultrasound to provide diagnostic image information. The results of foreign clinical studies were submitted.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 19, 2022 Total review time: 435 days Regulatory review time: 166 days	Apr. 12, 2019 510(k):K183599/Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter, TVC-C195-42 Foreign clinical study results	36	TVC Imaging System TVC-MC10 (Goodman Co., Ltd.)	Change	Instrument & apparatus 12 Intravascular near-infrared diagnostic imaging system	A diagnostic imaging device with a near-infrared spectroscopy (NIRS) function using NIRS to detect lipid core plaque in the vascular wall. This device provides imaging information for diagnosis. NIRS function presents one of the risk factors associated with major cardiovascular events. At the same time, the shape and characteristics of the central circulatory vascular lumen and vascular wall are visualized with ultrasound to provide diagnostic image information. The application was submitted to change the NIRS function from accessory function to main function (A "partial change" application). The results of foreign clinical studies were submitted.
Cardiopulmonary Circulation	Aug. 24, 2022 Total review time: 261 days Regulatory review time: 220 days	Mar. 13, 2019 Acticor 7 HF-T DF4 IS -1 ProMRI/Acticor 7 HF-T QP DF4 IS4 ProMRI/P050023/S125 Clinical evaluation report	37	Acticor 7 CRT-D ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillation feature	The device is an implantable biventricular pacing pulse generator with defibrillation feature. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a function to provide indicators related to the changes in the patient's biological information (HeartInsight function) based on the concept of "testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis" provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017)" (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted to demonstrate that the HeartInsight function can provide indicators related to changes in biological information.
Cardiopulmonary Circulation	Sep. 9, 2022 Total review time: 295 days Regulatory review time: 231 days	Apr. 23, 2020 Cobalt XT HF Quad CRT-D MRI SureScan/Cobalt XT HF CRT-D MRI SureScan/Cobalt HF Quad CRT-D MRI SureScan/Cobalt HF CRT-D MRI SureScan Other 2 types/P010031/S674 Clinical evaluation report	38	Cobalt MRI CRT- D Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillation feature	The device is an implantable biventricular pacing pulse generator with defibrillation feature. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to include improvement of symptoms or delay in progression of heart failure in the indication for patients with heart failure whose left ventricular ejection fraction is 50% or less and who are expected to frequently depend on ventricular pacing among patients indicated for a pacemaker or an implantable defibrillator (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted as data related to results of clinical study.
Cardiopulmonary Circulation	Sep. 9, 2022 Total review time: 295 days Regulatory review time: 231 days	May 6, 2017 Percepta Quad CRT-P MRI SureScan/Percepta CRT-P MRI SureScan/P010015/S317 Clinical evaluation report	39	Percepta MRI CRT- P Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillation feature	The device is an implantable biventricular pacing pulse generator without defibrillation feature. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to include improvement of symptoms or delay in progression of heart failure in the indication for patients with heart failure whose left ventricular ejection fraction is 50% or less and who are expected to frequently depend on ventricular pacing among patients indicated for a pacemaker (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted as data related to results of clinical study.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 14, 2022 Total review time: 128 days Regulatory review time: 114 days	Mar. 13, 2019 P050023/S125/Acticor 7 DR-T ProMRI / Acticor 7 VR-T ProMRI Clinical evaluation report	40	Acticor 7 ICD ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an automatic implantable defibrillator. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a function to provide indicators related to the changes in the patient's biological information (HeartInsight function) based on the concept of "testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis" provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017)" (A "partial change" application).
Cardiopulmonary Circulation	Oct. 18, 2022 Total review time: 263 days Regulatory review time: 155 days	Dec. 13, 2021 SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus Eluting Coronary Stent Rapid Exchange Delivery System/P210014 Global clinical trial	41	Svelte Sirolimus-eluting Coronary Stent System (Svelte Medical Systems, Inc.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 34 mm or less) with a reference vessel diameter of 2.25-4.00 mm, and a delivery catheter to implant the stent to the site of stenosis.
Program	Nov. 11, 2022 Total review time: 193 days Regulatory review time: 104 days	Date of license: Oct. 8, 2020 License No.: K201525 Brand name: ECG App Number of units shipped: 92,900 (2020), 16.4 million (2021) Clinical evaluation report	42	Apple's ECG App (Apple Inc.)	Change	Program 1 Software for home use electrocardiograph	A home-use software that creates, records, stores, transfers, and displays single channel ECGs similar to lead-I ECGs. It analyzes the obtained ECG, classifies the wave form as being suggestive of sinus rhythm or atrial fibrillation and notifies the results to the user. The application was submitted to add the classification results to notify the users, expand the range of heart rate to be analyzed, and change the signal processing requirements of the platform (A "partial change" application). A clinical evaluation report summarizing overseas clinical data including literature was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Nov. 25, 2022 Total review time: 224 days Regulatory review time: 58 days	- Japanese clinical study results	43	Agent Paclitaxel-coated Balloon Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A catheter for coronary balloon dilatation angioplasty used to inhibit restenosis in revascularization for coronary in-stent restenosis and de novo coronary lesions.
Cardiopulmonary Circulation	Dec. 20, 2022 Total review time: 265 days Regulatory review time: 105 days	Mar. 31, 2022 Foreign and Japanese clinical study results	44	Aveir LP (Abbott Medical Japan LLC)	Approval	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements.
Cardiopulmonary Circulation	Mar. 29, 2023 Total review time: 267 days Regulatory review time: 82 days	- Clinical evaluation report	45	OSYPKA DefiPace (Heiwa Bussan Co., Ltd.)	Approval	Instrument & apparatus 7 Invasive external cardiac pacemaker	An external cardiac pacemaker for temporary atrial pacing, ventricular pacing, or atrial-ventricular sequential pacing. The product was developed based on the company's approved product "Osypka PACE300" (Approval No.: 22400BZX00123000). The major improvement is that the electrode can be placed in both atria by the combined use of the cardiac electrode, "OSYPKA TMA" (Approval No.: 30500BZX00092000) with the device so that cardioversion can be performed for atrial fibrillation.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Program	Jun. 2, 2022 Total review time: 98 days Regulatory review time: 47 days	- Clinical evaluation report	46	COVID-19 Pneumonia Analysis Program SCO-PA01 (Canon Medical Systems Corporation)	Approval	Program 1 Software for diagnostic X-ray imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.
Program	Dec. 8, 2022 Total review time: 268 days Regulatory review time: 164 days	iSchemaView RAPID: Obtained 510(k) in Oct. 2013 (K121447), added the indication of usefulness of endovascular thrombectomy (K182130) in Dec. 2018, added CTA function (K172477) in Apr. 2018 RAPID ASPECTS: Obtained 510(k) in Jun. 2020 (K200760) RAPID LVO 1.0: Obtained 510(k) in Jul. 2020 (K200941) RAPID ICH: Obtained 510(k) in Mar. 2020 (K193087) Clinical evaluation report	47	Brain Image Analysis Program iSchemaView Rapid (iSchemaView, Inc.)	Approval	Program 1 Software for general-purpose imaging system workstation	A software for general-purpose imaging system workstation used to assist the determination on mechanical thrombectomy in patients with acute-phase cerebral infarction based on the results of analysis on the volume of ischemic core, hypoperfusion area and their differences/ratios.

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Reprocessed Single-Use Medical Devices Approved in FY2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	May 13, 2022 Total review time: 225 days Regulatory review time: 185 days	- No clinical study results	1	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 12 Reprocessed cuff for pneumatically-powered massager	Reprocessed single-use medical device originating from the component of "Flowtron ACS900 (Certification No.: 228ADBZX00013000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation. The application was submitted to extend the shelf life after the first reprocessing and the storage period before cleaning (A “partial change” application).
Orthopedic and Plastic Surgery	Aug. 17, 2022 Total review time: 294 days Regulatory review time: 227 days	- No clinical study results	2	Reprocessed Saw Blade S (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 40 Reprocessed single-use surgical saw	Reprocessed single-use medical device originating from the existing certified device, "Stryker Bone Saw Blade" (226AFBZX00019000), which is a surgical saw for cutting or separating anatomical structure.
Gastroenterology, Genitourinary and Reproductive Medicine	Jun. 7, 2022 Total review time: 211 days Regulatory review time: 106 days	- No clinical study results	3	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 49 Reprocessed single-use trocar sleeve	Reprocessed single-use medical device originating from “Endopath Trocar System” (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity. The application was submitted to add the manufacturing site in charge of sterilization and storage, a manufacturing flow as a dedicated product for manufacture, a lineup of the same product as that of the approved "Reprocessed Trocar E2 (HOGY)" (Approval No.: 30300BZX00079000), and an approved single-use trocar sleeve that can be used in combination with the sleeve of this product (A “partial change” application).
Gastroenterology, Genitourinary, and Reproductive Medicine	Aug. 19, 2022 Total review time: 141 days Regulatory review time: 125 days	- No clinical study results	4	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 25 Reprocessed single-use natural orifices endoscopic dilator	Reprocessed single-use medical device originating from “Vagi-pipe” (Notification No. 20B1X00005000001), which is an endoscopic dilator used to dilate the vaginal opening during total laparoscopic hysterectomy. The application was submitted to mainly add the large size and change the specifications related to performance and safety (A "partial change" application).
Cardiopulmonary Circulation	Jun. 7, 2022 Total review time: 442 days Regulatory review time: 295 days	May 8, 2019 No clinical study results	5	Reprocessed Intracardiac Ultrasound Catheter V (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Remanufactured central circulatory intravascular ultrasound catheter	A catheter for imaging of structure and blood flow of the heart, etc. with a built-in transducer whose tip transmits/receives ultrasound. The product is a reprocessed single-use medical device originating from "ViewFlex Xtra ICE Catheter" (Approval No.: 22600BZX00091000).
Cardiopulmonary Circulation	Sep. 1, 2022 Total review time: 505 days Regulatory review time: 285 days	Jul. 9, 2008 No clinical study results	6	Reprocessed Steerable Electrode Catheter (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Reprocessed cardiac catheter-tip electrode	A reprocessed single-use medical device originating from “Inquiry Catheter” (Approval No. 21600BZY00253000), which is a cardiac catheter-tip electrode and is used placed percutaneously and transluminally in the heart to perform a cardiac electrophysiological study and temporary pacing.

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

New Medical Devices Approved in FY2021

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Aug. 6, 2021 Total review time: 340 days Regulatory review time: 248 days	- Clinical evaluation report	1	Oncotype DX Breast Recurrence Score Program (Exact Sciences K.K.)	Approval	Program 1 Software program to support tumor malignancy determination	The application was submitted for marketing approval of a software program to support tumor malignancy determination which outputs a Recurrence Score that assists in determining chemotherapy use based on the RNA expression levels of 21 genes in tumor tissue of hormone receptor-positive, HER2-negative, early-stage invasive breast cancer patients.
Orthopedic and Plastic Surgery	Jun. 7, 2021 Total review time: 363 days Regulatory review time: 262 days	- Clinical evaluation report	2	EpiFix (MiMedx Group, Inc.)	Approval	Medical products 4 Tissue-healing promoting material using human amniotic membrane	A tissue-healing promoting material composed of human amniotic membranes intended to promote wound healing in patients with refractory ulcers who have not responded to conventional therapies. The product is made of dried human amniotic/chorionic membranes obtained from the human placenta, prepared by cleaning, drying, and sterilizing, and contains multiple types of amniotic/chorionic membrane-derived extracellular matrix proteins, growth factors, cytokines, etc. A clinical evaluation report primarily consisting of the results of a foreign post-marketing clinical study, a literature review, and an adverse event report was submitted to evaluate the efficacy and safety of the product as a tissue-healing promoting material.
Orthopedic and Plastic Surgery	Feb. 17, 2022 Total review time: 360 days Regulatory review time: 144 days	Sep. 20, 2018 Foreign clinical study results	3	RECELL Autologous Cell Harvesting and Non-cultured Cell Suspension Preparation Kit (Cosmotec Co., Ltd.)	Approval	Instrument & apparatus 58 Autologous skin cell grafting kit	An autologous skin cell grafting kit intended to produce a non-cultured cell suspension from a skin specimen collected from a patient and promote healing of the wound of acute burn and donor sites. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 13, 2021 Total review time: 364 days Regulatory review time: 113 days	Mar. 13, 2020 Foreign clinical study results	4	ALTO Abdominal Stent Graft System (Endologix LLC)	Approval	Instrument & apparatus 7 Aortic stent graft	The application was submitted for marketing approval of a stent graft system for the treatment of abdominal aorta that obtains adhesion to blood vessels by filling polymer.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 26, 2021 Total review time: 90 days Regulatory review time: 80 days	Apr. 30, 2014 P130008/INSPIRE II UPPER AIRWAY STIMULATOR May 5, 2017 P130008/S016/INSPIRE UPPER AIRWAY STIMULATOR, MODEL 3028 No clinical study results	5	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12 Hypoglossal nerve electrical stimulator	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure therapy. The application was submitted to add a manufacturing site for sterilization and a programmer cable used for wireless communication between the programmer for physicians and the pulse generator. (A “partial change” application submitted during the post-market performance review period)

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 8, 2021 Total review time: 97 days Regulatory review time: 39 days	- No clinical study results	6	GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates, G. K.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for intravascular treatment of thoracic aortic diseases. The application was submitted to add blue pigment to the surgical sutures used of the stent graft and delivery catheter, in order to enhance its identifiability during the manufacturing process, falling under a "specified partial change" based on "Acceleration of Procedure for Specified Change for Medical Devices" (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 17, 2021 Total review time: 56 days Regulatory review time: 47 days	- No clinical study results	7	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of thoracic aorta. The application was submitted to partially change the raw materials of the delivery system, falling under a "specified partial change" based on "Acceleration of Procedure for Specified Change for Medical Devices" (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 21, 2021 Total review time: 293 days Regulatory review time: 152 days	- No clinical study results	8	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)	Change	Instrument & apparatus 12 Focused ultrasound system	A focused ultrasound system intended for focally heating the target and causing focal coagulative necrosis to deliver focused ultrasound energy to the target in the thalamus through the skull. The device is used to alleviate essential tremor and symptoms of Parkinson's disease in patients who are not respond sufficiently to drug therapies. The application was submitted to add components including a patient table and dedicated head coil, due to the addition of the MR device used with the system, to add and make improvements in final confirmation function of the radiation parameter, and to change the evaluation method for the image quality of the MR device used with the system. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 13, 2021 Total review time: 98 days Regulatory review time: 71 days	- No clinical study results	9	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51 Catheter for balloon dilatation angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery (excluding those within a stent). The balloon surface of this product is coated with a drug primarily composed of paclitaxel. The application was submitted for deletion of the specification for heavy metal in the drug substance (paclitaxel), falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 14, 2021 Total review time: 135 days Regulatory review time: 116 days	May 5, 2019 Valiant Thoracic Stent Graft With The Captivia Delivery System (P100040 S038) No clinical study results	10	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of thoracic aorta. The application was submitted to add ethylene oxide gas processing to the manufacturing process of stent graft for bioburden reduction. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 26, 2021 Total review time: 356 days Regulatory review time: 217 days	Apr. 10, 2013 Jetstream SC/XC Atherectomy Catheter/ Oct. 19, 2012 Jetstream Console/ Japanese clinical study results	11	Jetstream Atherectomy System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Atherectomy ablative angioplasty catheter	The application was submitted for marketing approval of a catheter system used to remove hard atherosclerotic disease and stenosis in the superficial femoral artery and/or proximal popliteal artery to facilitate pre-dilation of severely calcified lesions (excluding in-stent restenosis lesions) that do not pass through or are difficult to dilate with a PTA balloon catheter used for pre-dilatation prior to drug-coated balloons.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2021 Total review time: 146 days Regulatory review time: 94 days	Feb. 25, 2015 VenaSeal Closure System No clinical study results	12	VenaSeal Closure System (Covidien Japan Inc.)	Change	Instrument & apparatus 51 Vascular embolization prosthesis	A vascular embolization prosthesis to occlude the blood vessel by injecting into the truncal saphenous veins with venous reflux. The application was submitted to change the raw material of the catheter hub and introducer hub and to change the specifications for leakage of the drug solution from the introducer hub. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary and Reproductive Medicine	Jul. 14, 2021 Total review time: 161 days Regulatory review time: 101 days	- Clinical evaluation report	13	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Purifier for blood cell removal	A purifier for blood cell removal to selectively adsorb and remove granulocytes and monocytes in peripheral blood by performing direct hemoperfusion using an extracorporeal circulation column which is filled with an adsorbent carrier made of cellulose acetate. The application was submitted to add the indication for maintaining remission during the remission phase in patients with refractory ulcerative colitis who have not responded, have not sufficiently responded, or are not amenable to conventional medications. A clinical evaluation report summarizing a Japanese clinical study and the contents of Japanese and foreign clinical literatures, etc. were submitted to evaluate the efficacy and safety of the product for this indication. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 13, 2021 Total review time: 359 days Regulatory review time: 178 days	Aug. 27, 2015 K150786/Rezum System Foreign clinical study results	14	Rezum System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 29 Water vapour delivery system for prostatic tissue	A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The results of a foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 8, 2022 Total review time: 776 days Regulatory review time: 520 days	Sep. 28, 2006 K060482/CYTORI CELUTION CELL CONCENTRATION DEVICE Japanese clinical study results	15	Celution Cell Therapy Kit SUI (Cytori Therapeutics, K.K.)	Approval	Instrument & apparatus 7 Adipose tissue separation kit	An adipose tissue separation kit to clean, separate, and process adipose tissue by centrifugation to be administered specific cells and adipose tissue for the treatment of patients who have not responded or have not sufficiently responded to behavioral therapy or drug therapy for mild to moderate male stress urinary incontinence associated with urethral sphincter incompetence secondary to a surgery for prostatic hyperplasia or prostate cancer. The results of Japanese clinical studies were submitted to evaluate the efficacy and safety of the treatment using this product.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 8, 2022 Total review time: 229 days Regulatory review time: 166 days	Dec. 21, 2017 DEN170024/Not described Foreign clinical study results	16	AQUABEAM Robotic System (PROCEPT BioRobotics Corporation)	Approval	Instrument & apparatus 12 Surgical robot unit	A device to resect an enlarged prostate by inserting a handpiece transurethrally and using a high-pressure water injection of physiological saline. A physician sets a resection plan preoperatively, and the robot system performs treatment following the plan. The application was submitted for marketing approval of a medical device used for resection and removal of prostate tissue of male patients with lower urinary tract symptoms associated with prostatic hyperplasia.
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 28, 2022 Total review time: 115 days Regulatory review time: 33 days	Aug. 27, 2015 K150786/Rezum System No clinical study results	17	Rezum System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 29 Water vapour delivery system for prostatic tissue	A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The application was submitted to add a model whose a pressure safety valve located at the tip of a tube for injection water is removed. (A “partial change” application).
Cardiopulmonary Circulation	Apr. 6, 2021 Total review time: 344 days Regulatory review time: 224 days (Review report, etc.)	Aug. 16, 2019 Global clinical study results	18	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This device has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic valve stenosis (Approval No.: 22800BZX00414000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk were submitted as the clinical study data on the indication expansion. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Apr. 6, 2021 Total review time: 281 days Regulatory review time: 161 days	Aug. 16, 2019 Global clinical study results	19	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This product has been approved as a medical device used for transcatheter aortic valve implantation and transcatheter pulmonary valve replacement (Approval No.: 22800BZX00094000). For the treatment of patients with severe symptomatic native aortic valve stenosis, this product has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option." In addition to the indication mentioned above, the application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk were submitted as the clinical study data on the indication expansion. (A “partial change” application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Apr. 7, 2021 Total review time: 208 days Regulatory review time: 111 days	Oct. 27, 2016 510K (K160121)/CorPath GRX System Mar. 1, 2018 510K (K173806)/CorPath GRX System: RoR added No clinical study results	20	CorPath GRX System (Corindus, Inc.)	Change	Instrument & apparatus 51 Catheter manipulation equipment for use in the cardiac and central circulatory system	Remote catheter manipulation equipment to be installed in a cardiac catheterization room to manipulate and hold guiding catheters, guidewires, rapid exchange balloon dilatation catheters for coronary angioplasty, and rapid exchange coronary stent catheters that are used for percutaneous coronary intervention. The application was submitted for an additional function to make several movements with this device (such as rotation and back and forward movement), which are commonly required when a guidewire and a therapeutic catheter are inserted to the lesion by a physician. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	May 13, 2021 Total review time: 286 days Regulatory review time: 191 days	Dec. 27, 2018 No clinical study results	21	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a bioprosthetic valve model in which the height of the outer skirt and the type of the cloth were changed in order to maintain the prevention of paravalvular regurgitation. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jun. 17, 2021 Total review time: 351 days Regulatory review time: 169 days (Review report, etc.)	May 8, 2020 Foreign clinical study results	22	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon-type laser ablation catheter with an endoscope to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to add a model with a laser autorotation mode (RAPID mode) in order to shorten procedure time. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the additional model. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jun. 30, 2021 Total review time: 159 days Regulatory review time: 145 days	Jan. 8, 2016 No clinical study results	23	Perceval Bioprosthetic Valve (LivaNova Canada Corp.)	Change	Instrument & apparatus 7 Bovine pericardium valve	A bovine pericardium valve designed to replace a diseased native aortic valve or a malfunctioning prosthetic aortic valve via open-heart surgery. The application was submitted to change the transportation time for bovine pericardium. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jul. 29, 2021 Total review time: 314 days Regulatory review time: 197 days	Jan. 15, 2020 Foreign clinical study results	24	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to mainly add a model with an atrioventricular synchronization function. The results of foreign clinical studies were submitted as clinical evaluation data. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Jul. 29, 2021 Total review time: 269 days Regulatory review time: 248 days	Sep. 19, 2019 P130021S059/Medtronic Evolut PRO+ System Global clinical study results	25	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This device has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic stenosis (Approval No.: 30200BZX00272000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic stenosis who are at a low surgical risk were submitted as the clinical study data on the indication expansion.
Cardiopulmonary Circulation	Aug. 23, 2021 Total review time: 266 days Regulatory review time: 116 days	Mar. 26, 2021 Global clinical study results	26	Harmony Transcatheter Pulmonary Valve Replacement System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A transcatheter porcine pericardial valve used in patients with severe pulmonary regurgitation who have a medical history of surgical repair of the right ventricular outflow tract or transcatheter intervention (balloon valvuloplasty) and for whom pulmonary valve replacement is clinically required. The results of a global clinical study were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Oct. 26, 2021 Total review time: 971 days Regulatory review time: 192 days	Nov. 2017 P170008/EluNIR Ridaforolimus Eluting Coronary Stent System Foreign and Japanese clinical study results	27	EluNIR Drug-Eluting Stent (Medinol Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent used for the treatment of patients with symptomatic heart disease who have de novo native coronary artery lesions (a lesion length of 42 mm or less) with a reference vessel diameter of 2.50-4.25 mm. The results of foreign and Japanese clinical studies were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Oct. 27, 2021 Total review time: 111 days Regulatory review time: 36 days	Jan. 27, 2021 No clinical study results	28	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a manufacturing site and to modify the descriptions in the manufacturing method column. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jan. 17, 2022 Total review time: 145 days Regulatory review time: 93 days	- No clinical study results	29	AMPLATZER PFO Occluder (Abbott Medical Japan LLC.)	Change	Medical products 4 Prosthetic material for artificial cardiac membrane	A percutaneous transcatheter closure device of a patent foramen ovale (PFO) intended to close PFO in patients with a history of cryptogenic cerebral infarction in whom the existence of PFO is determined to be related to the onset of cerebral infarction. The device is used to reduce the risk of recurrence of cerebral infarction. The application was submitted to change the left atrial disc, size of 30 mm and add a model in which the occluder is connected to the delivery cable in advance (A “partial change” application).
Cardiopulmonary Circulation	Jan. 17, 2022 Total review time: 292 days Regulatory review time: 223 days	- Foreign clinical study results	30	Navitor Transcatheter Aortic Valve Implantation System (Abbott Medical Japan LLC.)	Approval	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A self-expandable percutaneous aortic bioprosthetic valve system for a percutaneous aortic valve replacement used in symptomatic patients with severe aortic valve stenosis attributed to calcification and degeneration of the native aortic valve cusps, who are not eligible for surgery and of which this treatment is considered as their best therapeutic option. This product consists of a self-expanding bioprosthetic valve, delivery system, and loading system. As clinical evaluation data, the results of foreign clinical studies were submitted.

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Cardiopulmonary Circulation	Mar. 14, 2022 Total review time: 171 days Regulatory review time: 53 days	Feb. 17, 2021 No clinical study results	31	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to extend the shelf life of the bioprosthetic valve from 2 years to 3 years. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 23, 2022 Total review time: 170 days Regulatory review time: 141 days	Jan. 27, 2020 No clinical study results	32	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7 Implantable assistant artificial heart system	The device is an implantable ventricular assist device system used to assist the blood circulation for severe cardiac failure in patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system. The application was submitted to add HeartMate Touch monitor, etc. developed as an alternative to a component system monitor. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 23, 2022 Total review time: 111 days Regulatory review time: 91 days	- No clinical study results	33	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7 Implantable assistant artificial heart system	The device is an implantable ventricular assist device system used to assist the blood circulation for severe cardiac failure in patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system. The application was submitted to add a raw material of an outflow graft with bend relief, etc. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 28, 2022 Total review time: 363 days Regulatory review time: 162 days	Feb. 12, 2021 Foreign and Japanese clinical study results	34	IVL Generator (Shockwave Medical, Inc.)	Approval	Instrument & apparatus 29 Driving unit for angioplasty athelectomy catheter	A generator used to disrupt severely calcified *de novo* coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted.
Cardiopulmonary Circulation	Mar. 28, 2022 Total review time: 363 days Regulatory review time: 156 days	Feb. 12, 2021 Foreign and Japanese clinical study results	35	C^2 Coronary IVL Catheter (Shockwave Medical, Inc.)	Approval	Instrument & apparatus 51 Atherectomy ablative angioplasty catheter	A catheter used to disrupt severely calcified *de novo* coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted.

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Improved Medical Devices (With Clinical Data) Approved in FY 2021

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Apr. 21, 2021 Total review time: 246 days Regulatory review time: 110 days	Jun. 12, 2020 Foreign clinical study results	1	FreeStyle Libre 2 (Abbott Japan LLC)	Approval	Instrument & apparatus 20 Glucose monitor system	The application was submitted for marketing approval of a glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen.
Robotics, IoT, and other devices (not classified as other categories)	Sep. 17, 2021 Total review time: 340 days Regulatory review time: 267 days	Sep. 1, 2020 Foreign clinical study results	2	Medtronic MiniMed 700 Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 74 Portable insulin infusion pump	The application was submitted for marketing approval of a glucose monitoring system used for continuous subcutaneous infusion of basal insulin at a selectable rate and bolus infusion of insulin at a selectable dose.
Robotics, IoT, and other devices (not classified as other categories)	Oct. 27, 2021 Total review time: 359 days Regulatory review time: 274 days	- Foreign clinical study results	3	Octopal R Pulse Oximeter DMO-8000 (Nihon Kohden Corporation)	Approval	Instrument & apparatus 21 Pulse oximeter	This application was submitted for marketing approval of a pulse oximeter that has a function of measuring patients' vital signs (percutaneous arterial oxygen saturation, carboxyhemoglobin concentration, methemoglobin concentration, and pulse rate), displaying them on the screen, and issuing an alarm.
Robotics, IoT, and other devices (not classified as other categories)	Oct. 28, 2021 Total review time: 211 days Regulatory review time: 128 days	Oct. 26, 2012 Cyberknife M6 System Clinical evaluation report	4	CyberKnife M6 Series (Accuray Japan K.K.)	Change	Instrument & apparatus 9 Stereotactic radiotherapy accelerator system	A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application.
Robotics, IoT, and other devices (not classified as other categories)	Oct. 28, 2021 Total review time: 210 days Regulatory review time: 127 days	Jul. 14, 1999 CyberKnife Radiosurgery System Clinical evaluation report	5	CyberKnife Radiosurgery System (Accuray Japan K.K.)	Change	Instrument & apparatus 9 Stereotactic radiotherapy accelerator system	A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application.

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Robotics, IoT, and other devices (not classified as other categories)	Jan. 7, 2022 Total review time: 266 days Regulatory review time: 201 days	Nov. 16, 2018 K180881/HemoSphere advanced monitor, hemoSphere pressure cable May 21, 2019 K183646/Acumen hypotension prediction index-EV1000 clinical platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform-pressure Aug. 29, 2019 K190205/HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module Number of units shipped (total): Approximately 2500 units Foreign clinical study results	6	Acumen HPI System (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 21 Multiparameter monitor	The application was submitted for marketing approval of a multiparameter monitor to measure hemodynamics such as thermodilution cardiac output and arterial pressure-based cardiac output and to collect and monitor various biological information.
Robotics, IoT, and other devices (not classified as other categories)	Jan. 20, 2022 Total review time: 269 days Regulatory review time: 225 days	None Japanese clinical study results	7	ait (Peace of Mind Co., Ltd.)	Approval	Instrument & apparatus 12 Alternating magnetic field therapy device	The application was submitted for marketing approval of an alternating magnetic field therapy device used to relieve pain by transcutaneously irradiating 2 types of alternating magnetic fields and stimulating the nerves.
Orthopedic and Plastic Surgery	Jun. 16, 2021 Total review time: 266 days Regulatory review time: 147 days	- Japanese clinical study results	8	TNS Alloy Stem (Mizuho Corporation)	Approval	Medical products 4 Femoral component for hip prosthesis	A femoral component for hip prosthesis used for total hip replacement or prosthesis replacement in patients with hip joint functional disorders including osteoarthritis, rheumatoid arthritis and necrosis of the femoral head. The product has only a direct fixation type of femoral stem, and is used with an approved stem head. The product is made from Ti-Nb-Sn alloy, and obtains elastic gradient from proximal to distal by thermal processing of the base material. The results of a Japanese clinical study designed as a single-arm, open-label, multicenter study were submitted to evaluate the improvement in JOA hip score after surgery as efficacy and malfunctions and adverse events as safety.
Orthopedic and Plastic Surgery	Dec. 13, 2021 Total review time: 269 days Regulatory review time: 124 days	- Clinical evaluation report	9	Motiva Breast Implants (Establishment Labs S.A.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled mammary prosthesis made of a silicone gel used for breast reconstruction or augmentation in adult women to restore or form the shape of a breast. This product contains SmoothSilk Series implant and SmoothSilk Ergonomix Series implant as components, both of which are round in shape and have a smooth surface finish. A clinical evaluation report consisting of data related to foreign clinical study and clinical publications was submitted to prove there are not unacceptable risks of product-specific adverse events.
Orthopedic and Plastic Surgery	Feb. 10, 2022 Total review time: 182 days Regulatory review time: 144 days	Jul. 15, 2015 Clinical evaluation report	10	Phototherapy Device for Pigmentary Skin Disease Nordlys (Syneron Candela K.K.)	Approval	Instrument & apparatus 12 Phototherapy device for skin diseases	A phototherapy device for skin diseases used to treat benign superficial skin pigmentary disease by thermal action of continuous spectral light from visible to infrared rays using intense pulsed light. A clinical evaluation report summarizing clinical literatures, etc. on the previous generation product of this device and similar products of other companies was submitted to evaluate the improvement effect on pigmentary disease and the acceptability of anticipated adverse events for the efficacy.

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Orthopedic and Plastic Surgery	Mar. 14, 2022 Total review time: 391 days Regulatory review time: 183 days	Mar. 26, 2014 REGENETEN Implant Jul. 12, 2013 Tendon Staple Aug. 29, 2013 Bone Staple, Staple Delivery Set Dec. 22, 2011 Tendon Marker Dec. 22, 2011 Tendon Guide Clinical evaluation report	11	REGENETEN Implant (Smith & Nephew KK)	Approval	Medical products 4 Collagen-containing absorbable tendon regeneration material	A collagen containing absorbable tendon regeneration material that manages and protects tendons with oriented collagen fibers that act as a scaffold for tendon tissue, in order to promote repair of a cuff injury site without substantial loss of tissue. A clinical evaluation report organizing the results of non-GCP-compliant foreign clinical studies and clinical literatures, etc. was submitted to evaluate the facts that this product contributes to the repair of the cuff such as a tendency towards increased tendon thickness and that the risks associated with the use of this product are acceptable for the efficacy.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 23, 2021 Total review time: 263 days Regulatory review time: 118 days	May 4, 2020 Foreign clinical study results	12	TREO Abdominal Stent Graft System (Terumo Corporation)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft indicated for the intravascular treatment of infrarenal abdominal aortic aneurysm that satisfies the specific anatomical conditions. The results of a single-arm clinical study conducted in the US were submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2021 Total review time: 187 days Regulatory review time: 115 days	- Japanese clinical study results	13	LUNAWAVE (Terumo Corporation)	Change	Instrument & apparatus 12 Optical coherence tomography (OCT) imaging system	An optical coherence tomography (OCT) imaging system to perform intravascular optical coherence tomography (OCT), connected to the dedicated intravascular optical tomographic catheter, "FastView" (Approval No.: 22500BZX00057000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2021 Total review time: 187 days Regulatory review time: 109 days	- Japanese clinical study results	14	FastView (Terumo Corporation)	Change	Instrument & apparatus 51 Intravascular optical tomographic catheter	An intravascular optical tomographic catheter to perform intravascular optical coherence tomography (OCT), connected to the dedicated OCT imaging system, "LUNAWAVE" (Approval No.: 22500BZX00058000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 28, 2021 Total review time: 255 days Regulatory review time: 61 days	May 4, 2015 ERBECRYO2/K151041 Clinical evaluation report	15	ERBE CRYO2 (Amco Inc.)	Change	Instrument & apparatus 31 General-purpose cryosurgical unit	A cryosurgery unit used for tissue biopsy or removal of foreign matters by cooling/freezing the bronchus, bronchial peripheral tissues, or foreign matters in the bronchus by touching with the probe tip cooled by high-pressure carbon dioxide. The application was submitted to add removal of airway obstruction in patients in whom a tumor obstructs the central airway and who require immediate airway securing to the intended use (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 29, 2021 Total review time: 301 days Regulatory review time: 201 days	- Global clinical study results	16	RelayPro Thoracic Stent Graft System (Terumo Corporation)	Approval	Instrument & apparatus 7 Aortic stent graft	The application was submitted for marketing approval of an arterial stent graft used for the endovascular treatment of descending thoracic aortic aneurysm. The product was designed based on the company’s approved product "Relay Plus Thoracic Stent Graft System" (Approval No. 22500BZX00160000) and for which different stent graft types were added and the delivery system was improved. The results of physicochemical characterization tests, biological safety test, durability test, animal test, and clinical studies were submitted to secure the application content.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 30, 2021 Total review time: 179 days Regulatory review time: 125 days	- Clinical evaluation report	17	Wire for Lymphatic Vessels (TRS Co., Ltd.)	Approval	Instrument & apparatus 51 Non-vascular guidewire	The application was submitted for marketing approval of a non-vascular guidewire used to be inserted into the lymphatic vessels to confirm their courses, locations, etc. in lymphatic-venous anastomosis for treatment of lymphoedema. A clinical evaluation report summarizing literatures, etc. on lymphatic-venous anastomosis at the sites where this product is expected to be used was submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 2, 2022 Total review time: 485 days Regulatory review time: 145 days	- Clinical evaluation report	18	Histoacryl (B. Braun Aesculap Japan Co., Ltd.)	Change	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	The application was submitted to add the indication regarding vascular embolization for hemostasis, prevention of bleeding, alleviation of symptoms, etc. (A "partial change" application). A clinical evaluation report summarizing the contents of Japanese and foreign literatures, etc. was submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 2, 2022 Total review time: 243 days Regulatory review time: 106 days	- Clinical evaluation report	19	NEOVEIL (GUNZE LIMITED)	Change	Medical products 4 Absorbable tissue reinforcement material	The application was submitted to add reinforcement of defective and fragile parts in organs/tissue, and prevent of air leakage. (A "partial change" application). A clinical evaluation report summarizing literatures, etc. related to the results of use of this product in defective and fragile parts in organs and tissue was submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 28, 2022 Total review time: 364 days Regulatory review time: 144 days	Dec. 22, 2020 PMA approved/GORE EXCLUDER Conformable AAA Endoprosthesis Foreign clinical study results	20	GORE Excluder Conformable AAA Stent Graft System (W. L. Gore & Associates G.K.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for the intravascular treatment of infrarenal abdominal aortic aneurysm (including aneurysms extending from the abdominal aorta to the iliac artery) that satisfies the specific anatomical requirements. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 28, 2022 Total review time: 238 days Regulatory review time: 83 days	- Foreign clinical study results	21	EIT Monitor PulmoVista 500 (Draeger Japan Ltd.)	Approval	Instrument & apparatus 21 Respiratory function measuring system	The application was submitted for marketing approval of a respiratory function measuring system which displays information on changes in lung volume and local distribution in the internal electrode surface by measuring the biological impedance distribution in the chest using electric impedance tomography technology. This product displays the tomographic image data related to impedance changes in real time and analyzes the data.
Gastroenterology, Genitourinary and Reproductive Medicine	May 26, 2021 Total review time: 321 days Regulatory review time: 167 days	Nov. 22, 2011 Clinical evaluation report	22	RENASYS Abdominal Kit (Smith & Nephew KK)	Approval	Medical products 4 Open abdominal wound dressing kit	The application was submitted for marketing approval of a dressing kit intended to facilitate early closure of the peritoneum. The product provides the protection of abdominal contents from external environment, efficient drainage, suppression of inflammation, and alleviation of edema by covering the organs inside the abdomen and applying controlled negative pressure in the case where open abdominal wounds are accompanied by exposure of abdominal organs and also abdominal closure by primary suture is difficult. The product consists of an organ protective layer, form filler, drape, and soft port. An approved product, “RENASYS Wound Therapy System” is used in combination with the product for negative pressure control.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 27, 2021 Total review time: 245 days Regulatory review time: 147 days	- Japanese clinical study results	23	Tenaleaf (GUNZE LIMITED)	Approval	Medical products 4 Absorbable adhesion-prevention dressing	A sheet-type absorbable adhesion-prevention dressing to reduce the frequency, extent, and severity of postoperative adhesions in patients undergoing surgery of abdominal or pelvic cavity. The product becomes gel by absorbing water in the damaged site or abdominal cavity, prevents formation of fibrin networks in the damaged site and surrounding tissues as a physical barrier, and exerts an adhesion-reducing effect.
Gastroenterology, Genitourinary, and Reproductive Medicine	Dec. 24, 2021 Total review time: 228 days Regulatory review time: 118 days	- Clinical evaluation report	24	Cool-tip RFA System E Series (Covidien Japan Inc.)	Change	Instrument & apparatus 29 Radiofrequency ablation system	A radiofrequency ablation system used for coagulating and ablating tissues. The application was submitted to add the followings to the intended use of this product: "small-diameter renal malignant tumor" as well as "pulmonary malignant tumor," "malignant bone tumor," "osteoid osteoma," "pelvic malignant tumor," and "soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity" that are ineligible for or refractory to standard therapy (A “partial change” application). A clinical evaluation report based on Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the product.
Dentistry and Oral Medicine	Jul. 14, 2021 Total review time: 226 days Regulatory review time: 161 days	- Japanese clinical study results	25	Opalescence GO (ULTRADENT PRODUCTS, INC.)	Approval	Instrument & apparatus 62 Drug-containing dental tooth surface cleaner auxiliary material	A drug-containing dental tooth surface cleaner auxiliary material whose ready-made tray is pre-filled with 6% hydrogen peroxide. This product is used by patients on their teeth at home, etc., under the management of a dentist. The results of a Japanese clinical study designed as a multicenter, open-label controlled study were submitted to evaluate the efficacy and safety of the product.
Ophthalmology and Otorhinolaryngology	May 11, 2021 Total review time: 242 days Regulatory review time: 189 days	Jun. 2, 2020 Foreign clinical study results	26	Bausch & Lomb Aqualox One Day UV Shin (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (kalifilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 107 x 10^{-11} (cm^2/sec)·(mLO_2/[mL x mmHg]).
Ophthalmology and Otorhinolaryngology	Jun. 11, 2021 Total review time: 248 days Regulatory review time: 163 days	- Japanese clinical study results	27	2 Week Fresh View S (Rohto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (toufilcon B) with a moisture content of 50% and an oxygen permeability (Dk) of 91×10^{-11} (cm2/sec)·(mLO_2/[mL x mmHg]).
Ophthalmology and Otorhinolaryngology	Oct. 14, 2021 Total review time: 269 days Regulatory review time: 129 days	- Japanese clinical study results	28	1day SD01H-S (SEED Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel with a water content of 68% and an oxygen permeability (Dk) of 60 x 10^{-11} (cm^2/sec)·(mLO_2/[mL × mmHg]).
Ophthalmology and Otorhinolaryngology	Dec. 17, 2021 Total review time: 267 days Regulatory review time: 135 days	Dec. 31, 2013 Clinical evaluation report	29	Nasaleze (Nasaleze Limited)	Approval	Medical products 4 Home-use nasal mucosal protector	The application was submitted for marketing approval of a home-use nasal mucosal protector used for alleviation of symptoms associated with allergic rhinitis (sneezing, runny nose, and stuffy nose).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Dec. 20, 2021 Total review time: 264 days Regulatory review time: 190 days	- Foreign clinical study results	30	Total 14 (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Reusable colored vision corrective contact lens	The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (Lehfilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 123 x 10^{-11} (cm^2/sec)·(mLO_2/[mL × mmHg]).
Ophthalmology and Otorhinolaryngology	Feb. 24, 2022 Total review time: 269 days Regulatory review time: 114 days	- Foreign clinical study results	31	Preserflo MicroShunt Glaucoma Drainage System Core Kit (Santen Pharmaceutical Co., Ltd.)	Approval	Medical products 4 Intraocular drain	The application was submitted for marketing approval of an intraocular drain used to reduce intraocular pressure in patients with glaucoma whose intraocular pressure can not be sufficiently reduced by treatments including drug and laser therapies.
Cardiopulmonary Circulation	Apr. 27, 2021 Total review time: 270 days Regulatory review time: 155 days	May 30, 2008 K063727/IMPELLA 2.5 Apr. 15, 2009 K083111/IMPELLA 5.0 Sep. 6, 2012 K112892/IMPELLA CP Mar. 22, 2018 P140003_S026/IMPELLA CP SmartAssist (CP-Op) Clinical evaluation report	32	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51 Controler for temporary non-roller type cardiac support blood pump	A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery or axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The application was submitted to add a procedure for inserting the device through the axillary/subclavian artery as a part of the usage of the product, a model in which the shape and raw material of the pigtail at the tip of the Impella CP and CP-Op were changed, and a raw material of the lure connector on the branch connector line in the set for purge. A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted to evaluate the safety of the procedure for inserting the device through the axillary/subclavian artery.
Cardiopulmonary Circulation	Jun. 17, 2021 Total review time: 261 days Regulatory review time: 103 days	May 28, 2019 Foreign clinical study results	33	GORE Cardioform ASD Occluder (W. L. Gore & Associates G.K.)	Approval	Medical products 4 Artifitial pericardial prosthesis	An artifitial pericardial prosthesis used to percutaneously close ostium secundum atrial septal defect. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Jul. 21, 2021 Total review time: 250 days Regulatory review time: 102 days	- Foreign clinical study results	34	POLARx Cryoablation Balloon Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon catheter used for cryoablation of cardiac tissue in the treatment of drug-refractory, recurrent, symptomatic, paroxysmal atrial fibrillation. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Aug. 26, 2021 Total review time: 269 days Regulatory review time: 175 days	Jan. 28, 2021 Foreign clinical study results	35	DiamondTemp Ablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous cardiac ablation with high-frequency current for the treatment of patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation and common type atrial flutter. The results of foreign clinical studies were submitted as clinical evaluation data .
Cardiopulmonary Circulation	Oct. 5, 2021 Total review time: 256 days Regulatory review time: 181 days	- Global clinical study results	36	Ultimaster Nagomi (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo native coronary artery lesions (a lesion length of 45 mm or less) with a reference vessel diameter of 2.25-4.0 mm, and a delivery catheter used to implant a stent to the target lesion. The results from a subgroup analysis of global clinical study data using the previous generation product of this product “Ultimaster” (Approval No.: 22700BZX00224000) were submitted to evaluate the efficacy and safety of this product.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 21, 2021 Total review time: 262 days Regulatory review time: 224 days	- Clinical evaluation report	37	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon ablation catheter utilizing a high frequency current. The application was submitted to add drug-resistant recurrent symptomatic persistent atrial fibrillation to the conventional intended use (drug-resistant recurrent symptomatic paroxysmal atrial fibrillation) (A "partial change" approval application). A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to secure the application content.
Cardiopulmonary Circulation	Nov. 22, 2021 Total review time: 270 days Regulatory review time: 139 days	Sep. 24, 2019 None/IMPELLA 5.5 Clinical evaluation report	38	Impella 5.5 SmartAssist (Abiomed, Inc.)	Approval	Instrument & apparatus 51 Controler for temporary non-roller type cardiac support blood pump	A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The product is concomitantly used with a dedicated driving device “Impella Controller” (Approval No.: 22800BZX00031000). This product was developed with the aim of limiting the insertion site to the axillary/subclavian artery according to the clinical needs, increasing the circulatory support flow, and reducing the size of the catheter pump based on the approved "Impella Circulatory Assist Pump Catheter" (Approval No.: 228000BZI00032000). A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as the data for clinical evaluation of the product.
Cardiopulmonary Circulation	Jan. 25, 2022 Total review time: 147 days Regulatory review time: 100 days	Mar. 11, 2022 Foreign clinical study results	39	XIENCE Skypoint Drug-Eluting Coronary Stent System (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-5.25 mm, and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted to add stent sizes of 4.50 mm and 5.00 mm in diameter (A “partial change” application). As clinical evaluation data, the results of foreign clinical studies were submitted.
Cardiopulmonary Circulation	Feb. 15, 2022 Total review time: 251 days Regulatory review time: 125 days	Apr. 28, 2017 Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System Global clinical study results	40	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A “partial change” application). The results of a global clinical study were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Feb. 15, 2022 Total review time: 251 days Regulatory review time: 125 days	Apr. 28, 2017 Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System Global clinical study results	41	Resolute Onyx SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 27 mm or less) that have a reference vessel diameter of 2.0-2.25 mm and are considered as dissection of the blood vessel or acute or impending coronary occlusion associated with angioplasty. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A “partial change” application). The results of a global clinical study were submitted as clinical evaluation data.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Feb. 24, 2022 Total review time: 239 days Regulatory review time: 113 days	Nov. 4, 2021 Foreign clinical study results	42	TactiCath SE Irrigation Catheter (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous catheter ablation with high-frequency current. The application was submitted to add the treatment of drug-resistant symptomatic persistent atrial fibrillation to the conventional intended use (treatment of drug-resistant symptomatic paroxysmal atrial fibrillation and common atrial flutter) (A “partial change” application). As clinical evaluation data, the results of foreign clinical studies were submitted.
Cardiopulmonary Circulation	Mar. 31, 2022 Total review time: 489 days Regulatory review time: 147 days	- Foreign clinical study results	43	BioFreedom Ultra Drug-coated Stent (Biosensors Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a biolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 33 mm or less) with a reference vessel diameter of 2.5-4.0 mm and a delivery catheter used to implant the stent to the site of stenosis. As clinical evaluation data, the results of foreign clinical studies were submitted.
Program	May 26, 2021 Total review time: 65 days Regulatory review time: 35 days	- Clinical evaluation report	44	COVID-19 Pneumonia Image Analysis Program FS-AI693 (FUJIFILM Corporation)	Approval	Program 1 Software for general-purpose imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.
Program	Dec. 24, 2021 Total review time: 60 days Regulatory review time: 44 days	- Clinical evaluation report	45	HOPE LifeMark-CAD Pneumonia Image Analysis Program for COVID-19 (Fujitsu Japan Limited)	Approval	Program 1 Software for diagnostic X-ray imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.

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Reprocessed Single-Use Medical Devices Approved in FY2021

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	Sep. 17, 2021 Total review time: 171 days Regulatory review time: 155 days	- No clinical study results	1	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 12 Reprocessed cuff for pneumatically-powered massager	Reprocessed single-use medical device originating from the component of "Flowtron ACS900" (Certification No.: 228ADBZX00013000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation. The application was submitted to add a collection container of the original medical device and change the manufacturing site (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Dec. 24, 2021 Total review time: 267 days Regulatory review time: 231 days	- No clinical study results	2	Reprocessed cuff C (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 12 Reprocessed cuff for pneumatically-powered massager	Reprocessed single-use medical device originating from the component of “SCD 700 Series” (Certification No.: 223AABZX00029000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation.
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 26, 2021 Total review time: 217 days Regulatory review time: 171 days	- No clinical study results	3	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 25 Reprocessed single-use natural orifices endoscopic dilator	Reprocessed single-use medical device originating from “Vagi-pipe” (Notification No. 20B1X00005000001), which is an endoscopic dilator used to dilate the vaginal opening during total laparoscopic hysterectomy. The application was submitted to extend the storage period before cleansing (A “partial change” application).
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 26, 2021 Total review time: 150 days Regulatory review time: 113 days	- No clinical study results	4	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 49 Reprocessed single-use trocar sleeve	Reprocessed single-use medical device originating from “Endopath Trocar System” (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity. The application was submitted to extend the storage period before cleansing (A “partial change” application).

Review Reports: https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

New Medical Devices Approved in FY 2020

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Aug. 21, 2020 Total review time: 259 days Regulatory review time: 194 days	- Japanese clinical study results	1	CureApp SC Digital Therapeutic and CO Checker for Nicotine Dependence (CureApp, Inc.)	Approval	Instrument & apparatus 21 Smoking cessation treatment support system	This application was submitted for marketing approval of a smoking cessation treatment support system, consisting of a digital therapeutic and an exhaled CO meter to support the smoking cessation treatment for patients with nicotine dependence, to be used as an adjunct to the standard smoking cessation treatment program.
Robotic, ICT, and other devices (not classified as other categories)	Nov. 30, 2020 Total review time: 133 days Regulatory review time: 115 days	Aug. 28, 2020 No clinical study results	2	SpaceOAR System (Boston Scientific Corporation)	Change	Medical products 4 Absorbable tissue spacer for radiotherapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The application was submitted to add other types of powder vial and injection needle. (A “partial change” application submitted during the post-market performance review period)
Robotic, ICT, and other devices (not classified as other categories)	Mar. 22, 2021 Total review time: 356 days Regulatory review time: 208 days	Aug. 26, 2020 (P190032) Oct. 26, 2020 (P200006) No clinical study results	3	FoundationOne Liquid CDx Cancer Genomic Profile (Chugai Pharmaceutical Co., Ltd.)	Approval	Program 1 Software for gene variants analysis (for comprehensive genomic profiling for cancer)	This application was submitted for marketing approval of an analysis program to acquire comprehensive genomic profiling pertaining to 324 cancer-related genes in circulating tumor DNA in the whole blood obtained from patients with solid tumors which contributes to formulating a therapeutic policy and determining the eligibility of drugs. This product also falls under the category of a term name, “Software for analysis of somatic variants (for eligibility identification of antineoplastic agents).”
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 27, 2020 Total review time: 297 days Regulatory review time: 138 days	Mar. 22, 2019 No clinical study results	4	Gore Viabahn Stent Graft (W. L. Gore & Associates, G. K.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft with nitinol stent wires wound around the outside of the graft (external stent structure type) and a delivery catheter. The application was submitted to add the small diameter type that comprises the delivery catheters used for small diameter and stent grafts with diameter size of 9 to 13 mm combined (A "partial change" application). Although the number of folding back of a stent wire, etc. was changed for a loaded stent graft as a result of the additional combination of stent grafts and delivery catheters, the basic design of the stent graft has not changed. As tests to secure the performance and safety of the additional combination of stent grafts and delivery catheters, the test certificates of radial force testing, animal experiment, etc. were submitted. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 21, 2020 Total review time: 84 days Regulatory review time: 31 days	- No clinical study results	5	Woven EndoBridge Device (Terumo Corporation)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system intended to be used to occlude wide-necked (defined the size as neck width ≥4 mm or dome-to-neck ratio <2) intracranial aneurysms located in the branch of anterior or posterior circulation. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 23, 2020 Total review time: 334 days Regulatory review time: 233 days	- Global clinical study results	6	IN.PACT AV Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or restenotic lesions in the native arteriovenous dialysis fistulae. The balloon surface of this product is coated with paclitaxel as a drug. The results of a global clinical study including Japan were submitted to evaluate the efficacy and safety of the product.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 8, 2021 Total review time: 497 days Regulatory review time: 48 days	Oct. 30, 2020 Global clinical trial	7	Ranger Drug-Coated Balloon Catheter (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	This application was submitted for marketing approval of a paclitaxel-coated balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or non-stented restenotic lesions in the superficial femoral or proximal popliteal arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 8, 2021 Total review time: 221 days Regulatory review time: 68 days	Sep. 7, 2016 Foreign clinical study results	8	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A paclitaxel-coated balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the superficial femoral and popliteal arteries. The application was submitted for an additional indication of in-stent restenotic lesions. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 29, 2021 Total review time: 167 days Regulatory review time: 109 days	Sep. 11, 2016 No clinical study results	9	NeuroStar TMS Therapy System (Neuronetics, Inc.)	Change	Instrument & apparatus 12 Repetitive transcranial magnetic stimulator	A repetitive transcranial magnetic stimulator that provides treatment for adult patients with Major Depressive Disorder (MDD) (only for the patients who have not benefitted from conventional antidepressant medication). The application was submitted to add a model with a mechanism for cooling treatment coils. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 25, 2020 Total review time: 224 days Regulatory review time: 120 days	Apr. 8, 1987 Japanese clinical study results	10	Cellex ECP System (Mallinckrodt Pharmaceuticals Ireland Limited)	Approval	Instrument & apparatus 7 Extracorporeal photopheresis system	The product is a system used for extracorporeal photopheresis therapy for steroid-resistant or intolerant chronic graft versus host disease. The system consists of a main unit, kit, methoxsalen solution, and a UVA lamp. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
Gastroenterology, Genitourinary and Reproductive Medicine	Jan. 27, 2021 Total review time: 126 days Regulatory review time: 82 days	- No clinical study results	11	UroLift System (NeoTract, Inc.)	Change	Medical products 4 Implantable prostate tissue lifting system	An implantable prostate tissue lifting system indicated for the treatment of dysuria associated with prostatic hyperplasia. The system is composed of a delivery device and an implant. The application was submitted for design changes of the delivery device to reflect requests from clinical practice. (A "partial change" application submitted during the post-market performance review period)
Ophthalmology and Otorhinolaryngology	May 29, 2020 Total review time: 346 days Regulatory review time: 214 days	- Japanese clinical study results	12	Eustachian Tube Plug (Fuji Systems Corporation)	Approval	Medical products 4 Prosthetic material for eustachian tube	The application was submitted for marketing approval of a prosthetic material for the eustachian tube used to narrow the lumen by placing it into an excessively open eustachian tube to improve the symptoms of patients with refractory patulous eustachian tube who do not respond to conservative treatment. The results of Japanese clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Apr. 16, 2020 Total review time: 142 days Regulatory review time: 82 days	May 10, 2016 Foreign clinical study results	13	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted for the additional indication for patients who are difficult to undergo open heart surgery among the patients with symptomatic, severe MR (grade 3+ or 4+) whose left ventricular ejection fraction is 20% or higher but lower than 30% (A "partial change" application). As clinical evaluation data, the results of foreign clinical studies in patients with symptomatic, severe secondary MR (grade 3+ or 4+) were submitted. (A “partial change” application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Apr. 27, 2020 Total review time: 136 days Regulatory review time: 67 days	May 1, 2017 No clinical study results	14	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add another model of a delivery catheter system, and to modify the descriptions on the details of approved items. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jun. 5, 2020 Total review time: 98 days Regulatory review time: 53 days	- No clinical study results	15	WATCHMAN Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51 Endocardial prosthetic material	An endocardial prosthetic material intended to reduce a risk of thromboembolism attributed to the left atrial appendage in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism. The application was submitted to add a high density polyethylene with new raw material specifications as a raw material of a washer used in the hemostasis valve of an access system in order to enhance the production efficiency, falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jun. 19, 2020 Total review time: 245 days Regulatory review time: 128 days	Jul. 9, 2019 No clinical study results	16	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted to add variations of clip delivery system and steerable guide catheter. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Aug. 28, 2020 Total review time: 246 days Regulatory review time: 179 days	Sep. 19, 2019 Foreign clinical study results	17	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve or the surgically placed aortic bioprosthetic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets or patients with symptomatic valvular disease due to dysfunction (stenosis, insufficiency, or combined) of a surgically placed aortic bioprosthetic valve, and who are unable to undergo surgery. The product consists of a porcine pericardial-derived bioprosthetic valve, and a delivery set, which is composed of delivery catheter and loading system. The 23-mm, 26-mm, and 29-mm bioprosthetic valves are identical to those are approved as the components of "CoreValve Evolut PRO" (Approval No.: 23000BZX00196000). As for 34-mm bioprosthetic valve, it has an outer skirt attached to the inflow part of the 34-mm bioprosthetic valve which is approved as the components of "CoreValve Evolut R" (Approval No.: 22800BZX00414000). The profile of delivery catheter is smaller compared with that of CoreValve Evolut PRO. The results of some clinical studies on the previously approved products conducted in the US were submitted to evaluate the efficacy and safety of Evolut PRO+ System.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Sep. 11, 2020 Total review time: 260 days Regulatory review time: 170 days	Aug. 31, 2020 Foreign clinical study results	18	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system consists of a bovine pericardial-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This product has been approved as a medical device used for transcatheter aortic valve implantation (Approval No.: 22800BZX00094000). This application was submitted to add indications for the treatment of malfunctions of surgically implanted right ventricular outflow tract (RVOT) extracardiac conduit or the bioprosthetic valve in the pulmonic position in patients with a congenital heart diseases who are at high surgical risk, in accordance with the conditional early approval system for innovative medical devices based on “Conditional Early Approval System for Innovative Medical Device Products (Fast-Break Scheme)” (PSEHB Notification No. 0731-1, Director-General of the PSEHB, MHLW, dated on July 31, 2017). (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the product in the pulmonic position. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Nov. 19, 2020 Total review time: 238 days Regulatory review time: 34 days	- No clinical study results	19	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted for changes including addition of a mobile battery that has been improved in response to the discontinued production of the cell incorporated in the current mobile battery and the suspension of product shipment due to malfunctions of the mobile battery. (A ”partial change” application submitted during the reexamination period)
Cardiopulmonary Circulation	Dec. 2, 2020 Total review time: 246 days Regulatory review time: 118 days	Jul. 21, 2020 Foreign clinical study results	20	WATCHMAN FLX Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Endocardial prosthetic material	The device is an endocardial prosthetic material intended to reduce a risk of thromboembolism attributed to the left atrial appendage in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism. This device consists of a delivery system loaded with a closure device and an access system. The device was developed based on the company’s approved product “WATCHMAN Left Atrial Appendage Closure System” (Approval No. 23100BZX00049000). The improvement was made by changing the design for application to a wider range of left atrial appendage size, for easier position adjustment, and for further reduction of the risks of damaging left atrial appendage and of thrombosis. The intended use was also changed so that not only warfarin but also other general anticoagulants can be used in the postoperative period. As clinical evaluation data, the results of US clinical studies were submitted to evaluate the efficacy and safety of this product in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Dec. 28, 2020 Total review time: 357 days Regulatory review time: 145 days (Review report, etc.)	Oct. 18, 2018 Japanese and foreign clinical study results	21	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system (LVAD) used to assist the blood circulation for severe cardiac failure in patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system. The device has been approved for treatment with LVAD of severe cardiac failure in patients who are qualified to receive heart transplant as a bridge therapy until heart transplantation (Approval No. 23100BZI00006000). This application was submitted to add an indication of destination therapy, in which LVAD is used to improve the life prognosis and to provide home care for better quality of life for patients with serious heart failure for whom heart transplantation is not indicated (A “partial change” application). As clinical evaluation data, the results of the foreign clinical studies and the Japanese clinical studies for the previous generation product “HeartMate II Left Ventricular Assist System” (Approval No. 22400BZI00017000) were submitted to evaluate the efficacy and safety of the product in destination therapy.
Cardiopulmonary Circulation	Jan. 8, 2021 Total review time: 315 days Regulatory review time: 176 days	Jun. 17, 2015 (transfemoral approach) Dec. 2, 2016 (transapical/transaortic approach) Japanese clinical study results	22	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A transcatheter bioprosthetic valve replacement system primarily consists of a transcatheter bioprosthetic aortic valve derived from bovine pericardium and a delivery catheter system to deliver the bioprosthetic aortic valve to the position of the aortic or pulmonary valve. The product has already been approved for the indications of (1) symptomatic severe stenosis of the native aortic valve or symptomatic valvular disease attributed to dysfunction of a surgical bioprosthetic aortic valve, or (2) treatment for patients with dysfunction of an implanted extracardiac conduit in the right ventricular outflow tract or a bioprosthetic valve at the position of the pulmonary valve, for whom surgery cannot be performed, and who are not receiving chronic dialysis (Approval No. 22800BZX00094000). The application was submitted to expand the indication for patients on chronic dialysis with findings of (1) (A “partial change” application). The results of a Japanese prospective, single-arm study in 28 patients on chronic dialysis, and a prospective, single-arm trial conducted for humanitarian reasons (extension trial) in 13 patients on chronic dialysis, were submitted as the clinical study data on the indication expansion. (A “partial change” application submitted during the post-market performance review period)

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Improved Medical Devices (With Clinical Data) Approved in FY2020

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Jun. 26, 2020 Total review time: 268 days Regulatory review time: 232 days	- Japanese clinical study results	1	Automated Hematology Analyzer XN-31 (SYSMEX CORPORATION)	Approval	Instrument & apparatus 17 Malaria diagnostic device	Automated Hematology Analyzer XN-31 is a medical device that assists the diagnosis of malaria by counting DNA-containing erythrocytes including malaria parasites in the whole blood leveraging flow cytometry. To demonstrate the evaluation of malaria diagnosis made by Automated Hematology Analyzer XN-31, the study result, which agrees with that obtained by performing microscopy using peripheral blood smears was submitted as the clinical study.
Robotic, ICT, and other devices (not classified as other categories)	Jun. 29, 2020 Total review time: 27 days Regulatory review time: 22 days	- Clinical evaluation report	2	COVID-19 Pneumonia Image Analysis Program Ali-M3 (MIC Medical Corp.)	Approval	Program 1 Software for diagnostic X-ray imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.
Robotic, ICT, and other devices (not classified as other categories)	Aug. 11, 2020 Total review time: 22 days Regulatory review time: 18 days	- Japanese clinical study results	3	COVID-19 Pneumonia Image Analysis AI Program InferRead CT Pneumonia (CES Descartes Co., Ltd.)	Change	Program 1 Software for diagnostic X-ray imaging system workstation	A computer-aided detection support software that processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT images when performing the image diagnosis of pneumonia. This application was submitted to change the product name, the intended use or the efficacy, and the performance and safety specifications in order to reflect the results of a newly conducted clinical study on the approved product information (A "partial change" application).
Robotic, ICT, and other devices (not classified as other categories)	Nov. 13, 2020 Total review time: 259 days Regulatory review time: 167 days	Mar. 8, 2018 Foreign clinical study results	4	Medtronic Guardian Connect (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 20 Glucose monitoring system	The device is a glucose monitoring system that continuously measures glucose levels in the interstitial fluid under the skin in persons with diabetes. The application was submitted to add a new glucose sensor (A "partial change" application).
Robotic, ICT, and other devices (not classified as other categories)	Nov. 30, 2020 Total review time: 264 days Regulatory review time: 210 days	May 20, 2019 Clinical evaluation report	5	Leica Virtual Slide System AT2 DX (Leica Microsystems K.K.)	Approval	Instrument & apparatus 21 Diagnostic assistant device for pathological whole slide image	The application was submitted for marketing approval of a diagnostic assistant device for pathological whole slide image, which automatically captures, displays, and stores pathological whole slide images, and is intended to assist pathologists to evaluate and diagnose histopathological images.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 23, 2020 Total review time: 268 days Regulatory review time: 216 days	Aug. 29, 2019 Clinical evaluation report	6	HemoSphere Advanced Monitoring Platform (Edwards Lifesciences Ltd.)	Approval	Instrument & apparatus 21 Multiparameter monitor with critical parameters	The application was submitted for marketing approval of a multiparameter monitor with critical parameters intended to measure thermodilution cardiac output, arterial pressure-based cardiac output, blood pressure, venous oxygen saturation, and tissue oxygen saturation, and use to collect and monitor various physiological information.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 23, 2020 Total review time: 254 days Regulatory review time: 120 days	Sep. 27, 2017 Foreign clinical study results	7	FreeStyle Libre (Abbott Japan LLC)	Change	Instrument & apparatus 20 Glucose monitoring system	A glucose monitoring system to continuously measure and record glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. The application was submitted to mainly change the algorithm for calculation of glucose level with an aim to improve the accuracy of measuring glucose level in the interstitial fluid.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Jun. 9, 2020 Total review time: 253 days Regulatory review time: 127 days	- Clinical evaluation report	8	Vertecem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic bone cement	A bone cement for orthopedic surgery used by filling into the vertebral body through a spinal screw with fenestrations in order to fix and stabilize the screw when performing posterior spinal fusion for the spine with lowered bone strength due to osteoporosis, osteopenia, or malignant spinal tumor. The product is used with the company's "Expedium Verse Fenestrated Screw System (Approval No.: 30200BZX00193000)". A clinical evaluation report summarizing the foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the concomitant use of this product and spinal screw.
Orthopedic and Plastic Surgery	Jun. 9, 2020 Total review time: 253 days Regulatory review time: 156 days	Dec.20, 2016 Clinical evaluation report	9	Expedium Verse Fenestrated Screw System (Johnson & Johnson K.K.)	Approval	Medical products 4 Spinal internal fixation system	A spinal internal fixation system used for temporary fixation, support or alignment correction of the spine in patients with spinal diseases such as degenerative disease, trauma, and tumor in the thoracic vertebra, lumbar vertebra, and sacral vertebra. The fenestrations are provided on the screw shaft portion so that bone cement can be injected into the vertebral body. For the spine with lowered bone strength due to osteoporosis, osteopenia, or malignant spinal tumor and thereby may lose the fixability of the screw in the bone, the product is used with the company's bone cement "Vertecem V+ Bone Cement Kit (Approval No.: 30200BZX00192000)". A clinical evaluation report summarizing the foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the concomitant use of this product and bone cement.
Orthopedic and Plastic Surgery	Jul. 3, 2020 Total review time: 259 days Regulatory review time: 160 days	Sep. 28, 2017 Clinical evaluation report	10	Traumacem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic bone cement	Orthopedic bone cement used for augmentation of the head element of intramedullary femoral nail in patients with poor bone quality. This product consists of polymethylmethacrylate-based polymer powder and methylmethacrylate-based monomer liquid, and is used with the company's intramedullary femoral nail, "TFN-Advanced Proximal Femoral Nail System" (Approval No.: 22700BZX00142000). A clinical evaluation report summarizing the foreign clinical literatures was submitted to evaluate the safety and efficacy of this product used with the intramedullary femoral nail.
Orthopedic and Plastic Surgery	Jul. 3, 2020 Total review time: 259 days Regulatory review time: 160 days	Feb.28, 2014 Clinical evaluation report	11	TFN-Advanced Proximal Femoral Nail System (Johnson & Johnson K.K.)	Change	Medical products 4 Intramedullary femoral nail	An intramedullary femoral nail system made of titanium alloy for internal fixation of femoral fracture used for reduction and fixation proximal femoral fracture. This product consists of a nail, a head element (with or without fenestrations), and an end cap. The head element with fenestrations can be used with the company's orthopedic bone cement, "Traumacem V+ Bone Cement Kit" (Approval No.: 30200BZX00222000). A clinical evaluation report summarizing the clinical literatures was submitted to evaluate the safety and efficacy of this product used with the bone cement.
Orthopedic and Plastic Surgery	Aug. 4, 2020 Total review time: 223 days Regulatory review time: 202 days	- Foreign clinical study results	12	Juvederm Vista Volux XC (Allergan Japan K. K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material to a soft tissue using hyaluronic acid injected subcutaneously or into supraperiosteal space to correct volume loss and increase the volume in adult faces. This product consists of hyaluronic acid gel and a syringe. The hyaluronic acid gel contains lidocaine hydrochloride 0.3 wt% for pain relief during the procedure. The results of a foreign clinical study on injection of the product in the chin and jaw were submitted as an evaluation of the efficacy and safety.
Orthopedic and Plastic Surgery	Aug. 19, 2020 Total review time: 189 days Regulatory review time: 130 days	Oct. 19, 2018 Clinical evaluation report	13	Ultrasound Bone Densitometer EchoS System (Toyo Medic Co., Ltd.)	Approval	Instrument & apparatus 12 Ultrasound bone densitometer	An ultrasound bone densitometer to analyze the estimated bone density by measuring the ultrasound pulse reflected from the bone to diagnose the bone nature. This product consists of a main body of EchoS, a transducer, and a personal computer installed with the dedicated software and is not used for definitive diagnosis. A clinical evaluation report consisting of foreign clinical literatures was submitted to confirm the correlation of the estimated bone density analyzed by this product and the bone density measured by a dual-energy x-ray absorptiometry.

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Orthopedic and Plastic Surgery	Aug. 20, 2020	Mar. 9, 2012	14	Sientra Breast Implant (Medical U&A, Inc.)	Approval	Medical products 4	A gel-filled artificial breast made of a silicone gel used for breast reconstruction or augmentation in adult women to restore or form the shape of a breast. This product contains a breast implant (round smooth, round textured, and anatomical textured) and a sizer as components. A clinical evaluation report consisting of data related to foreign clinical studies and clinical literatures was submitted to evaluate the incidence of adverse events as the efficacy and safety of the artificial breast.
	Total review time: 181 days Regulatory review time: 54 days	Clinical evaluation report				Gel-filled mammary prosthesis	
Orthopedic and Plastic Surgery	Dec. 10, 2020	-	15	Juvederm Vista Volite XC (Allergan Japan K.K.)	Approval	Medical products 4	An injectable material to a soft tissue using hyaluronic acid intended to be used to correct superficial cutaneous depressions such as fine lines and for improvement of skin quality in face and neck in adults by injecting it intradermally. This product consists of hyaluronic acid gel and a syringe. The hyaluronic acid gel contains 0.3 wt% of lidocaine hydrochloride for pain relief during the procedure. The results of a foreign clinical study on injection of the product into the face and neck were submitted as the evaluation of the efficacy and the safety.
	Total review time: 163 days Regulatory review time: 147 days	Foreign clinical study results				Injectable material to a soft tissue using hyaluronic acid	
Orthopedic and Plastic Surgery	Dec. 24, 2020	-	16	VBS Vertecem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4	An orthopedic bone cement intended to be used to stabilize the fractured vertebral body and thereby relieves the pain of patients in acute phase of painful compression fracture of spine due to primary osteoporosis in the one vertebral body from the fifth thoracic vertebrae to the fifth lumbar vertebrate. The product is used for the patients whose lower back pain has not relieved after receiving sufficient conservative treatment. The results of a Japanese multicenter, single-arm study were submitted to evaluate the rate of restoration of vertebral height and pain score for the efficacy and the adverse events for the safety.
	Total review time: 267 days Regulatory review time: 205 days	Japanese clinical study results				Orthopedic bone cement	
Orthopedic and Plastic Surgery	Dec. 24, 2020	-	17	VBS Stent Balloon (Johnson & Johnson K.K.)	Approval	Medical products 4	A vertebral body support material which creates a cavity in the fractured vertebral body to restore and maintain the vertebral height of fractured vertebral body for patients in acute phase of painful compression fracture of spine due to primary osteoporosis in the one vertebral body from the fifth thoracic vertebrae to the fifth lumbar vertebrate. The product is used for patients whose lower back pain has not relieved after receiving sufficient conservative treatment. The results of a Japanese multicenter, single-arm study were submitted to evaluate the rate of restoration of vertebral height and pain score for the efficacy and the adverse events for the safety.
	Total review time: 262 days Regulatory review time: 200 days	Japanese clinical study results				Vertebral body support material	
Orthopedic and Plastic Surgery	Jan. 14, 2021	Jul. 2014	18	SHILLA Growth Guidance System (Medtronic Sofamor Danek, Co., Ltd.)	Approval	Medical products 4	A spinal internal fixation system used generally in patients aged less than 10 years, with potentially life-threatening, severe, progressive, early-onset scoliosis. The product is used in patients for whom surgical correction and maintaining of correction are necessary, who are with a Cobb angle of 50 degrees or greater, and whose spinal curvature covers at least 6 segments of the spine from the upper end vertebra to the lower end vertebra. The results of a Japanese multicenter study in patients with early-onset scoliosis were submitted to evaluate the level of correction of the Cobb angle at 24 months after surgery for efficacy, and the incidence rate of adverse events and device failures for safety.
	Total review time: 266 days Regulatory review time: 115 days	Japanese clinical study results				Spinal internal fixation system	

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Orthopedic and Plastic Surgery	Mar. 29, 2021 Total review time: 208 days Regulatory review time: 141 days	- Japanese clinical study results	19	ReBOSSIS-J (ORTHOREBIRTH Co., Ltd.)	Approval	Medical products 4 Absorbable bone regeneration material	An absorbable bone regeneration material used to fill bony defects caused by trauma, autogenous bone harvesting or treatment of diseases, and to support autogenous bone graft (allograft). The product is a cotton-shaped material consisting of fine fiber combined with β-tricalcium phosphate and a lactic acid-glycolic acid copolymer. The results of a multicenter, open-label study conducted in Japan were submitted to demonstrate the meeting of standard for achieving bone replacement capability based on results of clinical study conducted by another company for its approved product, and to confirm the state of developing no unacceptable adverse event peculiar to this product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 6, 2020 Total review time: 166 days Regulatory review time: 98 days	Jul. 16, 2010 Clinical evaluation report	20	Arctic Sun 5000 Temperature Management System (Medicon, Inc.)	Change	Instrument & apparatus 12 Water pad specific heating control unit	A water pad specific heating control unit used to cool or warm the patient's body. The application was submitted to add the indication of the product for “body temperature management (temperature management therapy) in adult with return of spontaneous circulation following cardiac arrest (A "partial change" application). A clinical evaluation report summarizing the clinical literature, etc. on the temperature management (temperature management therapy) using this product was submitted to evaluate the efficacy and safety for the additional indication.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 16, 2020 Total review time: 160 days Regulatory review time: 61 days	Apr. 2013 / Feb. 2018 Clinical evaluation report	21	Perclose PROGLIDE (Abbott Medical Japan LLC)	Change	Medical products 2 Non-absorbable suture set	A non-absorbable suture set used for hemostasis of femoral arterial or venous access sites following percutaneous catheterization procedures. The application was submitted to add the indications of the product for the procedure of using a large diameter introducer sheath such as endovascular aortic repair at femoral arterial access site and for the procedure at femoral venous access site such as percutaneous repair for mitral valve coaptation failure (A "partial change" application). The clinical evaluation report summarizing clinical literature, etc. was submitted as an evaluation material for the additional indications.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 16, 2020 Total review time: 267 days Regulatory review time: 150 days	- Japanese clinical study results	22	PuraStat (3-D Matrix, Ltd.)	Approval	Medical products 4 Absorbable topical hemostatic material	The product is an absorbable topical hemostatic material in a pre-filled syringe, which is filled with clear synthetic peptide solution, and used for reducing the number of ablation with hemostatic forceps to stop oozing in gastrointestinal endoscopy. In a Japanese clinical study using the frequency in use of hemostatic forceps in gastrointestinal endoscopy as the primary endpoint, it was evaluated that the frequency of use of hemostatic forceps was significantly lower when using this product compared with the conventional hemostatic method.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 3, 2020 Total review time: 263 days Regulatory review time: 102 days	- Japanese clinical study results	23	Rheocarna (Kaneka Corporation)	Approval	Instrument & apparatus 7 Adsorption hemoperfusion column	An adsorption hemoperfusion column filled with dextran sulfate and L-tryptophan immobilized cellulose beads used for improving ulcers in arteriosclerosis obliterans for which revascularization is not indicated. The results of Japanese clinical study that evaluated the efficacy and safety of the product were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 4, 2020 Total review time: 253 days Regulatory review time: 144 days	Dec. 14, 2018 Foreign clinical study results	24	Pipeline Flex Flow Diverter System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system intended to be used for endovascular therapy for intracranial aneurysms that are difficult to treat surgically or by coil embolization with a maximum diameter of 5 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from petrous segment to the supraclinoid segment of the internal carotid artery and the vertebral artery, except for the acute ruptured aneurysms. This application was submitted to primarily add supraclinoid segment of internal carotid artery and vertebral artery as indicated sites and change the maximum diameter (from 10 mm to 5 mm) of target aneurysms (A "partial change" application). The results of foreign clinical study including the additional indications as study subject were submitted as the clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 17, 2020 Total review time: 268 days Regulatory review time: 116 days	Aug. 11, 2010 Foreign clinical study results	25	Wingman Catheter System (Century Medical, Inc.)	Approval	Instrument & apparatus 51 Catheter for penetrating vascular stenosis	Catheter for penetrating vascular stenosis used to assist the passage of guide wire and secure the passing parts in chronic total occlusion lesions in the artery of lower extremity which the guide wire is difficult to pass, except the region of iliac arteries. The results of foreign clinical study conducted to evaluate the efficacy and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 9, 2020 Total review time: 266 days Regulatory review time: 62 days	Apr. 2017 Foreign clinical study results	26	LIFESTREAM Vascular Stent System (Medicon, Inc.)	Approval	Instrument & apparatus 7 Stent-graft for central circulatory system	The application was submitted for marketing approval of a stent-graft for central circulatory system which consists of a stent graft and a delivery catheter used to treat de novo or restenotic lesions in the iliac arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 8, 2021 Total review time: 262 days Regulatory review time: 80 days	- Clinical evaluation report	27	Prosthesis for Microvascular Decompression of Cranial Nerve (Kono Seisakusho Co.,Ltd.)	Approval	Medical products 4 Surgical mesh	A surgical mesh consisting of polytetrafluoroethylene (PTFE) resin used to keep blood vessels away from nerves during microvascular decompression for trigeminal neuralgia, hemifacial spasm or glossopharyngeal neuralgia. The clinical evaluation report was submitted to evaluate the efficacy and safety of microvascular decompression of cranial nerve.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 21, 2021 Total review time: 269 days Regulatory review time: 68 days	Jul. 13, 2018 Foreign and Japanese clinical study results	28	Surpass Streamline Flow Diverter System (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system intended to be used for endovascular therapy for intracranial aneurysms that are difficult to treat surgically or by coil embolization with a maximum diameter of 10 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment to the supraclinoid segment of the internal carotid artery (except for the acute ruptured aneurysms). The results of foreign and Japanese clinical studies to evaluate the efficacy and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 5, 2021 Total review time: 245 days Regulatory review time: 91 days	Jun. 14, 2017 Clinical evaluation report	29	ULTRASCORE Scoring PTA Balloon Catheter 035 OTW (Medicon, Inc.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	The application was submitted for marketing approval of a balloon-dilating catheter for angioplasty used for expanding lesions that are resistant to expansion by a normal balloon catheter in the renal artery, artery of lower extremity, or shunt in the percutaneous transluminal angioplasty (PTA) or for post-expansion at the time of stent placement in these blood vessels.
Ophthalmology and Otorhinolaryngology	Apr. 16, 2020 Total review time: 170 days Regulatory review time: 130 days	Dec. 11, 2018 Foreign clinical study results	30	Clariti 1 Day (CooperVision Japan Inc.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	The application was submitted for marketing approval of daily wear, single-use, colored contact lenses for correction of visual acuity, which are intended to be used for visual correction. The lens is composed of silicone hydrogel (Somofilcon A) with a moisture content of 56% and an oxygen permeability (Dk) of 60.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Apr. 28, 2020 Total review time: 123 days Regulatory review time: 109 days	- Foreign clinical study results	31	Tecnis Synergy TVB Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The device is a posterior chamber lens with an injector in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye with corneal astigmatism. The results of foreign clinical studies were submitted as clinical evaluation data.
Ophthalmology and Otorhinolaryngology	Jul. 17, 2020 Total review time: 260 days Regulatory review time: 161 days	- Foreign clinical study results	32	Clareon TORIC Intraocular Lens AutonoMe Auto-pre-loaded Delivery System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The application was submitted for marketing approval of posterior chamber lenses with an injector having cylindrical refractivity, which are intended to be used for visual correction of corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Sep. 2, 2020 Total review time: 253 days Regulatory review time: 217 days	- Foreign clinical study results	33	Clareon TORIC Aspherical Hydrophobic Acryl Intraocular Lens (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The application was submitted for marketing approval of posterior chamber lenses having cylindrical refractivity, which are intended to be used for visual correction of corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Sep. 2, 2020 Total review time: 167 days Regulatory review time: 115 days	- Clinical evaluation report	34	BioBlade Laser System (Rakuten Medical Japan K.K.)	Approval	Instrument & apparatus 31 PDT semiconductor laser	The application was submitted for marketing approval of a laser system to be used in combination with Akalux IV Infusion 250 mg (non-proprietary name: cetuximab sarotalocan sodium [genetical recombination]) for the treatment of unresectable, locally advanced or recurrent head and neck cancer.
Ophthalmology and Otorhinolaryngology	Jan. 26, 2021 Total review time: 244 days Regulatory review time: 170 days	- Foreign clinical study results	35	Tecnis Symfony Plus VB Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The application was submitted for marketing approval of a posterior chamber lens with an injector in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of an aphakic eye.
Ophthalmology and Otorhinolaryngology	Feb. 9, 2021 Total review time: 266 days Regulatory review time: 49 days	Dec. 26, 2017 Foreign clinical study results	36	iLux System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 12 Eyelid thermal pulsation system	The application was submitted for marketing approval of an eyelid thermal pulsation system used for providing localized heat and pressures to the eyelids in patients with meibomian gland dysfunction.
Ophthalmology and Otorhinolaryngology	Mar. 15, 2021 Total review time: 474 days Regulatory review time: 223 days	- Foreign clinical study results	37	1-Day Acuvue Theravision K (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 72 Single-use colored drug-containing contact lenses for correcting visual acuity	The application was submitted for marketing approval of single-use colored drug-containing contact lenses used for vision correction, and alleviation of ocular allergic symptoms when wearing contact lenses in patients with allergic conjunctivitis.
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 411 days Regulatory review time: 80 days	- Japanese clinical study results	38	Coroflex ISAR Neo Coronary Stent (Nipro Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-4.25 mm, and a delivery catheter used to implant a stent to the site of stenosis. Probucol is used for the product instead of non-biodegradable polymers, as a base to retain the drug. The results of Japanese clinical studies were submitted as clinical evaluation data.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 151 days Regulatory review time: 122 days	Jun. 23, 2020 Global clinical trial	39	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is used for cardiac cryoablation to treat drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation. The application was submitted to add drug refractory recurrent symptomatic persistent atrial fibrillation as the intended use (A "partial change" application). The results of global clinical studies evaluating the efficacy and safety of the product in patients with drug refractory recurrent symptomatic persistent atrial fibrillation were submitted.
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 151 days Regulatory review time: 122 days	Jun. 23, 2020 Global clinical trial	40	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is intended to be used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites for the treatment of atrial fibrillation, or creation of an ablation line between the inferior vena cava and the tricuspid valve when performing the procedure of cryoablation for the treatment of drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation. The application was submitted to add drug refractory recurrent symptomatic persistent atrial fibrillation as the intended use (A "partial change" application). The results of global clinical studies evaluating the efficacy and safety of the product in patients with drug refractory recurrent symptomatic persistent atrial fibrillation were submitted.
Cardiopulmonary Circulation	Jul. 9, 2020 Total review time: 195 days Regulatory review time: 93 days	May 2, 2017 Clinical evaluation report	41	RESONATE CRT-D Series (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a model with a function to provide indicators related to the changes in the patient’s biological information (HeartLogic function) based on the concept of “testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis” provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017). " (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted to demonstrate that the HeartLogic function can provide indicators related to changes in biological information.
Cardiopulmonary Circulation	Aug. 4, 2020 Total review time: 151 days Regulatory review time: 84 days	May 28, 2020 Foreign clinical study results	42	Synergy Stent System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo coronary artery lesions (legion length of 44 mm or less) with a reference vessel diameter of 2.25-5.00 mm and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted for additional stent size of 48 mm in length (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the additional size.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 20, 2020 Total review time: 265 days Regulatory review time: 94 days	- Japanese clinical study results	43	ECMO System HLS SET Advanced-LT (Getinge Group Japan K.K.)	Approval	Instrument & apparatus 7 Heparin-coated percutaneous cardiopulmonary support system	This device is a heparin coated extracorporeal circulation system used for cardiopulmonary support. This device consists of a centrifugal pump with an oxygenator, a blood parameter measuring cell, a patient circuit, a gas line filter, a priming set, and a cannulae, and is used with a dedicated driving device, "CARDIOHELP Console" (Approval No.: 22500BZX00277000). This device is a combination of the approved product, "ECMO System HLS Set Advanced" (Approval No.: 22800BZX00092000) and "HLS Cannulae" (Approval No.: 22600BZX00042000), and developed as an ECMO for mid to long-term use by extending the maximum designed duration of use from conventional 6 hours to 14 days. The results of Japanese clinical study were submitted as clinical evaluation data to evaluate clinical efficacy and safety of the product for the use in maximum designed duration.
Cardiopulmonary Circulation	Aug. 21, 2020 Total review time: 162 days Regulatory review time: 58 days	Apr. 28, 2017 Foreign clinical study results	44	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a zotarolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesions (legion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm and a delivery catheter to place the stent at the site of stenosis. The application was submitted for additional stent size of 2.25 mm in diameter and the stent length of 34 mm and 38 mm (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the additional sizes.
Cardiopulmonary Circulation	Sep. 4, 2020 Total review time: 119 days Regulatory review time: 50 days	Sep. 11, 2018 Clinical evaluation report	45	Apple's ECG App (Apple Inc.)	Approval	Program 1 Home-use ECG program	A home-use program that creates, records, stores, transfers, and displays single channel ECGs similar to lead-I ECGs. It analyzes the obtained ECG, classifies the wave form as being suggestive of sinus rhythm or atrial fibrillation and notifies the results to the user. A clinical evaluation report summarizing overseas clinical literature was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Sep. 4, 2020 Total review time: 116 days Regulatory review time: 47 days	Sep. 11, 2018 Clinical evaluation report	46	Apple's Irregular Rhythm Notification Feature (Apple Inc.)	Approval	Program 1 Home-use cardiac rate monitoring program	A home-use program that analyzes pulse rate data, detects irregular heartbeats suggestive of atrial fibrillation and notifies the user. A clinical evaluation report summarizing overseas clinical literature was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Oct. 19, 2020 Total review time: 146 days Regulatory review time: 89 days	- Foreign clinical study results	47	XIENCE Skypoint 48 Drug-Eluting Stent (Abbott Medical Japan LLC)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesions (a lesion length of 44 mm or less) with a reference vessel diameter of 2.25-4.25 mm, and a delivery catheter used to implant a stent to the site of stenosis. The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Mar. 29, 2021 Total review time: 292 days Regulatory review time: 140 days	- Japanese clinical study results	48	Biofloat Console (Nipro Corporation)	Change	Instrument & apparatus 7 Assistant artificial heart driving unit	A blood circulation device that drives an exclusive centrifugal pump incorporated in the extracorporeal circuit is used for extracorporeal circulation in patients for whom cardiotomy or cardiac functional recovery is necessary, or for assisted circulation intended to maintain normal systemic circulation and improve the cardiac insufficiency in patients with severe heart failure. The application was submitted to add "Biofloat Ventricular Assist Device Set HC" (Approval No. 30300BZX00093000) as a concomitant device, and also to add the indication of the product as an assistant artificial heart driving unit (A "partial change" application). As clinical evaluation data, the results of a Japanese clinical study were submitted to evaluate the clinical efficacy and safety of the combined use with the additional concomitant device.

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Cardiopulmonary Circulation	Mar. 29, 2021	-	49	Biofloat Ventricular Assist Device Set HC (Nipro Corporation)	Approval	Instrument & apparatus 7	A single-use extracorporeal assistant artificial cardiac pump used to maintain normal systemic circulation including the heart itself and improve cardiac insufficiency in patients with severe heart failure exceeding the limit that can be treated with conventional medication or existing assisted circulation (such as intraaortic balloon pumping or venoarterial bypass) due to severe heart failure or cardiogenic shock. This product is concomitantly used with a dedicated driving device “Biofloat Console” (Approval No. 22800BZX00322000). The product adopts an approved device “Biofloat Centrifugal Pump” (Approval No. 22800BZX00321000) as a blood pump. The product was developed to increase auxiliary flow and reduce the risk of hemolysis and thrombus compared to the similar approved device with a pulsating type pump, “Nipro Heparin-Coated Ventricular Assist Device Set” (Approval No. 21700BZZ00011000). As clinical evaluation data, the results of a Japanese clinical study were submitted to evaluate the clinical efficacy and safety of the product for the use in maximum designed duration.
	Total review time: 292 days Regulatory review time: 140 days	Japanese clinical study results				Single-use extracorporeal assistant artificial cardiac pump	

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Reprocessed Single-Use Medical Devices Approved in FY2020

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Aug. 20, 2020 Total review time: 511 days Regulatory review time: 360 days	- No clinical study results	1	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 12 Reprocessed cuff for pneumatically-powered massager	Reprocessed single-use medical device originating from the component of "Flowtron ACS900 (Certification No.: 228ADBZX00013000), which is a pneumatically-powered massager to prevent venous thrombosis by compressing the patient's leg with pneumatic pressure to promote venous blood circulation.
Gastroenterology, Genitourinary and Reproductive Medicine	Nov. 24, 2020 Total review time: 333 days Regulatory review time: 222 days	- No clinical study results	2	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 25 Reprocessed single-use natural orifices endoscopic dilator	Reprocessed single-use medical device originating from "Vagi-pipe" (Notification No. 20B1X00005000001), which is an endoscopic dilator used to dilate the vaginal opening during total laparoscopic hysterectomy.
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 10, 2020 Total review time: 259 days Regulatory review time: 182 days	- \	3	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 49 Reprocessed single-use trocar sleeve	Reprocessed single-use medical device originating from "Endopath Trocar System" (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity.
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 18, 2021 Total review time: 170 days Regulatory review time: 129 days	- No clinical study results	4	Reprocessed Trocar E2 (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 49 Reprocessed single-use trocar sleeve	Reprocessed single-use medical device originating from "Endopath Trocar System" (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity. The difference from the company's approved device "Reprocessed Trocar E (HOGY)" (Approval No. 30200BZX00393000) is that this product originates from the original medical device made with different components.

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New Medical Devices Approved in FY 2019

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Jul. 9, 2019 Total review time: 81 days Regulatory review time: 35 days	- No clinical study results	1	SpaceOAR System (Augmenix, Inc.)	Change	Medical products 4 Absorbent tissue spacer for radiation therapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Robotic, ICT, and other devices (not classified as other categories)	Aug. 1, 2019 Total review time: 69 days Regulatory review time: 21 days	- No clinical study results	2	SpaceOAR System (Augmenix, Inc.)	Change	Medical products 4 Absorbent tissue spacer for radiation therapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Robotic, ICT, and other devices (not classified as other categories)	Mar. 11, 2020 Total review time: 152 days Regulatory review time: 91 days	- Japanese clinical study results	3	NeuCure BNCT Dose Engine (Sumitomo Heavy Industries, Ltd.)	Approval	Program 2 Treatment planning program for boron neutron capture therapy	The application was submitted for marketing approval of a supporting program to decide on boron neutron capture therapy (BNCT) treatment planning for unresectable locally advanced/recurrent head and neck cancer by calculating dose distribution given by BNCT based on contour information and irradiation conditions with the concomitant use of Steboronine 9000 mg/300 mL for infusion (Non-proprietary Name: Borofalan [^{10}B]) as a boron drug.
Robotic, ICT, and other devices (not classified as other categories)	Mar. 11, 2020 Total review time: 152 days Regulatory review time: 91 days	- Japanese clinical study results	4	NeuCure BNCT System (Sumitomo Heavy Industries, Ltd.)	Approval	Instrument & apparatus 9 Neutron irradiation system for boron neutron capture therapy	The application was submitted for marketing approval of a neutron irradiation system intended to be used for boron neutron capture therapy (BNCT) for unresectable locally advanced/recurrent head and neck cancer with the concomitant use of Steboronine 9000 mg/300 mL for infusion (Non-proprietary Name: Borofalan [^{10}B]) as a boron drug.
Orthopedic and Plastic Surgery	Jun. 10, 2019 Total review time: 956 days Regulatory review time: 232 days	- Japanese clinical study results	5	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Purifier for blood cell removal	A purifier for blood cell removal to selectively adsorb and remove granulocytes and monocytes in peripheral blood by performing direct hemoperfusion using an extracorporeal circulation column which is filled with an adsorbent carrier made of cellulose acetate. The application was submitted to add the indication for improving clinical symptoms in patients with psoriatic arthritis who have not responded, have not sufficiently responded, or are not amenable to conventional systemic treatments with multiple biological products (A “partial change” application). The results of Japanese clinical studies were submitted to evaluate the efficacy and safety of the product for the indication. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2019 Total review time: 359 days Regulatory review time: 197 days	Feb. 25, 2015 Foreign clinical study results	6	VenaSeal Closure System (Covidien Japan, Inc.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in blood vessels	A prosthetic material for embolization in blood vessels to treat venous reflux by injecting it into primary varicose vein in the lower extremity truncal saphenous vein. This device consists of the adhesive composed mainly of n-butyl-2-cyanoacrylate and the delivery system to inject the adhesive into the vein. The results of foreign controlled clinical studies with high-frequency ablation as conventional treatment, were submitted to evaluate the efficacy and safety of the device.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 17, 2019 Total review time: 108 days Regulatory review time: 87 days	ICY Catheter: Oct. 23, 2003 Quattro Catheter: Feb. 15, 2007 No clinical study results	7	Quattro • ICY IVTM Catheter (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A central venous catheter with a balloon for heat exchange used for body temperature management therapy in patients under cardiac arrest or after return of (spontaneous) circulation, or for maintaining normal body temperature in patients who require central venous catheterization. The catheter is intended for used in a central venous placement temperature management system. The application was submitted to make modifications associated with discrepancy in the descriptions on the inactivation processing conditions for the raw material, heparin sodium in the master file and to add other adjustments in the raw materials column and manufacturing methods column in the approval document. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 25, 2019 Total review time: 259 days Regulatory review time: 143 days	Apr. 30, 2014 No clinical study results	8	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12 Hypoglossal nerve stimulator	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure (CPAP) therapy. The application was submitted to modify the product as a new model for the implantable pulse generator, sensing lead, and programmer for physicians. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 20, 2019 Total review time: 358 days Regulatory review time: 233 days	- Foreign and Japanese clinical study results	9	FRED System (Terumo Corporation)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system intended to be used to occlude intracranial aneurysms (including fusiform aneurysm) that are difficult to treat surgically or by coil embolization with a maximum diameter of 5 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment of the internal carotid artery to the proximal regions of the middle cerebral artery and anterior cerebral artery, and in basilar and vertebral arteries, except for the acute phase of aneurysms that are at risk of rupture. As clinical study data, results of foreign clinical studies to evaluate the efficacy and safety of the product and a Japanese clinical study to confirm the compatibility of the device with the medical environment in Japan were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 25, 2019 Total review time: 365 days Regulatory review time: 84 days	Oct. 19, 2018 Foreign clinical study results Clinical evaluation report	10	Valiant Navion Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft system is used to treat patients with descending thoracic aortic aneurysms or complicated Stanford type B aortic dissection (including dissecting aortic aneurysm) who do not respond to medical treatment. The product was designed based on “Valiant Thoracic Stent Graft System” (Approval No. 22400BZX00124000) and for which the graft material and stent design, etc. were changed to have a delivery catheter with a smaller diameter for improved accessibility to lesions. The result of foreign clinical study in aortic aneurysm and clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. on chronic complicated Stanford type B aortic dissection were submitted to evaluate the efficacy and safety of the product.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 7, 2019 Total review time: 312 days Regulatory review time: 154 days	Dec. 15, 2013 Foreign clinical study results	11	Gore Viabahn Stent Graft (W. L. GORE & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft with nitinol stent wires wound around the outside of the graft (external stent structure type) and a delivery catheter. The application was submitted for an additional indication of stenosis or obstruction at the vein-side anastomosis of synthetic arteriovenous shunt (A "partial change" application). The result of foreign clinical study conducted for angioplasty using a standard balloon catheter as a control was submitted to evaluate the efficacy and safety of the product. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2019 Total review time: 103 days Regulatory review time: 34 days	- No clinical study results	12	Ovation Abdominal Stent Graft System (Endologix, Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system for treatment of abdominal aortic aneurysms that obtains adhesion to blood vessels by filling polymer. The product is delivered and placed in a transcatheter manner to abdominal aortic aneurysms and prevents aortic rupture by excluding blood flow into aortic aneurysms. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 25, 2019 Total review time: 141 days Regulatory review time: 40 days	- No clinical study results	13	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12 Hypoglossal nerve stimulator	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure (CPAP) therapy. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 25, 2019 Total review time: 82 days Regulatory review time: 35 days	- No clinical study results	14	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or non-stented restenotic lesions in the superficial femoral or popliteal arteries. The balloon surface of this product is coated with paclitaxel as a drug. The application was submitted for deletion of the specification for the drug substance (paclitaxel), falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 26, 2019 Total review time: 302 days Regulatory review time: 214 days	Dec. 31, 2018 Foreign clinical study results	15	Woven EndoBridge Device (Terumo Corporation)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system intended to be used to occlude wide-necked (defined the size as neck width ≥4 mm or dome-to-neck ratio <2) intracranial aneurysms located in the branch of anterior or posterior circulation. The results of foreign clinical studies conducted to evaluate the efficacy and safety of the product were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 15, 2020 Total review time: 636 days Regulatory review time: 97 days	- Foreign clinical study results	16	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)	Change	Instrument & apparatus 12 Focused Ultrasound System	A device intended for heating the target and causing focal coagulative necrosis to deliver focused ultrasound energy to a specific target on the deep brain tissue through the skull. The application was submitted to add the indication of alleviating Parkinson's disease in patients who are medication resistant targeting the globus pallidus and symptom of tremor of Parkinson's disease in patients who are medication resistant targeting the thalamus (A “partial change” application). Foreign clinical study results and a clinical evaluation report were submitted as the substantial data to the expansion of the intended use targeting the globus pallidus, and the clinical evaluation report was submitted as the substantial data to the expansion of the intended use targeting the thalamus.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 19, 2020 Total review time: 103 days Regulatory review time: 101 days	Jan. 26, 2015 No clinical study results	17	Pipeline Flex Flow Diverter System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system used for endovascular therapy for large or giant wide-neck intracranial aneurysms in internal carotid artery from petrous through superior hypophyseal segment, except for the acute phase of aneurysms that are at risk of rupture. The application was submitted to add “Phenom Catheter” (Approval No.: 30100BZX00190000) as a micro catheter used with the system. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 31, 2020 Total review time: 105 days Regulatory review time: 18 days	- No clinical study results	18	NovoTTF-100A System (NovoCure Ltd.)	Change	Instrument & apparatus 12 Alternating electric field tumor treatment system	This non-invasive medical device delivers alternating electric fields referred to as Tumor Treating Fields (TTField) - that disrupt cancer cell division - through insulated transducer arrays (INE transducer array) placed on the scalp. The application was submitted to change the manufacturing site. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 31, 2020 Total review time: 208 days Regulatory review time: 185 days	Jan. , 2013 No clinical study results	19	Brainsway TMS System (Century Medical, Inc.)	Change	Instrument & apparatus 12 Repetitive transcranial magnetic stimulator	A repetitive transcranial magnetic stimulator that provides treatment for adult patients with Major Depressive Disorder (MDD) who have not benefitted from conventional antidepressant medication, by stimulating neurons with the electric current induced in the local area of the cerebral cortex using a pulsed magnetic field. The application was submitted to change the shape of connecting part between a coil adapter and a uni-coil cable into one unit in order to improve the convenience and the durability, and to invalidate the enhanced function. (A “partial change” application submitted during the post-market performance review period)
Ophthalmology and Otorhinolaryngology	Oct. 31, 2019 Total review time: 335 days Regulatory review time: 298 days	Jun. 12, 2018 Foreign clinical study results	20	iStent inject Trabecular Micro-Bypass System (Glaukos Corporation)	Approval	Medical products 4 Heparin-using intraocular drain	A stent and the injector used simultaneously in cataract surgery for lowering intraocular pressure in patients with mild to moderate open-angle glaucoma. This device is the successor product of “iStent Trabecular Micro-Bypass Stent System” (Approval No. 22800BZI00013000). The improvements were made to the product in that two stents were loaded within the injector and the operability was refined.
Ophthalmology and Otorhinolaryngology	Jan. 28, 2020 Total review time: 341 days Regulatory review time: 265 days	- Japanese clinical study results	21	RETISSA Medical (QD Laser, Inc.)	Approval	Instrument & apparatus 71 Laser retinal scanning type eyewear	Laser projector type eyewear intended to be used for visual correction in patients whose vision is affected by irregular astigmatism (whose vision cannot be corrected sufficiently by conventional glasses or contact lenses). The results of Japanese clinical studies were submitted as clinical evaluation data.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Apr. 25, 2019 Total review time: 62 days Regulatory review time: 56 days	Jul. 20, 2018 No clinical study results	22	WATCHMAN Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51 Endocardial prosthetic material	This device is a percutaneous left atrial appendage closure system to reduce the risk of ischemic stroke and systemic embolism from the left atrial appendage thrombus. The application was submitted to add raw material of the filter, access system, and manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	May 28, 2019 Total review time: 333 days Regulatory review time: 193 days	Oct. 28, 2016 Foreign clinical study results	23	AMPLATZER PFO Occluder (Abbott Medical Japan L.L.C.)	Approval	Medical products 4 Prosthetic material for artificial cardiac membrane	A percutaneous transcatheter closure device of a patent foramen ovale (PFO) is used to reduce the risk of recurrence of cerebral infarction in patients with a history of cryptogenic cerebral infarction in whom the existence of PFO is determined to be related to the onset of cerebral infarction. Data from foreign clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Jul. 5, 2019 Total review time: 127 days Regulatory review time: 94 days	- No clinical study results	24	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing a high frequency current to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted for an additional model with electrodes placed on the tip that allows an acquisition of intracardiac potential signals and a performance of temporary cardiac pacing (A "partial change" application).
Cardiopulmonary Circulation	Jul. 8, 2019 Total review time: 102 days Regulatory review time: 62 days	Jul. 8, 2010 No clinical study results	25	Impella Controller (Abiomed, Inc.)	Change	Instrument & apparatus 7 Controller of implantable pump catheter for ventricular support	An external controller that controls an exclusive catheter-based blood pump, “Impella Circulatory Assist Pump Catheter” (Approval No. 22800BZI00032000) and an exclusive purge cassette. The application was submitted for an additional component to show the operating status of “Impella Circulatory Assist Pump Catheter” displayed on the main controller, on an external monitor, etc. through the internet. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Aug. 1, 2019 Total review time: 244 days Regulatory review time: 82 days	- No clinical study results	26	EXCOR Pediatric Ventricular Assist Device (Cardio Incorporated)	Change	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	This device is a single-use extracorporeal ventricular assist device. It is used for severe pediatric heart failure patients who cannot expect improvement of symptom in conventional medication, surgery and circulation support. If the system is judged as best for the patients, it is used for the patients to improve circulation until reaching heart transplantation or recovery of cardiac function.The application was submitted to add an injection molding cannula. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Sep. 10, 2019 Total review time: 263 days Regulatory review time: 130 days	Jan. 11, 2019 Foreign clinical study results	27	AMPLATZER Piccolo Occluder (Abbott Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A self-expanding duct occluder and delivery system intended to be used for percutaneous closure of an opening of the arterial duct in patients with patent ductus arteriosus (PDA). As clinical evaluation data, the results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product in patients with PDA including low birth weight infants.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Dec. 5, 2019 Total review time: 244 days Regulatory review time: 103 days	Oct. 26, 2016 Foreign clinical study results	28	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	The product consists of a porcine pericardial-derived transcatheter aortic valve (hereinafter referred to as TAV), a dedicated delivery catheter system that is used to deploy the TAV at the position of the aortic valve, and a loading system that loads the TAV into the delivery catheter. The application was submitted to mainly add a TAV with a diameter of 34 mm and the corresponding loading system to the additional TAV (A "partial change" application). The test results of physical and chemical properties were submitted for the application. As clinical evaluation data, the results of US clinical studies were also submitted to evaluate the efficacy and safety of the additional size. (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Dec. 26, 2019 Total review time: 301 days Regulatory review time: 145 days	Apr. 23, 2019 Foreign and Japanese clinical study results	29	Lotus Edge Valve System (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A self-expandable percutaneous aortic bioprosthetic valve system for a percutaneous aortic valve replacement used in symptomatic patients with severe aortic valve stenosis attributed to calcification and degeneration of the native aortic valve, who are not eligible for surgery and of which this treatment is considered as their best therapeutic option. The bioprosthetic valve has 3 pairs of locking mechanisms and is locked to a specified frame height and diameter after being implanted. As clinical evaluation data, the results of foreign and Japanese clinical studies were submitted.
Cardiopulmonary Circulation	Jan. 9, 2020 Total review time: 328 days Regulatory review time: 144 days	Jun. , 2017 Foreign clinical study results	30	Edwards SAPIEN 3 (Edwards Lifesciences Limited.)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation for patients with severe symptomatic aortic valve stenosis and for whom surgical aortic valve replacement cannot be performed due to the patients' general conditions or presence of complications. The application was submitted mainly for an additional indications of “failures (stenosis, dysfunction, or both) of a surgically placed aortic bioprosthetic valve” (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Mar. 12, 2020 Total review time: 168 days Regulatory review time: 114 days	Jul. 8, 2010 No clinical study results	31	Impella Controller (Abiomed, Inc.)	Change	Instrument & apparatus 7 Controller of implantable pump catheter for ventricular support	An external controller that controls an exclusive catheter-based blood pump and an exclusive purge cassette. The application was submitted to add a new type of the concomitant device, “Impella Circulatory Assist Pump Catheter” (Approval No. 22800BZI00032000). (A “partial change” application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar.12,2020 Total review time: 168 days Regulatory review time: 72 days	Mar. 22, 2018 No clinical study results	32	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51 Implantable Pump Catheter for Ventricular Support	The catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery and placed in the left ventricle. This device pulls blood directly from the left ventricle and expels the blood from the catheter into the ascending aorta. The application was submitted to add a new type IMPELLA CP-Op in which a position sensor system of IMPELLA CP has been improved. (A “partial change” application submitted during the post-market performance review period)

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Improved Medical Devices (With Clinical Data) Approved in FY 2019

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Apr. 3, 2019 Total review time: 259 days Regulatory review time: 230 days	Sep. 27, 2017 Foreign clinical study results	1	SpaceOAR System (Augmenix, Inc.)	Change	Instrument & apparatus 20 Glucose monitoring system	A glucose monitoring system to continuously measure and record glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. The application was submitted to change the intended use in association with the change of the clinical standpoint of the product as daily self-management device for diabetes mellitus based on information regarding glucose levels in the interstitial fluid obtained from the product (A "partial change" application). Data from the results of foreign clinical studies using the product were submitted.
Robotic, ICT, and other devices (not classified as other categories)	Oct. 31, 2019 Total review time: 230 days Regulatory review time: 101 days	May 14, 2008 Clinical evaluation report	2	INVOS 5100C System (Covidien Japan, Inc.)	Approval	Instrument & apparatus 21 Cerebral oximeter	A medical device measuring regional hemoglobin oxygen saturation (rSO_2) of blood in the brain or in other tissue beneath the sensor and using as an adjunct trend monitor of them.
Robotic, ICT, and other devices (not classified as other categories)	Feb. 19, 2020 Total review time: 266 days Regulatory review time: 130 days	Mar. 27, 2018 Foreign clinical study results	3	Dexcom G6 CGM System (Dexcom, Inc.)	Approval	Instrument & apparatus 20 Glucose monitoring system	The application was submitted for marketing approval of a continuous glucose monitoring system that continuously measures and records glucose concentration in the interstitial fluid in persons with diabetes and displays the trends and the patterns of glucose fluctuation.
Orthopedic and Plastic Surgery	May 23, 2019 Total review time: 290 days Regulatory review time: 280 days	Dec. 15, 2011 Clinical evaluation report	4	PICO Wound Therapy System (Smith & Nephew KK)	Change	Medical products 4 Single-use negative pressure wound therapy system	A single-use negative pressure wound therapy system to provide controlled negative pressure to the indications. The application was submitted to add the indication of closed surgical incisions in patients at high risk due to surgical site infection (SSI) in order to reduce the SSI risk along with refractory wounds that have not responded to or may not respond to existing treatments as the conventional indication (A "partial change" application). A clinical evaluation report summarizing foreign clinical papers and information on malfunctions and adverse events, including meta-analyses for comparison between the product and existing treatments, was submitted to evaluate the added indication.
Orthopedic and Plastic Surgery	May 23, 2019 Total review time: 267 days Regulatory review time: 256 days	Jun. 11, 2010 Clinical evaluation report	5	PREVENA Incision Management System (KCI K.K.)	Approval	Medical products 4 Single-use negative pressure wound therapy system	A single-use negative pressure wound therapy system intended to reduce the risk of surgical site infection (SSI) by maintaining the closure environment for closed surgical incisions in patients at high SSI risk and providing controlled negative pressure to remove effusion. The following improvement was made to the product: Approved devices for negative pressure maintenance/management therapy are indicated for refractory wounds that have not responded or are considered unlikely to respond to conventional treatments, whereas the product is intended to reduce the risk of SSI with the indication of closed surgical incisions. A clinical evaluation report summarizing meta-analyses for comparison between the product and conventional treatments and information on malfunctions and adverse event was submitted to evaluate the efficacy and safety of the product.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Sep. 30, 2019 Total review time: 166 days Regulatory review time: 132 days	2012 Clinical evaluation report	6	Fractional RF Elos Plus (Syneron Candela K. K.)	Approval	Instrument & apparatus 29 Therapeutic electrosurgical device	A therapeutic electrosurgical device intended to be used ablation of soft tissue for fractional skin resurfacing for cosmetic improvement. The intended use of this product is equivalent to that of the company's approved product, “CO2RE Carbon Dioxide Laser with Fractional Mode” (Approval No. 22900BZX00428000). This product is improved by the use of radiofrequency, while the company's approved product uses the principle of CO2 laser. A clinical evaluation report consisting of published clinical literatures of this product and results from a foreign clinical study of the previous generation product was submitted to confirm that performance for skin resurfacing and adverse events are acceptable for cosmetic uses.
Orthopedic and Plastic Surgery	Oct. 28, 2019 Total review time: 269 days Regulatory review time: 125 days	May 2004 Clinical evaluation report	7	Palacos R+G Bone Cement (AquaMed Japan, Inc.)	Approval	Medical products 4 Orthopedic bone cement	Orthopedic bone cement intended for use in fixation of joint prostheses (prosthetic hip, knee, shoulder, elbow, hand, foot, head prosthesis, etc.) to living bone at the second stage in two-stage reimplantation accompanied by post-surgery infection due to prosthetic joint replacement. It consists of powdered and liquid components and a mixing device. The improvement was made to the product in that an antibiotic (gentamicin) was contained into the company’s approved powdered polymer. A clinical evaluation report summarizing foreign clinical papers and information on foreign post-marketing malfunctions was submitted to compare with the product without gentamicin and evaluate that the clinical results of prosthetic joint replacement using the product are equivalent.
Orthopedic and Plastic Surgery	Jan. 10, 2020 Total review time: 197 days Regulatory review time: 99 days	Apr. 7, 2006 Clinical evaluation report	8	LightSheer Duet Diode Laser System (Lumenis Japan Co., Ltd.)	Approval	Instrument & apparatus 31 Diode laser	A diode laser is intended to achieve stable long-term hair reduction by selective photothermolysis. In addition to ET handpiece mounted a sapphire tip to reduce complications by cooling the skin, the improvement was made by developing HS handpiece to perform laser irradiation by skin suction. The clinical evaluation report consisting of data from foreign clinical studies and published clinical literatures was submitted to confirm that long-term hair reduction and expected adverse events could be acceptable as a cosmetic medical device.
Orthopedic and Plastic Surgery	Feb. 6, 2020 Total review time: 230 days Regulatory review time: 94 days	- Clinical evaluation report	9	RM Pressfit vitamys cup (Mathys Ltd.)	Approval	Medical products 4 Artificial hip joint, acetabular component	A hip arthroplasty acetabular component used for replacement and repair of the acetabulum at the pelvic side in order to substitute for the function of the hip joint. This product was improved by developing as a monoblock cup which is directly fixed in order to avoid friction caused by the difference of hardness between the cup and liner, while the conventional type was a modular cup which is used by combining the cup and liner. The clinical evaluation report consisting of data from foreign post-marketing clinical trials, foreign registry data, and published clinical literatures was submitted to confirm that product-specific adverse events have not been found.
Orthopedic and Plastic Surgery	Mar. 6, 2020 Total review time: 266 days Regulatory review time: 115 days	- Japanese clinical study results	10	Scalp Cooling Device CellGuard (Hair Clinic Reve21. Co. Ltd.)	Approval	Instrument & apparatus 12 Instrument and device for cooling therapy	An instrument and device for cooling therapy that cools the scalp to prevent drug-induced alopecia in patients with solid cancer. The product is composed of a cooling unit, cooling water, a silicon cap, an inner cap, and an outer cap. The results of Japanese clinical study conducted to evaluate the effectiveness of preventing alopecia and safety of this product in breast cancer patients were submitted as evaluation data. A clinical evaluation report summarizing the literature review of similar foreign medical devices was also submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2019 Total review time: 268 days Regulatory review time: 140 days	May 16, 2016 Foreign clinical study results	11	Surgiflo (Johnson & Johnson K.K.)	Approval	Medical products 4 Gelatin-based local absorbable hemostatic material with human thrombin	A gelatin-based local absorbable hemostatic material with human thrombin used in surgical procedures (other than in ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. The results of foreign clinical studies using the previous-generation product were submitted. Based on the results of animal studies, literature reports, etc., it was explained that the changes from the previous-generation product would not greatly affect the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2019 Total review time: 121 days Regulatory review time: 71 days	May 13, 2014 Clinical evaluation report	12	Penumbra System (Medico's Hirata Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system used for revascularization by removing thrombus for patients with acute ischemic stroke (in principle, within 8 hours of the onset) who failed in revascularization with intravenous tissue plasminogen activator (t-PA) therapy. The application was submitted to add the usage of product in which thrombus is aspirated and retrieved only with a catheter without using a separator (a Direct Aspiration first Pass Technique [ADAPT]) for catheters whose tip portion has an inner diameter of ≥0.054 inches (A "partial change" application). A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of ADAPT.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 22, 2019 Total review time: 147 days Regulatory review time: 75 days	Mar. 18, 2018 Clinical evaluation report	13	AXS Catalyst Aspiration Catheter (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system used for revascularization of patients with acute ischemic stroke (in principle, within 8 hours of symptom onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed in revascularization with intravenous t-PA therapy. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the procedure for aspirating and retrieving thrombus only with a catheter (a Direct Aspiration first Pass Technique).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 10, 2019 Total review time: 257 days Regulatory review time: 111 days	May 9, 2018 Foreign clinical study results	14	EmboTrap Revascularization Device (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A revascularization device in the central circulatory system used for revascularization of patients with acute ischemic stroke (in principle, within 8 hours of symptom onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed in revascularization with intravenous t-PA therapy. The product is characterized by proprietary design of its dual-layered stent. The results of foreign clinical studies which were conducted to verify the efficacy and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 2, 2019 Total review time: 172 days Regulatory review time: 152 days	Apr. 5, 2007 Clinical evaluation report	15	Tegaderm CHG Dressing (3M Japan Limited)	Change	Medical products 4 Antibacterial catheter dressing and protecting material	A film dressing composed of a transparent adhesive film and a transparent gel pad containing antimicrobial chlorhexidine gluconate (CHG). The product is directly applied to an insertion site of a vascular catheter or insertion site of the needle to protect and cover the sites. It was judged that a clinical evaluation was necessary for addition of the text, “To reduce catheter related blood stream infection (CRBSI) and local infection in patients inserted with central venous catheter or arterial catheter,” to the intended use.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 9, 2019 Total review time: 180 days Regulatory review time: 150 days	- Clinical evaluation report	16	Cosmotec Stent (Cosmotec Co., Ltd.)	Change	Instrument & apparatus 7 Vena cava stent	A stainless steel stent intended to maintain the patency of narrowed trachea, bronchus, or vena cava due to malignant tumors and improve patients' QOL by palliating the symptoms. The application was submitted for the additional indication of narrowed vena cava in patients with malignant vena cava syndrome (A "partial change" application). A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the product for this indication.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 4, 2019 Total review time: 71 days Regulatory review time: 57 days	Mar. 6, 2019 Clinical evaluation report	17	Solitaire FR Revascularization Device (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system intended for use to restore blood flow in patients with acute ischemic stroke in whom intravenous tissue plasminogen activator（t-PA）therapy is not indicated or fails to achieve reperfusion. The application was submitted to add the indication of the product for patients with occlusion in the proximal part of the anterior major artery whose outcome is expected to improve with clot retrieval therapy and who are within 24 hours from when s/he was confirmed to be healthy last time (A "partial change" application). The results of usability testing and the animal study included in the previous application were reevaluated and a clinical evaluation report summarizing the contents of clinical literatures regarding the indication was submitted to evaluate the efficacy and safety of the indication.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 24, 2019 Total review time: 267 days Regulatory review time: 160 days	Jun. 19, 2017 Foreign clinical study results	18	PulseRider (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A device intended for the treatment of wide-necked cerebral aneurysms at a vessel bifurcation that are difficult to treat with surgery or coil embolization with embolic coils alone. It consists of a device for cerebral aneurysms at a vessel bifurcation to be placed for preventing a coil mass from protruding into and/or dropout into the parent artery during the coil embolization treatment and a detachment system. The results of foreign clinical studies conducted to evaluate the performance and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2019 Total review time: 237 days Regulatory review time: 149 days	- Japanese clinical study results	19	CASPER Rx Carotid Artery Stent (Terumo Corporation)	Approval	Instrument & apparatus 7 Carotid artery stent	A stent system used for extending and maintaining the vascular lumen via a catheter percutaneously inserted and placed in the site of stenosis in the carotid artery (common carotid artery and internal carotid artery). The main difference between the previously approved product and the product is that the previously approved carotid artery stent is indicated only for use in patients with a high risk of carotid endarterectomy (CEA), while the product is indicated for use in patients regardless of CEA risk. As data from results of non-clinical studies related to the product, data on physicochemical characterizations, biological safety and animal study results were submitted. The data related to the results of Japanese clinical studies using the product were also submitted. Patients with carotid stenosis were included in the clinical studies regardless of CEA risk, and the efficacy and safety of the product were evaluated.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 19, 2019 Total review time: 268 days Regulatory review time: 151 days	Oct. 4, 2018 Global clinical trial	20	BioMimics 3D Stent System (Medico's Hirata Inc.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A vascular stent used for treatment of symptomatic peripheral arterial disease with reference vessel diameter of 4-6 mm and a lesion length up to 140 mm in the native superficial femoral artery and/ or proximal popliteal artery, and for treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The product is characterised in that the product has a unique helical shape that enables the kink and fracture to be suppressed with interspersed mechanical strain as the knee/hip is bent, while previously approved stents are straight shapes. The result of a global clinical trial was submitted to confirm the efficacy and safety of the product in patients with symptomatic peripheral arterial disease.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 19, 2020 Total review time: 267 days Regulatory review time: 140 days	Dec. 15, 2008 Clinical evaluation report	21	Embozene Microspheres (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A non-absorbable prosthetic material for embolization in vessels of the central circulation system intended to be used for arterial embolization in patients with hypervascular tumors or arteriovenous malformation. The product is characterized by a higher uniformity and a wider range of particle sizes (including smaller sizes [40 μm, 75 μm] and a larger size [1300 μm]) compared to the original product, “Embosphere” (Approval No. 22500BZX00269000). As clinical evaluation data, the clinical evaluation report consisting of data from publications on the equivalence of the similar medical devices was submitted to confirm the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 20, 2020 Total review time: 211 days Regulatory review time: 113 days	Jul. 4, 2018 (React68) Nov. 14, 2018 (React71) Clinical evaluation report	22	React Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system used for revascularization for patients with acute ischemic stroke (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) therapy or who failed in revascularization with the t-PA therapy. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the procedure for aspirating and retrieving thrombus only with a catheter (a Direct Aspiration first Pass Technique [ADAPT]).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 13, 2020 Total review time: 259 days Regulatory review time: 68 days	- Clinical evaluation report	23	Matsudaito (Sanyo Chemical Industries,. Ltd.)	Change	Medical products 4 Non-absorbable local hemostatic material for central circulation system	Non-absorbable local hemostatic material for central circulatory system consisting of polyether-based fluorine-containing urethane prepolymer with isocianate groups (-NCO) at the both ends. The application was submitted for an additional indication of hemostasis at the anastomotic site in abdominal and peripheral revascularization (A "partial change" application). A clinical evaluation report summarizing the results of Japanese clinical trial attached to the initial approval application, clinical results of this product in post-marketing surveillance, and clinical literatures was submitted.
Gastroenterology, Genitourinary and Reproductive Medicine	Oct. 21, 2019 Total review time: 236 days Regulatory review time: 160 days	- Japanese clinical study results	24	Hemofeel CH (Toray Industries, Inc.)	Change	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter that gently eliminates and adjusts toxic substances in the blood such as water, electrolytes, uremic toxins, hepatotoxic substances, and other toxic substances induced by multiple organ failure through a continuous extracorporeal circulation. The device for life saving and prolonging life treats renal failure, liver failure, respiratory failure, multiple organ failure, sepsis, and postoperative/traumatic/burn cases in patients with unstable hemodynamics. The application was submitted to add an equivalent raw material of polymethyl methacrylate (one of the raw materials of hollow fiber) whose production was discontinued. (A "partial change" application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary and Reproductive Medicine	Jan. 28, 2020 Total review time: 312 days Regulatory review time: 151 days	- Japanese clinical study results	25	Bipolar RFA Celon Power System (Olympus Medical Systems Corporation)	Change	Instrument & apparatus 29 Radiofrequency ablation system	A radiofrequency ablation system used for percutaneous or surgical ablation of malignant hepatic tumor and for percutaneous ablation of adrenal adenoma in patients with primary aldosteronism caused by unilateral aldosterone hypersecretion. The system consists of bipolar RFA power unit, a water supply unit, and applicators. The application was submitted for the additional intended use for “ablation of adrenal adenoma in patients with primary aldosteronism caused by unilateral aldosterone hypersecretion” (A "partial change" application).
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 5, 2020 Total review time: 157 days Regulatory review time: 127 days	- Clinical evaluation report	26	Immunopure (Nikkiso Co., Ltd.)	Approval	Instrument & apparatus 7 Purifier for blood cell removal	A purifier for blood cell removal used for leucocyte-removing therapy intended to induce remission in patients with ulcerative colitis in the active phase, especially in patients with refractory moderate ulcerative colitis. A clinical evaluation report evaluating the efficacy and safety of the product as equivalent to similar medical devices was submitted.
Dentistry and Oral Medicine	May 29, 2019 Total review time: 527 days Regulatory review time: 165 days	- Japanese clinical study results	27	Bonarc (TOYOBO CO., LTD.)	Approval	Medical products 4 Artificial bone using collagen	A bone void filler made of octacalcium phosphate and collagen intended for bone regeneration treatments with filling it into bone defects or gaps in the upper/lower jaw bones and alveolar bones. These treatments include bone regeneration assuming placement of dental implants and bone regeneration for cleft palate and cyst cavities. The results of Japanese clinical studies that evaluated the efficacy and safety of the product were submitted.
Dentistry and Oral Medicine	Jul. 9, 2019 Total review time: 252 days Regulatory review time: 79 days	Sep. 21, 2005 Clinical evaluation report	28	TMJ Replacement System (Medical U&A, Inc.)	Approval	Medical products 4 Total temporomandibular joint prosthesis	A total temporomandibular joint prosthesis is used in patients with oral and maxillofacial symptoms that are difficult to cure or alleviate by any treatments other than replacement or reconstruction of the glenoid cavity and mandibular condyle. The improvement in the product was made to enable replacement or reconstruction of the glenoid cavity as well as the mandibular condyle. A clinical evaluation report summarizing foreign clinical studies, post-marketing prospective observational studies, and clinical papers was submitted.
Dentistry and Oral Medicine	Mar. 11, 2020 Total review time: 251 days Regulatory review time: 215 days	2009 Foreign clinical study results	29	Inicell implant (Morita Corporation)	Approval	Medical products 4 Dental implant body	The application was submitted for marketing approval of a dental implant body used as an artificial dental root which is surgically placed into the jawbone. As a method capable of early loading, a surface of the device is cleaned with sodium hydroxide aqueous solution packed together with the device immediately before implant placement.
Ophthalmology and Otorhinolaryngology	Jun. 26, 2019 Total review time: 250 days Regulatory review time: 193 days	- Clinical evaluation report	30	da Vinci X Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery) (A “partial change” application).

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Aug. 20, 2019 Total review time: 266 days Regulatory review time: 113 days	Jun. 2, 2017 Foreign clinical study results	31	Zepto System (Mynosys Cellular Devices, Inc.)	Approval	Instrument & apparatus 31 Ophthalmic electrosurgical unit	The application was submitted for marketing approval of an ophthalmic electrosurgical device that is indicated for use in performing anterior capsulotomy during cataract surgery.
Ophthalmology and Otorhinolaryngology	Nov. 5, 2019 Total review time: 251 days Regulatory review time: 88 days	Jun. 28, 2011 Clinical evaluation report	32	LipiFlow Thermal Pulsation System (AMO Japan K.K.)	Approval	Instrument & apparatus 12 Eyelid thermal pulsation system	The application was submitted for marketing approval of a device designed for providing localized heat and pressures to the eyelids in patients with meibomian gland dysfunction (MGD).
Ophthalmology and Otorhinolaryngology	Nov. 18, 2019 Total review time: 172 days Regulatory review time: 140 days	- Japanese clinical study results	33	LENTIS Comfort Toric (Santen Pharmaceutical Co., Ltd)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct far and intermediate vision of an aphakic eye with corneal astigmatism. The improvement was made to the product in that cylindrical refractivity was added in the posterior optical zone of the company's approved product "Lentis Comfort" (Approval No.: 23000BZX00243000).
Ophthalmology and Otorhinolaryngology	Dec. 12, 2019 Total review time: 259 days Regulatory review time: 149 days	Dec. 11, 2018 Foreign clinical study results	34	Precision 1 (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	The device is a single-use, colored contact lens for correcting visual acuity consisting of silicone hydrogel with a water content of 51% (Verofilcon A).
Ophthalmology and Otorhinolaryngology	Feb. 20, 2020 Total review time: 143 days Regulatory review time: 61 days	- Foreign clinical study results	35	Tecnis Synergy VB Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The device is a posterior chamber lens with an injector in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye. The results of foreign clinical studies were submitted as clinical evaluation data.
Ophthalmology and Otorhinolaryngology	Mar. 27, 2020 Total review time: 245 days Regulatory review time: 205 days	Jul. 20, 2018 Foreign clinical study results	36	MED-EL Bonebridge Bone Conduction Implant (MED-EL Elektro-Medizinische Geräte GmbH)	Approval	Instrument & apparatus 73 Bone-anchored hearing aid	A bone-anchored hearing aid used to improve the ability to hear environmental sounds and speech sounds in bilateral hearing-impaired patients who are not expected to achieve improvement with existing treatment and have normal bone conduction thresholds or mild impairment at least in one ear. The results of foreign clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Apr. 16, 2019 Total review time: 370 days Regulatory review time: 130 days	Aug. 23, 2017 Foreign clinical study results	37	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplantation. The device is used for patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The blood pump of the product is a downsized centrifugal pump compared to that of the approved product "HeartMate II Left Ventricular Assist System" (Approval No. 22400BZI00017000) so that it is not necessary to create a pump pocket at the time of implantation. The blood is discharged by rotating the rotor inside the pump with magnetic levitation. The results of foreign clinical studies were submitted as clinical evaluation data.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Jul. 5, 2019 Total review time: 695 days Regulatory review time: 193 days	Nov. 16, 2017 Global clinical trial	38	Resolute Onyx SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 27 mm or less) that have a reference vessel diameter of 2.0-2.25 mm and are considered as vascular dissection or acute or impending coronary occlusion associated with angioplasty, and a delivery catheter to place the stent at the site of stenosis. As clinical evaluation data, the results of global clinical studies including Japan were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Sep. 18, 2019 Total review time: 384 days Regulatory review time: 172 days	- Global clinical trial	39	COMBO Plus Coronary Stent (OrbusNeich Medical K. K.)	Approval	Instrument & apparatus 7 Coronary stent using murine antibody	A coronary stent system used for treating patients with symptomatic ischemic cardiac disease who have a de novo coronary artery lesion (a lesion length of 28 mm or less) with a reference vessel diameter of 2.5-3.5 mm. A murine-derived anti-CD34 antibody to capture endothelial progenitor cells (ECPs) in circulating blood and sirolimus to inhibit cell proliferation are coated on the stent surface. As clinical evaluation data, the results of global clinical studies including Japan were submitted to evaluate the effectiveness and safety of this product.
Cardiopulmonary Circulation	Oct. 31, 2019 Total review time: 188 days Regulatory review time: 74 days	- Japanese clinical study results	40	Avalus Aortic Valve (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve is intended to be used as a substitute for the malfunctioning native or prosthetic aortic valve. The application was submitted for an additional biological valve of 17 mm in diameter (A "partial change" application). The test results of physical and chemical properties were submitted for the application. As clinical evaluation data, the results of Japanese clinical studies were submitted to evaluate the efficacy and safety of the additional size.
Cardiopulmonary Circulation	Dec. 10, 2019 Total review time: 265 days Regulatory review time: 241 days	Dec. 19, 2018 Foreign clinical study results	41	CathWorks FFRangio (CathWorks Ltd.)	Approval	Instrument & apparatus 21 Circulatory dynamics analysis instrument	A diagnosis support device that calculates the FFRangio (Fractional Flow Reserve) by numerical analysis of the reconstructed three dimensional coronary artery model based on the images of coronary angiography in patients suspected of having coronary artery diseases. The device is installed and used in the catheterization laboratory. It is characterized in that the results can be calculated and displayed on the spot, without transferring data of contrast image, etc. to outside the hospital. As clinical evaluation data, the results of foreign clinical studies conducted to evaluate the efficacy and safety of the product were submitted.
Cardiopulmonary Circulation	Jan. 14, 2020 Total review time: 102 days Regulatory review time: 91 days	Oct. 18, 2018 Global clinical trial	42	Synergy Stent System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo coronary artery lesions (lesions length of 34 mm or less) with a reference vessel diameter of 2.25-5.00 mm and a delivery catheter used to implant a stent at the site of stenosis. The application was submitted for additional stent sizes of 4.50 mm and 5.00 mm in diameter (A "partial change" application). As clinical evaluation data, the additional analysis results of global clinical trials were submitted to evaluate the efficacy and safety of the additional sizes.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	N0.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Feb. 13, 2020 Total review time: 254 days Regulatory review time: 205 days	- Foreign clinical study results	43	QDOT Micro Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter to be used for conducting cardiac electrophysiologic mapping, and cardiac ablation with high-frequency current for the treatment of patients with drug refractory symptomatic paroxysmal or persistent atrial fibrillation, atrial flutter, and patients with ventricular tachycardia who cannot be successfully treated by other therapies. The device was developed based on “Thermocool Smarttouch SF” (Approval No. 22800BZX00244000). The major changes were the location and the number of temperature sensors, additional micro electrodes, and two ablation modes; QMODE (temperature control mode for this device only) and QMODE+ (mode for the delivery of high power, short duration ablation). As clinical evaluation data, the results of foreign clinical studies were submitted to evaluate the efficacy and safety of the QMODE+ mode.
Cardiopulmonary Circulation	Mar. 2, 2020 Total review time: 311 days Regulatory review time: 204 days	- Foreign clinical study results	44	Attain Stability Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	The device is a coronary venous lead of implantable biventricular pacing pulse generator for cardiac resynchronization therapy. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The product was developed based on the company’s approved product. The improvement of the device is its side helix mechanism which enables active fixation to the coronary vein wall. As clinical evaluation data, the results of foreign clinical studies were submitted to evaluate the efficacy and safety of the helix for fixation to the vessel wall.
Cardiopulmonary Circulation	Mar. 5, 2020 Total review time: 212 days Regulatory review time: 68 days	Sep. 14, 2018 Clinical evaluation report	45	PK Papyrus Covered Coronary Stent System (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Coronary arterial stent graft	A coronary arterial stent graft used for the life-saving urgent intervention for perforations in coronary artery with a reference vessel diameter ranging from 2.5 mm to 5.0 mm or coronary bypass graft. The product achieved excellent flexibility, a low crossing profile, and a small stent diameter for the treatment of small vessels, and was designed based on the concept of improving the success rate for the treatment of coronary perforations and reducing the risk involving suitability of guiding catheters. As clinical evaluation data, the clinical evaluation report summarizing clinical literatures on the evaluation of the efficacy and safety of the product was submitted.

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Reprocessed Single-Use Medical Devices Approved in FY2019

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 30, 2019	Sep. 16, 2008	Reprocessed LASSO 2515 (Stryker Japan K.K.)	SpaceOAR System	Instrument & apparatus 51	Reprocessed single-use medical device originating from “LASSO 2515” (Approval No. 21600BZY00209000) and “LASSO 2515 Navi” (Approval No. 22200BZX00740000) that are catheter-based electrodes for heart and percutaneously and transluminally placed in the heart to perform a cardiac electrophysiological study and temporary pacing. The results of studies on cleanliness, biological safety, stability and durability, and performance were submitted.
	Total review time: 576 days Regulatory review time: 157 days	No clinical study results			Reprocessed cardiac catheter-tip electrode	

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Products Approved in FY 2018: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Apr. 4, 2018 Total review time: 310 days Regulatory review time: 135 days	Jun. 22, 2017 No clinical study results	1	Oncomine Dx Target Test CDx System (Life Technologies Japan Ltd.)	Approval	Instrument & apparatus 17 System for analysis of somatic variants (for eligibility identification of antineoplastic agents)	A companion diagnostic system used to determine if dabrafenib mesylate in combination with trametinib dimethyl sulfoxide are indicated based on a V600E mutation in the BRAF gene in patients with non-small cell lung cancer (NSCLC). The system consists of template DNA preparation reagents, a DNA sequencer, and an analysis program. As a study used to evaluate the clinical utility of the product, the result from a foreign study assessing the equivalence between this product and the test method used for the inclusion of subjects in a phase II study of above drugs were submitted.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 11, 2018 Total review time: 355 days Regulatory review time: 231 days	- Japanese clinical study results	2	NESKEEP (Alfresa Pharma Corporation)	Approval	Medical products 4 Absorbable tissue spacer for radiation therapy	A biologically absorbable spacer to provide a space between a malignant tumor and organs at risk in particle radiotherapy. The spacer is an absorbable non-woven fabric made of polyglycolic acid and is placed by laparotomy as a spacer between malignant tumor and organs at risk. A clinical study was conducted in Japan to verify the necessary space was secured and to confirm the safety of the device for patients who have malignant tumors in abdominal cavity or pelvis that require sufficient space between such tumors and organs for particle therapy and have no other effective therapy than particle therapy, and the report was submitted.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 25, 2018 Total review time: 180 days Regulatory review time: 133 days	- No clinical study results	3	OncoGuide NCC Oncopanel System (Sysmex Corporation)	Approval	Instrument & apparatus 17 Gene variants analysis set (for comprehensive genomic profiling for cancer)	A template DNA preparation reagent and an analysis program to acquire comprehensive genomic profiling pertaining to 114 cancer-related genes obtained from patients with solid tumors which contributes to formulating a therapeutic policy and determining the eligibility of drugs. The study results on analysis performance and clinical performance as a profiling test were submitted.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 27, 2018 Total review time: 286 days Regulatory review time: 186 days	Nov. 30, 2017 No clinical study results	4	FoundationOne CDx Cancer Genomic Profile (Chugai Pharmaceutical Co., Ltd.)	Approval	Program 1 Software for gene variants analysis (for comprehensive genomic profiling for cancer)	An analysis program to acquire comprehensive genomic profiling pertaining to 324 cancer-related genes obtained from patients with solid tumors which contributes to formulating a therapeutic policy and determining the eligibility of drugs. The study results on analysis performance, clinical performance as a profiling test, and concordance with approved companion diagnostics were submitted. This product also falls under the category of a term name, “Software for analysis of somatic variants (for eligibility identification of antineoplastic agents).”
Orthopedic and Plastic Surgery	May 2, 2018 Total review time: 356 days Regulatory review time: 137 days	Aug. 23, 2013 Foreign clinical study results	5	Mobi-C Artificial Cervical Disc (Zimmer Biomet G.K.)	Approval	Medical products 4 Total disc replacement prothesis	An artificial cervical disc to restore the functions of one disc or two adjacent discs in the cervical vertebrae (C3 to C7). The product consists of cobalt chromium molybdenum alloy endplates coated with plasma sprayed titanium and hydroxyapatite coating and an ultra-high molecular weight polyethylene mobile bearing insert. The results of foreign clinical studies were submitted to verify the non-inferiority of the treatment using this product to the conventional therapy of anterior cervical discectomy and fusion (ACDF).
Orthopedic and Plastic Surgery	May 2, 2018 Total review time: 187 days Regulatory review time: 152 days	Jul. 7, 2016 Foreign clinical study results	6	PRESTIGE LP Cervical Disc System (Medtronic Sofamor Danek, Co., Ltd.)	Change	Medical products 4 Total disc replacement prothesis	An artificial cervical disc intended to maintain intervertebral mobility by replacing the affected cervical disc with this device after removing factors causing compression, such as herniated nucleus pulposus or osteophytes. The application was submitted to add two-level cervical disc replacement to its intended use and indications. The results of a foreign clinical study were submitted as clinical evaluation data on the product for use in two-level cervical disc replacement.

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Orthopedic and Plastic Surgery	Jun. 4, 2018 Total review time: 363 days Regulatory review time: 209 days	Oct. 25, 2013 Foreign clinical study results	7	miraDry System (JMEC Co., Ltd.)	Approval	Instrument & apparatus 29 Microwave scalpel	The device used to ablate and coagulate eccrine glands through microwave heating of the deep dermal layer of skin for the treatment of severe primary axillary hyperhidrosis. The handpiece of the product functions to cool the surface of the skin to prevent damage caused by the heat. The results of foreign clinical studies using the previous-generation products were submitted to evaluate the efficacy in severe primary axillary hyperhidrosis and the acceptability of the anticipated adverse events in comparison with the efficacy.
Orthopedic and Plastic Surgery	Aug. 20, 2018 Total review time: 356 days Regulatory review time: 217 days	Dec. 16, 2005 Clinical evaluation report	8	Grafton DBM (Medtronic Sofamor Danek, Co., Ltd.)	Approval	Medical products 4 Resorbable bone reconstruction material using human demineralized bone matrix	A resorbable bone reconstruction material using human demineralized bone matrix to fill bony voids and gaps for the purpose of bone tissue reconstruction. The product consists of human demineralized bone matrix and glycerol. A clinical evaluation report primarily consisting of the results of a foreign post-marketing clinical study, a literature review, and an adverse event report was submitted to evaluate the efficacy and safety of the product as a bone reconstruction material.
Orthopedic and Plastic Surgery	Nov. 12, 2018 Total review time: 52 days Regulatory review time: 17 days	- No clinical study results	9	Mobi-C Artificial Cervical Disc (Zimmer Biomet G. K.)	Change	Medical products 4 Total disc replacement prothesis	An artificial cervical disc to restore the functions of one disc or two adjacent discs in the cervical vertebrae (C3 to C7). The product consists of cobalt chromium molybdenum alloy endplates coated with plasma sprayed titanium and hydroxyapatite coating and an ultra-high molecular weight polyethylene mobile bearing insert. The application was submitted to add a manufacturing site in charge of the primary assembling work. (A "partial change" application submitted during the post-market performance review period)
Orthopedic and Plastic Surgery	Mar. 27, 2019 Total review time: 362 days Regulatory review time: 178 days	- Japanese clinical study results	10	Paxman Scalp Cooling System Orbis (Century Medical, Inc.)	Approval	Instrument & apparatus 12 Instrument and device for cooling therapy	An electronically controlled cooling device that cools the scalp to prevent hair loss in patients receiving drug therapy for their solid cancer. The product is used in connection with “Paxman Scalp Cooling Cap” (23100BZX00088000). The results of Japanese clinical study for evaluation of the efficacy and safety of this product to prevent chemotherapy induced hair loss in patients with breast cancer were submitted as evaluation data. The results of foreign clinical studies, results of literature search, etc. were also submitted as reference data.
Orthopedic and Plastic Surgery	Mar. 27, 2019 Total review time: 362 days Regulatory review time: 178 days	Jun. 7, 2018 Japanese clinical study results	11	Paxman Scalp Cooling Cap (Century Medical, Inc.)	Approval	Instrument & apparatus 12 Instrument and device for cooling therapy	A cooling cap that cools the scalp to prevent hair loss in patients receiving drug therapy for their solid cancer. The product is composed of a silicon cap and a cap cover that protects the cap, and it is used in connection with “Paxman Scalp Cooling System Orbis” (23100BZX00087000). The results of Japanese clinical study for evaluation of the efficacy and safety of this product to prevent chemotherapy induced hair loss in patients with breast cancer were submitted as evaluation data. The results of foreign clinical studies, results of literature search, etc. were also submitted as reference data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 7, 2018 Total review time: 103 days Regulatory review time: 49 days	— No clinical study results	12	Gore Viabahn Stent Graft (W. L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft with nitinol stent wires wound around the outside of the graft (external stent structure type) and a delivery catheter. The application was submitted to correct discrepancies in descriptions of the raw materials. (A "partial change" application submitted during the post-market performance review period)

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 25, 2018 Total review time: 363 days Regulatory review time: 151 days	Apr. 30, 2014 Foreign clinical study results	13	Inspire (Inspire Medical Systems, Inc.)	Approval	Instrument & apparatus 12 Hypoglossal nerve stimulator	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure (CPAP) therapy. The product consists of a pulse generator, stimulation lead, sensing lead, programmer for physicians, and programmer for patients. The results of a foreign clinical study that was conducted to confirm the efficacy and safety of the product in patients who are ineligible for, or intolerant to, CPAP were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 29, 2018 Total review time: 102 days Regulatory review time: 24 days	— No clinical study results	14	Revive SE Thrombectomy device (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system to restore blood flow by removing clots from blood vessels in the brain in patients with acute-phase cerebral infarction (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 7, 2018 Total review time: 222 days Regulatory review time: 90 days	— No clinical study results	15	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery (excluding those within a stent). The balloon surface of this product is covered with a drug coating primarily consisting of paclitaxel. The application was submitted to add the RX（Rapid exchange)-type catheter form. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 30, 2018 Total review time: 37 days Regulatory review time: 16 days	— No clinical study results	16	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	Vascular embolization beads used for arterial embolization of “hypervascular tumors” and “arteriovenous malformations.” The application was submitted to remove “uterine fibroids” and “arteriovenous malformations” from the intended use and indications. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 8, 2019 Total review time: 95 days Regulatory review time: 84 days	- No clinical study results	17	Pipeline Flex Flow Diverter System (Covidien Japan, Inc.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system used for endovascular therapy for large or giant wide-neck intracranial aneurysms in internal carotid artery from petrous through superior hypophyseal, except for the acute phase of aneurysms that are at risk of rupture. The application was submitted to add a model that supplements MPC polymer to the wire surface of a flow diverter. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 21, 2019 Total review time: 364 days Regulatory review time: 197 days	Jan. 1, 2013 Foreign clinical study results	18	Brainsway TMS System (Century Medical, Inc.)	Approval	Instrument & apparatus 12 Repetitive transcranial magnetic stimulator	A repetitive transcranial magnetic stimulator that provides treatment for adult patients with Major Depressive Disorder (MDD) who have not benefitted from conventional antidepressant medication, by stimulating neurons with the electric current induced in the local area of the cerebral cortex using a pulsed magnetic field. The results of foreign clinical studies using the previous-generation products were submitted to evaluate the efficacy and safety of the product in patients with MDD who have not benefitted from conventional antidepressant medication in comparison with the sham treatment group.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 23, 2019 Total review time: 362 days Regulatory review time: 178 days	Apr. 27, 2004 Foreign clinical study results	19	Excimer Laser Turbo Catheter (Spectranetics Corporation)	Approval	Instrument & apparatus 51 Laser angioplasty catheter	A laser angioplasty catheter used for percutaneous endovascular treatment given to restenotic or reocclusive lesions that occur within a stent placed in the femoropopliteal artery. The product is used with an exclusive laser oscillator, “Excimer Laser Angioplasty Device” (Approval No.21300BZY00528000). The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product compared to a standard balloon-alone treatment.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 21, 2019 Total review time: 329 days Regulatory review time: 146 days	Dec. 11, 2012 Foreign clinical study results	20	Ovation Abdominal Stent Graft System (Endologix, Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft system for the treatment of abdominal aortic aneurysms that obtains adhesion to blood vessels by filling polymer. The product is delivered and placed in a transcatheter manner to abdominal aortic aneurysms and prevents aortic rupture by excluding blood flow into the aortic aneurysms. The result of foreign clinical study was submitted to evaluate the efficacy and safety of the product in patients with abdominal aortic aneurysms.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 28, 2019 Total review time: 269 days Regulatory review time: 147 days	Aug. 23, 2011 Clinical evaluation report	21	GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for intravascular treatment of thoracic aortic diseases. The application was submitted to add the indication of the product for chronic complicated Stanford type B aortic dissections. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the product for this indication. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 25, 2019 Total review time: 279 days Regulatory review time: 66 days	- No clinical study results	22	GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for intravascular treatment of thoracic aortic diseases. The application was submitted to mainly add a delivery catheter that expands a stent graft in two deployment steps. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Jul. 25, 2018 Total review time: 212 days Regulatory review time: 121 days	— Clinical evaluation report	23	Cool-tip RFA System E Series (Covidien Japan, Inc.)	Change	Instrument & apparatus 29 Radiofrequency ablation system	A radiofrequency ablation system to achieve coagulation and ablation for the purpose of blocking blood flow to part of, or an entire liver tumor, or to an acardiac fetus of acardiac twins. The system primarily consists of an active electrode used to puncture tissues to be coagulated and ablated and a generator unit to supply power to the active electrode. In acardiac twins, the structurally normal fetus may supply blood to the acardiac fetus (a mass of tissue without organ structure that has no chance of growth outside the mother’s body) through abnormal vascular connections in the placenta and may eventually develop heart failure due to cardiac overload, which may lead to death. The product has already been approved for the indication of “liver tumor” on August 2, 2011 (Approval No. 22300BZX00335000). The application was submitted for the additional indication of “blood flow blockage to an acardiac fetus of acardiac twins".

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Gastroenterology, Genitourinary, and Reproductive Medicine	Jul. 25, 2018 Total review time: 212 days Regulatory review time: 143 days	Apr. 2000 Clinical evaluation report	24	RFA system (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 29 Radiofrequency ablation system	A radiofrequency ablation system for coagulating and ablating malignant hepatic tumor or an acardiac fetus of acardiac twins (only for the purpose of blocking blood flow to the acardiac fetus). The system consists of an electrode used to puncture tissues to be coagulated and ablated and a generator to supply power to the electrode. In acardiac twins, the structurally normal fetus may supply blood to the acardiac fetus (a mass of tissue without organ structure that has no chance of growth outside the mother's body) through abnormal vascular connections in the placenta and may eventually develop heart failure due to cardiac overload, which may lead to death. The product has already been approved for use in "hepatic malignancy" on March 2, 2005 (Approval No. 21700BZY00127000). The application was submitted for the additional indication of "acardiac fetus of acardiac twins (only for the purpose of blocking blood flow to the acardiac fetus)."
Gastroenterology, Genitourinary and Reproductive Medicine	Oct. 31, 2018 Total review time: 201 days Regulatory review time: 147 days	Nov. 30, 2017 Foreign clinical study results	25	UroLift System (NeoTract, Inc.)	Approval	Medical products 4 Implantable prostate tissue lifting system	An implantable prostate tissue lifting system indicated for the treatment of dysuria associated with prostatic hyperplasia. The system is composed of an implant to be placed in the prostate and a delivery device which delivers the implant transurethrally to the prostate. By placing the implant in the prostate, the product compresses enlarged prostate tissues and relieves compression on the urethra. The results of foreign clinical studies which were conducted to verify the efficacy and safety of the product in patients with prostatic hyperplasia were submitted.
Ophthalmology and Otorhinolaryngology	Oct. 31, 2018 Total review time: 394 days Regulatory review time: 219 days	- No clinical study results	26	iStent Trabecular Micro-Bypass Stent System (Glaukos Corporation)	Change	Medical products 4 Heparin using intraocular drain	A device consisting of the iStent, a titanium-alloy glaucoma implant designed to maintain a patent outflow of aqueous humor through the trabecular meshwork facilitating its drainage from anterior chamber to the Schlemm's canal and its subsequent natural outflow. This device accompanies its inserter. The application was submitted to add heparin sodium which is a raw material of heparin coating agent for the implant. The humidity test and biological safety test that show the characteristics of heparin coating agent demonstrated its equivalences to these of the approved products, and these test results on the quality of heparin sodium were submitted. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Jun. 5, 2018 Total review time: 872 days Regulatory review time: 359 days	Jan. 8, 2016 Foreign clinical study results	27	Perceval Bioprosthetic Valve (Sorin Group Italia S.r.l.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	The device is designed to replace a diseased native aortic valve or a malfunctioning prosthetic aortic valve via open heart surgery. The device primarily consists of a bioprosthetic valve composed of bovine pericardium and a self-expandable metallic stent made of nickel-titanium alloy, a holder handle to position and deploy the bioprosthetic valve at the aortic valve position, and a dilating balloon to expand the bioprosthetic valve after implantation. Unlike conventional bioprosthetic valves for aortic valve replacement (AVR), this device does not require suturing of the bioprosthetic valve with suturing threads because all sutures are eventually removed. The stent's radial force allows stable anchoring of the bioprosthetic valve as the stent of the valve fits in the aortic root (the sinus of Valsalva). The results of a clinical study conducted in Europe were submitted to evaluate the efficacy and safety of the product in patients with aortic valve stenosis or aortic valve stenosis and regurgitation requiring AVR.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Jun. 7, 2018 Total review time: 359 days Regulatory review time: 147 days	Oct. 27, 2016 Foreign clinical study results	28	CorPath GRX System (Corindus, Inc.)	Approval	Instrument & apparatus 51 Catheter manipulation equipment for use in the cardiac and central circulatory system	Remote catheter manipulation equipment to be installed in a cardiac catheterization room to manipulate and hold guiding catheters, guidewires, rapid exchange balloon dilatation catheters for coronary angioplasty, and rapid exchange coronary stent catheters that are used for percutaneous coronary intervention (PCI). The product consists of a remote work space, a bed-side unit, and single-use articles. The results of a foreign clinical study using the previous generation model of the product were submitted to evaluate the efficacy and safety of the product in patients who undergo PCI.
Cardiopulmonary Circulation	Jun. 29, 2018 Total review time: 301 days Regulatory review time: 225 days	Mar. 20, 2017 Foreign clinical study results	29	CoreValve Evolut PRO (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets, and who are unable to undergo surgery. The product consists of a porcine pericardial-derived bioprosthetic valve and a delivery set composed of a delivery catheter system and a loading system. An outer skirt is attached to the inflow part of the bioprosthetic valve of the approved product, “CoreValve Evolut R” (Approval No. 22800BZX00414000) to reduce paravalvular regurgitation. The results of a clinical study conducted in the US to examine the efficacy and safety of the product were submitted.
Cardiopulmonary Circulation	Jul. 11, 2018 Total review time: 107 days Regulatory review time: 61 days	Apr. 1, 2016 No clinical study results	30	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon-type laser ablation catheter with an endoscope to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to add a method to sterilize balloon fill media, a manufacturing site in charge of sterilization, and a method to re-sterilize the endoscope fiber. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Sep. 27, 2018 Total review time: 34 days Regulatory review time: 29 days	— No clinical study results	31	EDWARDS INTUITY Elite Valve System (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Bovine pericardial valve	A bioprosthetic valve with a bovine pericardial-derived valve intended as a substitute for the function of a malfunctioning cardiac valve. The application was submitted primarily to add bovine pericardium produced in Australia as a raw material for valve leaflets and to add raw materials for band-covering and wire-shaped fabrics. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Oct. 9, 2018 Total review time: 285 days Regulatory review time: 217 days	- Clinical evaluation report	32	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted to add a PA model which has the same blood pump portion as that of the existing abdominal model but is fixed with an intracorporeal cable in the postauricular region, and a kink preventing cover, etc. (A ”partial change” application submitted during the reexamination period)
Cardiopulmonary Circulation	Dec. 5, 2018 Total review time: 103 days Regulatory review time: 88 days	- No clinical study results	33	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing a high-frequency current to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to add a highly rigid model, a dilution rate of an applicable contrast media, an esophagus cooling tube as a component, and to change the maximum guide wire diameter for use in combination, and also to make other adjustments to the descriptions. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Jan. 24, 2019 Total review time: 139 days Regulatory review time: 101 days	Mar. 1, 2018 No clinical study results	34	CorPath GRX System (Corindus, Inc.)	Change	Instrument & apparatus 51 Catheter manipulation equipment for use in the cardiac and central circulatory system	Catheter manipulation equipment for use in the cardiac and central circulatory system that remotely performs the delivery and manipulation of guidewires, rapid exchange balloon catheter, stent catheter, and guiding catheter during percutaneous coronary intervention (PCI). The application was submitted to add a function that allows a guidewire to automatically rotate when the guidewire is pulled back and also a change of the guidewire's rotation angle on a touch panel. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Feb. 21, 2019 Total review time: 267 days Regulatory review time: 99 days	Mar. 13, 2015 Foreign and Japanese clinical study results	35	WATCHMAN Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Endocardial prosthetic material	This device was developed to reduce the risk of ischemic stroke and systemic embolism from the left atrial appendage in patients with non-valvular atrial fibrillation who are at increased risk for thromboembolism. The device consists of a delivery system loaded with a closure device, a sheath for delivering the delivery system to the left atrial appendage, and a dilator. By closing the left atrial appendage with a percutaneously delivered closure device, it is intended to reduce the risk of ischemic stroke and systemic embolism caused by left atrial appendage thrombus. The results of foreign and Japanese clinical studies using the product were submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Feb. 22, 2019 Total review time: 113 days Regulatory review time: 19 days	- No clinical study results	36	EDWARDS INTUITY Elite Valve System (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve intended as a substitute for the function of a malfunctioning aortic valve. The application was submitted to add a manufacturing site in charge of the primary assembling work and to adjust the descriptions in the manufacturing method column. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 25, 2019 Total review time: 179 days Regulatory review time: 143 days	Jul. 8, 2010 No clinical study results	37	Impella Controller (Abiomed, Inc.)	Change	Instrument & apparatus 7 Controller of implantable pump catheter for ventricular support	An external controller for exclusive catheter-based blood pump (hereinafter referred to the catheter pump) that controls the performance and monitors the catheter position of the catheter pump, and controls the flow rate of the purge cassette. The application was submitted in connection with the addition of a new type of pump catheter for the concomitant device, “Impella Circulatory Assist Pump Catheter” (Approval No. 22800BZI00032000). (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 25, 2019 Total review time: 179 days Regulatory review time: 84 days	May 30, 2008 No clinical study results	38	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51 Implantable pump catheter for ventricular support	The catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery and placed in the left ventricle. This device pulls blood directly from the left ventricle and expels the blood from the catheter into the ascending aorta. The application was submitted to add Impella CP as a new type of pump catheter. (A "partial change" application submitted during the post-market performance review period)

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Products Approved in FY 2018: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	May 25, 2018 Total review time: 428 days Regulatory review time: 96 days	Oct. 5, 2012 Foreign clinical study results	1	Dexcom G4 PLATINUM System (Dexcom, Inc.)	Approval	Instrument & apparatus 20 Glucose monitoring system	The device is a continuous glucose monitoring system indicated for detecting trends and tracking patterns by measuring interstitial fluid glucose concentration in persons with diabetes. The device continuously records interstitial fluid glucose concentration obtained by a sensor that is inserted subcutaneously and displays the collected information on a monitor. Patterns and trends of interstitial fluid glucose concentration obtained by the device can be used to optimize the management of diabetes. It is used to complement self-blood glucose monitoring. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of this product.
Orthopedic and Plastic Surgery	Apr. 10, 2018 Total review time: 256 days Regulatory review time: 183 days	— Japanese clinical study results	2	PELNAC G plus (GUNZE Limited)	Approval	Medical products 4 Collagen-based artificial skin	PELNAC G plus is a bilayer collagen-based artificial dermis made of a gelatin-containing collagen sponge and a silicone film. This product is based on the company's approved product, “PELNAC” and its improvements are the inclusion of gelatin in the raw material as well as the introduction of a single-layer fenestrated type. The results of a single-arm clinical study on patients with refractory skin ulcers in Japan were submitted to evaluate the efficacy and safety of this product.
Orthopedic and Plastic Surgery	Apr. 26, 2018 Total review time: 121 days Regulatory review time: 65 days	— Clinical evaluation report	3	Comprehensive Shoulder Nanostem (Zimmer Biomet G.K.)	Approval	Medical products 4 Humeral component for shoulder prosthesis	A humeral stem component system used proximally in the humerus to substitute for shoulder joint functions during total shoulder arthroplasty or shoulder humeral head replacement. The improved point is the adoption of a humeral stem that is shorter than the conventional one to reduce the invasiveness to the bone marrow cavity, thereby allowing bone preservation. A clinical evaluation report summarizing the contents of foreign clinical literatures, post-marketing surveillance, and malfunction reports was submitted to evaluate the risks of looseness, dislocation, etc. caused by this improved point.
Orthopedic and Plastic Surgery	May 7, 2018 Total review time: 138 days Regulatory review time: 89 days	Dec. 26, 2013 Clinical evaluation report	4	Long-Pulsed Laser GentleMax Pro (Syneron Candela K.K.)	Approval	Instrument & apparatus 31 Neodymium:YAG laser	The device intended to achieve stable long-term hair reduction by selective photothermolysis. The device is a combination device with which 755 nm Alexandrite laser or 1064 nm Nd:YAG laser can be selected. The functions of the Alexandrite laser are the same as those of the company’s previous model, "Long-Pulsed Alexandrite Laser GentleLase Pro" (Approval No. 22800BZX00446000). A clinical evaluation report summarizing clinical literatures on the previous generation product was submitted to evaluate the long-term hair reduction effect and the absence of permanent adverse events.
Orthopedic and Plastic Surgery	May 18, 2018 Total review time: 259 days Regulatory review time: 94 days	Mar. 10, 2015 Clinical evaluation report	5	Mediostar Next Pro (Medical U&A, Inc.)	Approval	Instrument & apparatus 31 Diode laser	The device is intended to achieve stable long-term hair reduction by selective photothermolysis. Diode lasers at wavelengths of 808 nm and 940 nm are delivered simultaneously. A clinical evaluation report summarizing clinical literatures on the previous generation product was submitted to evaluate the long-term hair reduction effect and the absence of permanent adverse events.
Orthopedic and Plastic Surgery	Jun. 1, 2018 Total review time: 430 days Regulatory review time: 137 days	Mar. 17, 2017 Foreign clinical study results	6	Juvederm Vista Volift XC (Allergan Japan K.K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material to a soft tissue using hyaluronic acid to be injected into the middle and deep dermis to correct moderate to severe wrinkles and folds in the facial skin. The improved point is that a lower concentration of the hyaluronic acid gel of the company’s approved product 1, "Juvederm Vista Voluma XC" (22800BZX00338000) used for correcting volume deficit, is used for optimal correction of wrinkles and folds. The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the impact of the improved point on the correction of wrinkles and folds.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Oct. 26, 2018 Total review time: 648 days Regulatory review time: 423 days	May 31, 2016 Foreign clinical study results	7	Juvederm Vista Volbella XC (Allergan Japan K. K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An Injectable material to a soft tissue using hyaluronic acid used to correct facial wrinkles by injecting it intradermally (from the middle to deep dermis), to correct facial hollows by injecting it subcutaneously or into the deep part on the periosteum, and to augment the lip by injecting it subcutaneously into the lip mucosa. The improvement was made for the product to optimize the injection into the lip or more shallow part of the facial skin by decreasing the concentration of hyaluronic acid gel of the company's approved product, "Juvederm Vista Voluma XC" (22800BZX00338000). The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product by this improvement.
Orthopedic and Plastic Surgery	Dec. 11, 2018 Total review time: 257 days Regulatory review time: 132 days	Mar. 5, 2008 Clinical evaluation report	8	XTRAC (JMEC Co., Ltd.)	Approval	Instrument & apparatus 31 Excimer laser	An excimer laser that treats skin diseases subject to medium-wave UV therapy by irradiating laser light with wavelength 308 nm in the UV region which is generated by gas mixture containing xenon and chloride to the affected site through a handpiece. While the existing certified UV treatment device used for the equivalent purpose uses excimer lamp as a light source, but this product uses excimer laser as a light source. This point is the difference between this product and the existing certified products. The clinical evaluation report prepared based on overseas literatures, including the clinical results of this device and the previous generation device in other countries, was submitted to evaluate the efficacy and safety of the product equivalent to those of the existing UV treatment devices.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 23, 2018 Total review time: 257 days Regulatory review time: 96 days	May 22, 2015 Foreign and Japanese clinical study results	9	Misago 2 (Terumo Corporation)	Approval	Instrument & apparatus 7 Stent for iliac artery	A nickel-titanium alloy vascular stent used for vascular expansion and maintenance of a lumen in symptomatic artery disease of the iliac arteries and the superficial femoral artery region, and for the treatment of acute or impending occlusion associated with unsuccessful intervention treatment of the superficial femoral artery region. Sharing the basic design with the approved product, "Misago" (Approval No. 22400BZX00463000), a stent for use in superficial femoral arteries, Misago 2 has an additional sized model with a wider diameter for iliac artery. The results of a clinical study of the product for use in the iliac arteries and the superficial femoral artery region were submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2018 Total review time: 264 days Regulatory review time: 116 days	— Japanese clinical study results	10	ONYX Liquid Embolic System LD (Covidien Japan, Inc.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A liquid embolic agent comprised of ethylene vinyl alcohol copolymer dissolved in dimethyl sulfoxide, and that is used for the embolization of cerebral vascular malformations. The application was submitted for the additional indication of dural arteriovenous fistula for which it is difficult to achieve satisfactory treatment goals with intravenous embolization. The results of a Japanese clinical study that evaluated the efficacy and safety of the product in patients with dural arteriovenous fistula were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 18, 2018 Total review time: 927 days Regulatory review time: 338 days	Mar. 30, 2015 Foreign clinical study results	11	Adherus Dural Sealant (Medical U&A, Inc.)	Approval	Medical products 4 Absorbable tissue reinforcement material	A synthetic absorbent material used as an absorbable prosthetic material to close a gap between the dura maters, the sutured site of the dura mater, or a gap between the duraplasty material and the dura mater. The results of a foreign clinical study conducted to verify the non-inferiority of this product to approved products for cerebrospinal fluid (CSF) leaks after surgery, etc. were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 5, 2018 Total review time: 252 days Regulatory review time: 158 days	Jun. 11, 2018 Clinical evaluation report	12	Cerebral Thrombus Aspiration Catheter (Terumo Corporation)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system used for revascularization of patients with acute ischemic stroke (in principle, within 8 hours of symptom onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed in revascularization with intravenous t-PA therapy. The product is different from the approved product, “Penumbra System” (Approval No. 22300BZX00269000) in that it aspirates and retrieves thrombus only with a catheter without using a separator (A Direct Aspiration first Pass Technique, hereinafter referred to as “ADAPT”), and also it aspirates thrombus manually with a syringe. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of ADAPT.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 5, 2018 Total review time: 250 days Regulatory review time: 201 days	Mar. 28, 2014 Foreign clinical study results	13	Supera Stent (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A self-expanding vascular stent used for the treatment of symptomatic vascular disease with a lesion length up to 140 mm in the native superficial femoral artery and proximal popliteal artery with reference vessel diameter of 4.0-6.5mm, and for the treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The results of foreign clinical studies conducted to evaluate the performance of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 6, 2018 Total review time: 190 days Regulatory review time: 150 days	Sep. 18, 2018 Global clinical trial	14	Eluvia Drug-Eluting Vascular Stent System (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 7 Drug-eluting femoral artery stent	A drug-eluting stent used for the treatment of symptomatic vascular disease with a lesion length up to 190 mm in the native femoropopliteal artery with reference vessel diameter of 4 -6 mm for each limb, and for the treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The product is a combination of the company's approved stent system and drug coating. The results of the randomized controlled global clinical study conducted to evaluate the performance of the product with a lesion length up to 140 mm using other company’s approved product, “Zilver PTX Drug-Eluting Peripheral Stent” (Approval No. 22400BZX00013000) as a control and the results of the single-arm global clinical study conducted to evaluate the performance of the product with a lesion length up to 190 mm were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 11, 2018 Total review time: 256 days Regulatory review time: 160 days	- Japanese clinical study results	15	Tron FX Thrombectomy Device (JIMRO Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A Central circulatory system embolectomy catheter that is intended for use in removing intracerebral clots to restore blood flow in patients with acute ischemic stroke (generally within 8 hours of symptom onset) in whom IV t-PA therapy is not indicated or fails to achieve reperfusion. The results of Japanese clinical studies that evaluated the efficacy and safety of the product for acute ischemic stroke were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 7, 2019 Total review time: 629 days Regulatory review time: 206 days	Jul. 1999 Clinical evaluation report	16	DuraGen Artificial Dura Mater (EPJ Medical Service Co., Ltd.)	Approval	Medical products 4 Collagen-using absorbent artificial dura mater	A collagen-using absorbent artificial dura mater used for prosthesis for deficiency part of dura mater. The product is different from the existing artificial dura maters in that the spinal dura mater is included as the indicated site and suture is not necessary for prosthesis. A clinical evaluation report summarizing the contents of foreign clinical studies, literatures, etc. was submitted to evaluate the efficacy and safety of the product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 20, 2019 Total review time: 229 days Regulatory review time: 200 days	Feb. 15, 2018 Foreign clinical study results	17	Trevo Pro Clot Retriever (Stryker Japan K. K.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system intended to restore blood flow by removing thrombus for patients with acute-phase cerebral infarction who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application was submitted to add the indication of the product for patients with occlusion in the proximal part of the anterior major artery whose outcome is expected to improve with endovascular thrombectomy and who are within 24 hours from when s/he was confirmed to be healthy last time. The results of foreign clinical study conducted for this indication were submitted.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar.26, 2019 Total review time: 236 days Regulatory review time: 48 days	- Foreign clinical study results Clinical evaluation report	18	COOK Zenith Dissection Endovascular System (Cook Japan Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of complicated Stanford type B aortic dissection. The application was submitted to add chronic complicated Stanford type B aortic dissection to the indication of the product. A clinical evaluation report compiling the data from a foreign clinical study and Japanese and foreign literature reports was submitted to evaluate the efficacy and safety of the product for this indication.
Gastroenterology, Genitourinary, and Reproductive Medicine	Apr. 17, 2018 Total review time: 183 days Regulatory review time: 131 days	— Clinical evaluation report	19	EBL Device (Akita Sumitomo Bakelite Co., Ltd.)	Approval	Instrument & apparatus 30 Device for endoscopic loop ligation	A medical device to be mounted on the end of an endoscope, and that is intended to be used to ligate internal hemorrhoids or colonic diverticular bleeding points with an O ring by drawing them into the device. Ligation of tissues with an O ring stops bleeding and causes tissue necrosis to block the diverticula. The device was developed by improving the company's approved product, "Pneumatic EVL Device (with cuff)" (Approval No. 22100BZX01110000), an endoscopic esophageal varix ligation set, and is designed for use in the large intestine. Three different sizes are available depending on the size of the endoscope.
Gastroenterology, Genitourinary, and Reproductive Medicine	Apr. 24, 2018 Total review time: 109 days Regulatory review time: 59 days	— Japanese clinical study results	20	Hemodiafilter FX HDF (Fresenius Medical Care Japan K.K.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. This device is indicated for patients with extremely impaired renal function caused by chronic or acute kidney failure. The improved point is that the product uses a semi-permeable membrane that is identical to the one used in the company's approved product, a hollow fiber dialyzer "Fresenius Dialyzer FX Series (Approval No. 22000BZX00037000)", as a hemodiafilter to meet market needs.
Gastroenterology, Genitourinary, and Reproductive Medicine	Sep. 10, 2018 Total review time: 167 days Regulatory review time: 129 days	— Japanese clinical study results	21	UT Filter A (Nipro Corporation)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	The device is used for slow continuous hemofiltration in patients with acute renal failure or those with chronic renal failure with unstable hemodynamics. The device slowly removes and adjusts unwanted metabolites, water, and electrolytes in the blood. The device was developed as a slow continuous hemofilter by changing the size variation of the approved hemodiafilter product (Brand name: Fineflux, Approval No. 22600BZX00004000).
Gastroenterology, Genitourinary and Reproductive Medicine	Oct. 26, 2018 Total review time: 182 days Regulatory review time: 113 days	Feb. 2003 Clinical evaluation report	22	ABTHERA Dressing Kit (KCI K.K.)	Approval	Medical products 4 Dressing kit for open abdominal wounds	A dressing kit for open abdominal wounds intended to facilitate early closure of the peritoneum. The product provides the protection of abdominal contents from external environment, efficient drainage, suppression of inflammation, and alleviation of edema by covering the organs inside the abdomen and applying controlled negative pressure in the case where open abdominal wounds are accompanied by exposure of abdominal organs and also abdominal closure by primary suture is difficult. The product is composed of the tubing set, drape, blue foam, and protective layer. An optional item of the product, ABTHERA Negative Pressure Maintenance Controller, is used to transmit negative pressure. Also, this device may be used in combination with the negative pressure maintenance controller of the approved product, "InfoV.A.C. Therapy System" or "V.A.C.Ulta Therapy System."
Gastroenterology, Genitourinary and Reproductive Medicine	Nov. 21, 2018 Total review time: 265 days Regulatory review time: 156 days	- Japanese clinical study results	23	Liftal K (Kaigen Pharma Co., Ltd.)	Approval	Medical products 4 Submucosal filling material for endoscope	A vial product filled with 20 mL of 0.6% sodium alginate solution. The product largely dissociates a gap between the mucosal layer and the muscle layer by staying the submucosa using its viscoelasticity which is the feature of sodium alginate solution. As a result, it allows to form and maintain the bulge of lesions site (mucosal layer) when resecting or dissecting the mucosal layer. Thus, the product is a submucosal filling material for endoscopy intended to improve the operability of resection or dissection of lesion sites during Endoscopic Submucosal Dissection (EDS) and Endoscopic Mucosal Resection (EMR). The results of Japanese clinical studies conducted to verify the efficacy and safety of the product were submitted.

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Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 20, 2018 Total review time: 266 days Regulatory review time: 130 days	- Clinical evaluation report	24	Okamoto Condoms VG (Okamoto Industries, Inc.)	Approval	Hygiene products 2 Contraceptive condom for males	A contraceptive condom for males intended to help contraception and prevention of sexually transmitted diseases. The product is composed of a condom itself and dressing agent (anti-adhesion agent, lubricant). The lubricant contains 0.5% of SPL7013. Regarding the safety evaluation for SPL7013, a clinical evaluation report that mainly includes the overseas clinical study data of SPL7013 gel for bacterial vaginosis, which has not been approved in Japan, was submitted.
Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 7, 2019 Total review time: 195 days Regulatory review time: 145 days	Mar. 18, 2016 Clinical evaluation report	25	FibroScan 530 Compact (Echosens)	Change	Instrument & apparatus 12 Versatile ultrasound diagnostic imaging device	A Versatile ultrasound diagnostic imaging device that provides qualitative information by measuring liver stiffness non-invasively. The application was submitted to add a measuring function of controlled attenuation parameter (CAP) level that quantitatively measures the liver fat volume. A clinical evaluation report on the evaluation of fatty liver grade using the CAP level in liver biopsy was submitted.
Ophthalmology and Otorhinolaryngology	Jul. 10, 2018 Total review time: 270 days Regulatory review time: 132 days	— Japanese clinical study results	26	Neo Sight One Day Aero (Aire Inc.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Daily wear, single-use, colored contact lenses for correction of visual acuity. The lens is composed of silicone hydrogel with a moisture content of 45% and an oxygen permeability (Dk) of 58.5. Due to the novelty of the raw material, a Japanese clinical study was conducted to confirm the efficacy and safety of the product as a contact lens for visual correction.
Ophthalmology and Otorhinolaryngology	Aug. 17, 2018 Total review time: 268 days Regulatory review time: 224 days	— Japanese clinical study results	27	Lentis Comfort (Santen Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct far and intermediate vision of an aphakic eye. The improved points are that the product has a refractive multifocal mechanism with two regions with different curvature radius of the optic zone, a pair of plate supports, and that it uses new raw materials. A Japanese clinical study was conducted to confirm the clinical efficacy and safety of the product including visual function as a multifocal posterior chamber lens.
Ophthalmology and Otorhinolaryngology	Aug. 21, 2018 Total review time: 266 days Regulatory review time: 212 days	Dec. 16, 2009 Clinical evaluation report	28	da Vinci Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery). A clinical evaluation report, which summarized a Japanese clinical study and a US clinical study in patients with oropharyngeal cancer, hypopharyngeal cancer, laryngeal cancer, etc., and foreign literatures, was submitted to evaluate the efficacy and safety of the product in transoral head and neck surgery.
Ophthalmology and Otorhinolaryngology	Aug. 21, 2018 Total review time: 266 days Regulatory review time: 212 days	Dec. 16, 2009 Clinical evaluation report	29	da Vinci Si Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery). A clinical evaluation report, which summarized a Japanese clinical study and a US clinical study in patients with oropharyngeal cancer, hypopharyngeal cancer, laryngeal cancer, etc., and foreign literatures, was submitted to evaluate the efficacy and safety of the product in transoral head and neck surgery.

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Ophthalmology and Otorhinolaryngology	Aug. 21, 2018 Total review time: 266 days Regulatory review time: 212 days	— Clinical evaluation report	30	da Vinci Xi Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery). A clinical evaluation report, which summarized a Japanese clinical study and a US clinical study in patients with oropharyngeal cancer, hypopharyngeal cancer, laryngeal cancer, etc., and foreign literatures, was submitted to evaluate the efficacy and safety of the product in transoral head and neck surgery.
Ophthalmology and Otorhinolaryngology	Aug. 24, 2018 Total review time: 269 days Regulatory review time: 90 days	May 26, 2016 Foreign clinical study results	31	Ultimate 1 Day SH (Sincere Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Daily wear, single-use, colored contact lenses for correction of visual acuity. The lens is composed of silicone hydrogel (Olifilcon B) with a moisture content of 47% and an oxygen permeability (Dk) of 120.0. Due to the novelty of the raw material, a foreign clinical study was conducted to confirm the efficacy and safety of the product as a contact lens for visual correction.
Ophthalmology and Otorhinolaryngology	Sep. 14, 2018 Total review time: 266 days Regulatory review time: 211 days	Apr. 3, 2016 Foreign clinical study results	32	Triggerfish Sensor (SEED Co., Ltd.)	Approval	Instrument & apparatus 72 Measuring device for corneal curvature variation	A contact lens-type pressure sensor that is mounted on the front part of the eye to monitor changes in the corneal curvature induced by changes in the intraocular pressures and to detect peak patterns of variation in intraocular pressure. The device is used in combination with Triggerfish (Approval No. 23000BZX00273000). The results of a foreign clinical study in patients with primary open-angle glaucoma and healthy adults were submitted to confirm the capability to detect changes in corneal curvature, etc.
Ophthalmology and Otorhinolaryngology	Sep. 14, 2018 Total review time: 266 days Regulatory review time: 209 days	Apr. 3, 2016 Foreign clinical study results	33	Triggerfish (SEED Co., Ltd.)	Approval	Instrument & apparatus 21 Telemetry measuring device for biological signals	A device to monitor changes in the corneal curvature induced by changes in the intraocular pressure, to detect peak patterns of variation in intraocular pressure, and to receive and record data measured by Triggerfish Sensor (Approval No. 23000BZX00272000), etc. The results of a foreign clinical study in patients with primary open-angle glaucoma and healthy adults were submitted to confirm the capability to detect changes in corneal curvature, etc.
Ophthalmology and Otorhinolaryngology	Oct. 23, 2018 Total review time: 208 days Regulatory review time: 170 days	Jul. 13, 2016 Foreign clinical study results	34	Avaira v (CooperVision Japan Inc.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored contact lenses for daily wear intended for the correction of visual acuity. The lens is made of fanfilcon A, a silicone hydrogel. A novel material was developed to improve oxygen permeability and UV absorption, and the results of foreign clinical studies, etc. conducted to evaluate the efficacy and safety were submitted.
Ophthalmology and Otorhinolaryngology	Oct. 23, 2018 Total review time: 208 days Regulatory review time: 170 days	- No clinical study results	35	Rohto 2 Week Clear View (CooperVision Japan Inc.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A product with multiple brand name of "Avaira v."
Ophthalmology and Otorhinolaryngology	Oct. 23, 2018 Total review time: 208 days Regulatory review time: 170 days	- No clinical study results	36	Rohto 2 Week Fresh View (CooperVision Japan Inc.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A product with multiple brand name of "Avaira v."
Ophthalmology and Otorhinolaryngology	Nov. 7, 2018 Total review time: 257 days Regulatory review time: 223 days	Jul. 31, 2015 Foreign clinical study results	37	Tecnis Toric 1-Piece (AMO Japan K.K.)	Change	Instrument & apparatus 72 Posterior chamber lens	A one-piece monofocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery accompanied with corneal astigmatism. The application was submitted to mainly add a high cylindrical power model. The results of foreign clinical studies, etc. to evaluate the efficacy and safety of the product in patients with aphakic eyes with severe corneal astigmatism were submitted.

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Ophthalmology and Otorhinolaryngology	Dec. 26, 2018	Apr. 5, 2017	38	XprESS ENT Dilation System (Entellus Medical, Inc.)	Approval	Instrument & apparatus 51	XprESS is a balloon catheter used for dilation of the cartilaginous portion to the isthmus of the Eustachian tube for treating persistent Eustachian tube stenosis through transnasal approach. The product has a new intended use and indication. The improved feature of the product is that it is used for a different treatment site from that of the existing “endoscopic dilatation catheter” in Japan. The results of foreign clinical studies were submitted to evaluate the clinical efficacy and safety of the product for Eustachian tube dysfunction.
	Total review time: 383 days Regulatory review time: 276 days	Foreign clinical study results				Endoscopic dilatation catheter	
Ophthalmology and Otorhinolaryngology	Dec. 26, 2018	-	39	HOYA Vivinex Toric (HOYA Corporation)	Approval	Instrument & apparatus 72	The product is a one-piece monofocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery accompanied with corneal astigmatism. The improvement was made to the product in that correction function of corneal astigmatism was added to the rear face of the monofocal posterior chamber lens of the company’s approved product, “HOYA Vivinex iSert” (Approval No. 22400BZX00498000). The results of Japanese clinical studies were submitted to evaluate the clinical efficacy and safety of the product including astigmatic correction function.
	Total review time: 147 days Regulatory review time: 104 days	Japanese clinical study results				Posterior chamber lenses with an injector	
Ophthalmology and Otorhinolaryngology	Feb. 20, 2019	-	40	Alcon AcrySof IQ PanOptix Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72	The product is a single-piece multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery. The improvement was made to the product in that it has a trifocal diffractive structure, while the company’s approved product, “Alcon AcrySof IQ ReSTOR Single-Piece” (Approval No. 22000BZX00970000) has a bifocal diffractive structure. The results of Japanese clinical studies were submitted to evaluate the clinical efficacy and safety of the product including its multifocal mechanism, in addition to the performance evaluation of its multifocal mechanism.
	Total review time: 216 days Regulatory review time: 156 days	Japanese clinical study results				Multifocal posterior chamber lens	
Ophthalmology and Otorhinolaryngology	Feb. 20, 2019	-	41	Alcon AcrySof IQ PanOptix Toric Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72	The product is a single-piece multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery accompanied with corneal astigmatism. The improvement was made to the product in that it has a trifocal diffractive structure the same as that of “Alcon AcrySof IQ PanOptix Single Piece” (Approval No. 23100BZX00042000), while the company’s approved products, “Alcon AcrySof IQ ReSTOR +2.5D Toric Single Piece” (Approval No. 22700BZX00006000) and “Alcon AcrySof IQ ReSTOR Toric Single Piece” (Approval No. 22600BZX00007000) each have a bifocal diffractive structure. Since the evaluation of aberrations of cylindrical axis for the company’s approved products showed that trifocusing on the front of the optical part does not affect the rotation, the efficacy and safety of the product were evaluated based on the results of a Japanese clinical study of “Alcon AcrySof IQ PanOptix Single Piece.”
	Total review time: 211 days Regulatory review time: 152 days	Japanese clinical study results				Multifocal posterior chamber lens	
Cardiopulmonary Circulation	Apr. 4, 2018	—	42	XIENCE Xpedition Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary lesion (a lesion length of 42 mm or less) with a reference vessel diameter of 2.25-3.75 mm and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted to add a 48 mm long stent to allow further variation in size. Data related to the results of a foreign clinical study on the additional model were submitted.
	Total review time: 243 days Regulatory review time: 178 days	Foreign clinical study results				Coronary stent	
Cardiopulmonary Circulation	Apr. 4, 2018	May 22, 2018	43	XIENCE Sierra Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-4.25 mm and a delivery catheter used to implant the stent to the site of stenosis. The product was developed by slightly changing the design of the stent and changing the design of the delivery system to improve deliverability from those of the company’s approved product, "XIENCE Alpine Drug Eluting Stent" (Approval No. 22600BZX00529000). The results of Japanese and foreign clinical studies were attached to evaluate the efficacy and safety of the product.
	Total review time: 182 days Regulatory review time: 115 days	Foreign and Japanese clinical study results				Coronary stent	

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Cardiopulmonary Circulation	May 24, 2018 Total review time: 206 days Regulatory review time: 116 days	Dec. 2, 2016 Foreign clinical study results	44	Edwards Sapien 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation for patients with severe symptomatic aortic valve stenosis and for whom surgical aortic valve replacement cannot be performed. The application was submitted to add transapical/transaortic delivery systems to achieve transapical/transaortic approaches in transcatheter aortic valve replacement. The results of a foreign clinical study were submitted to evaluate the efficacy and safety of implantation of the product by transapical/transaortic approaches.
Cardiopulmonary Circulation	May 24, 2018 Total review time: 265 days Regulatory review time: 113 days	— Foreign clinical study results	45	PLATINIUM SonR CRT-D (Sorin CRM SAS)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillation function to supply an appropriate defibrillation pulse to the myocardium to reduce the heart rate to the normal range as necessary when tachycardia is detected, and to supply a pacing pulse to increase the heart rate to the normal range when bradycardia is detected. This device was developed based on the approved product, "PLATINIUM CRT-D" (Approval No. 22800BZI00022000). A major improved point is the addition of a CRT optimization function to automatically regulate AV and VV delays according to the endocardial acceleration signals from the acceleration sensor equipped in "SonRtip lead" (Approval No. 23000BZI00013000), which is used in combination with the device. The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the CRT optimization function.
Cardiopulmonary Circulation	May 24, 2018 Total review time: 265 days Regulatory review time: 113 days	— Foreign clinical study results	46	SonRtip lead (Sorin CRM SAS)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A pacemaker lead with an acceleration sensor to convert endocardial acceleration into electrical signals equipped in the tip, which is used as an atrial pacing lead for "PLATINIUM SonR CRT-D" (Approval No. 23000BZI00012000) with CRT optimization function. The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the CRT optimization function.
Cardiopulmonary Circulation	Jun. 20, 2018 Total review time: 145 days Regulatory review time: 121 days	Feb. 22, 2019 Foreign clinical study results	47	Orsiro Sirolimus Eluting Coronary Stent System (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary lesion (a lesion length of 36 mm or less) with a reference vessel diameter of 2.25-4.0 mm and a delivery catheter used to implant a stent to the site of stenosis. The application was submitted for additional stent size variations of 35 mm and 40 mm. Data related to the results of a foreign clinical study on the additional stent size models were submitted.
Cardiopulmonary Circulation	Aug. 2, 2018 Total review time: 464 days Regulatory review time: 93 days	May 6, 2017 Foreign clinical study results	48	Percepta MRI CRT-P Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	The device is an implantable biventricular pacing pulse generator without a defibrillator function. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The device was developed based on the approved product, "Medtronic Viva CRT-P" (Approval No. 22600BZX00304000). Major improved points are conditionally allowed MRI scans and an additional feature to assess the efficacy of CRT pacing during atrial fibrillation (AF) and to regulate the pacing rates according to the assessment (EffectivCRT during AF feature). The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the EffectivCRT during AF feature.
Cardiopulmonary Circulation	Aug. 21, 2018 Total review time: 174 days Regulatory review time: 92 days	Apr. 11, 2016 Foreign clinical study results	49	BioMonitor 2 (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 21 Implantable data recorder for electrocardiogram	An implantable data recorder for electrocardiogram, subcutaneously implanted to diagnose arrhythmia in patients who presented with symptoms such as syncope and in whom the cause of the symptom could not be identified despite a careful examination, and to detect atrial fibrillation in patients with cryptogenic cerebral infarction. The results of a foreign clinical study were submitted to evaluate the arrhythmia detection function and safety.

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Cardiopulmonary Circulation	Sep. 21, 2018 Total review time: 267 days Regulatory review time: 109 days	Feb. 5, 2016 Clinical evaluation report	50	Bridge Occlusion Balloon Catheter (Spectranetics Corporation)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	A balloon catheter for temporary use in the superior vena cava for the purpose of emergency hemostasis during lead extraction. Since the existing occlusion balloon catheter has a shorter balloon length that is not long enough to achieve emergency hemostasis during lead extraction, this product was developed as a balloon catheter that can cover the entire superior vena cava. A clinical evaluation report summarizing the foreign literatures on the use of this product or similar products was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Nov. 20, 2018 Total review time: 270 days Regulatory review time: 108 days	Aug. 18, 2013 Foreign clinical study results	51	PDA Closure Set II (Abbott Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A self-expanding duct occluder and delivery system intended to be used for percutaneous closure of an opening of the arterial duct in patients with patent ductus arteriosus (PDA). The product was developed to improve the placement of the product into smaller arterial ducts and the compatibility with different forms of arterial ducts based on the approved product, “PDA Closure Set” (Approval No. 22000BZX01768000). The results of foreign clinical studies were submitted to verify the clinical efficacy and safety of the product.
Cardiopulmonary Circulation	Dec. 6, 2018 Total review time: 462 days Regulatory review time: 122 days	Nov. 20, 2012 Foreign and Japanese clinical study results	52	Implantable Ventricular Assist Device System HVAD (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. A blood pump of the product is a small-sized centrifugal pump compared to that of similar approved products. An impeller inside the pump rotates by the magnetic levitation mechanism and dynamic pressure mechanism. As clinical evaluation data, the results of foreign and Japanese clinical studies were submitted.

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Products Approved in FY 2017: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	May 26, 2017 Total review time: 365 days Regulatory review time: 128 days	Apr. 1, 2015 Foreign clinical study results	SpaceOAR System (Augmenix, Inc.)	Approval	Medical products 4 Absorbable tissue spacer for radiation therapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The components include an injection syringe and injection needle, etc. The results from a foreign clinical study which compared two groups undergoing Intensity Modulated Radiation Therapy (IMRT) with and without the device were submitted to evaluate the effectiveness in reduction of radiation exposure to the rectum.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 14, 2017 Total review time: 78 days Regulatory review time: 51 days	— No clinical study results	SpaceOAR System (Augmenix, Inc.)	Change	Medical products 4 Absorbable tissue spacer for radiation therapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Robotic, ICT, and other devices (not classified as other categories)	Mar. 29, 2018 Total review time: 163 days Regulatory review time: 95 days	Dec. 19, 2014 No clinical study results	BRACAnalysis diagnostic system (Myriad Genetic Laboratories, Inc.)	Approval	Program 1 Software for analysis of germline variants (for eligibility identification of antineoplastic agents)	A companion diagnostic program used to determine if olaparib is indicated based on BRCA mutation data in patients with breast cancer. As a study used to evaluate the clinical utility of the product, the result from a foreign study assessing the equivalence between this product and the test method used for the inclusion of subjects in a phase III study of olaparibt were submitted.
Orthopedic and Plastic Surgery	May 12, 2017 Total review time: 347 days Regulatory review time: 295 days	Jul. 24, 2014 Foreign clinical study results	PRESTIGE LP Cervical Disc System (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Total Disc Replacement Prothesis	An artificial cervical disc intended to maintain intervertebral mobility by replacing the affected cervical disc with this device after removing factors causing compression, such as herniated nucleus pulposus or osteophytes. The results from a foreign, multi-center, prospective, non-inferiority, controlled study verifying the non-inferiority to the conventional therapy (Anterior Cervical Discectomy and Fusion [ACDF]) in patients who require surgery for cervical degenerative disc disease were submitted to evaluate the efficacy and safety of this device.
Orthopedic and Plastic Surgery	Dec. 15, 2017 Total review time: 434 days Regulatory review time: 149 days	Sep. 15, 2010 Foreign clinical study results	CoolSculpting Control Unit (JMEC Co., Ltd.)	Approval	Instrument & apparatus 12 Instrument and device for cooling therapy	A device intended to partially reduce the fat layer thickness by cooling of the subcutaneous fat without surgical invasion for cosmetic reasons. This device is used with dedicated applicators and consumables such as liners and gel pads. The dedicated applicators include vacuum applicators that vacuum the skin and subcutaneous fat while cooling them, and a non-vacuum applicator. The results of foreign clinical studies were submitted to evaluate the efficacy of the product for fat thickness reduction and the risks of complications.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 3, 2017 Total review time: 486 days Regulatory review time: 206 days	Oct. 9, 2014 Foreign clinical study results; Japanese clinical study results	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery (excluding those within a stent). The balloon surface of this product is coated with a drug composed of paclitaxel and excipients, polysorbate and sorbitol. The results from a foreign pivotal study conducted to evaluate the performance of the product and those from a Japanese study conducted to investigate whether the pivotal data can be extrapolated to Japanese population were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 6, 2017 Total review time: 342 days Regulatory review time: 199 days	Dec. 30, 2014 Foreign clinical study results; Japanese clinical study results	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or non-stented restenotic lesions in the superficial femoral or popliteal arteries. The balloon surface of this product is coated with paclitaxel as drug. The results from a foreign pivotal study conducted to evaluate the performance of the product and those from a Japanese study conducted to investigate whether the pivotal data can be extrapolated to Japanese population were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 29, 2017 Total review time: 1127 days Regulatory review time: 667 days	Oct. 7, 2008 Foreign clinical study results	NeuroStar TMS Therapy System (Neuronetics,Inc.)	Approval	Instrument & apparatus 12 Repetitive transcranial magnetic stimulator	A therapy system utilizing Repetitive Transcranial Magnetic Stimulation for the treatment of adult patients with Major Depressive Disorder (MDD) who have not benefitted from conventional antidepressant medication. The results from foreign clinical studies were submitted to evaluate the efficacy and safety of this product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 10, 2017 Total review time: 1117 days Regulatory review time: 410 days	Jun. 17, 2008 Foreign clinical study results	NeuRx Diaphragm Pacing System (DPS) (USCI Japan Ltd.)	Approval	Instrument & apparatus 12 Phrenic nerve stimulator	A diaphragm pacer that supports respiratory movement of the diaphragm by electrical stimulation to the phrenic nerve through motor points on the diaphragm in patients with respiratory failure due to diaphragmatic dysfunction of central nervous or neurogenic origin. The device is used for respiratory support in patients with ventilator-dependent spinal cord (cervical) injury or central hypoventilation syndrome. The results of a foreign clinical study for evaluation of the efficacy and safety of the device were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 8, 2017 Total review time: 91 days Regulatory review time: 85 days	Nov. 14, 2016 No clinical study results	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery (excluding those within a stent). The balloon surface of this product is covered with a drug coating primarily consisting of paclitaxel. The application was submitted for an extension of expiration period from the previously approved 24 months to 36 months. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Total review time: 359 days Regulatory review time: 286 days	No clinical study results	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)		Focused ultrasound system	The device is a focused ultrasound surgery system intended for focally heating and ablating targeted brain tissues by irradiating focused ultrasound to the target in the thalamus from outside the skull. By connecting to an MR device, the device can be used to alleviate essential tremor which does not respond sufficiently to drug therapies. The application was submitted for changes including an addition of an aberration correction method in patients in whom the existing aberration correction method is inadequate, addition of a treatment mode for radiation output control based on cavitation that is detected during therapy. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 31, 2017 Total review time: 154 days Regulatory review time: 102 days	Aug. 5, 2015 Foreign clinical study results	Hot AXIOS System (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Prosthesis for pancreatic fistulation	A system intended to form a fistula in the wall of the gastrointestinal tract and cyst through the gastrointestinal tract with endoscopic ultrasound for treatment of the cyst with accumulation of exudate and necrotic material in a pancreatic pseudocyst or walled-off necrosis associated with acute pancreatitis including acute exacerbation of chronic pancreatitis. The system consists of a prosthesis for pancreatic fistulation and a delivery system. The results of a foreign clinical study for investigation of the efficacy and safety of the device in patients in whom endoscopic drainage is indicated were submitted.
Ophthalmology and Otorhinolaryngology	Dec. 15, 2017 Total review time: 168 days Regulatory review time: 127 days	— Japanese clinical study results	TITANBRIDGE (Nobelpharma Co., Ltd.)	Approval	Medical products 4 Fixture for thyroid cartilage	A hinge-type titanium bridge made of titanium is used to fix the thyroid cartilage with the incision gap made during type II thyroplasty to improve symptoms of adductor spasmodic dysphonia. While there has been no relatively less invasive and permanent treatment for adductor spasmodic dysphonia, the product realized the treatment based on a novel principle and its development for early commercialization was anticipated in Japan ahead of the rest of the world. Therefore, the product has been designated as an item to be reviewed under the sakigake designation fast-track review system. The results of an investigator-initiated clinical study conducted in Japan were submitted to evaluate the safety and clinical efficacy of the product. [SAKIGAKE designation, Orphan device]
Cardiopulmonary Circulation	Jun. 20, 2017 Total review time: 356 days Regulatory review time: 135 days	Aug. 12, 2016 Foreign clinical study results	EDWARDS INTUITY Elite Valve System (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 7 Bovine pericardial valve	This device is a system to surgically deliver a biological valve to the aortic valve position, and has a structure added with cloth-covered frame for fixation to the company’s approved product “Carpentier-Edwards Bovine Pericardial Biological Valve Magna EASE ThermaFix Process” (Approval No. 22300BZX00320000) to enable the valve to be transplanted with fewer sutures than existing valves for conventional aortic valve replacement (AVR). The results of a clinical study conducted in the United States were submitted to evaluate the efficacy and safety of the device in patients with aortic stenosis or aortic stenosis with insufficiency, both requiring AVR.
Cardiopulmonary Circulation	Total review time: 357 days Regulatory review time: 144 days	Foreign clinical study results	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)		Cardiovascular ablation catheter	An ablation system utilizing laser for performing percutaneous transluminal myocardial ablation to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The system consists of a balloon catheter, console, endoscope fiber, solution to expand balloon catheter and accessories. The results from a US clinical study conducted to verify the efficacy and safety of this product in patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation and compared with the safety and efficacy of a radiofrequency ablation catheter were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 22, 2017 Total review time: 116 days Regulatory review time: 93 days	Sep. 28, 2012 No clinical study results	S-ICD Lead (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A subcutaneous implantable cardioverter-defibrillator (S-ICD) lead used in patients at a high risk of sudden cardiac death caused by ventricular tachyarrhythmias. This application was submitted to add in-house model in order to optimize its design and manufactureing. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Aug. 31, 2017 Total review time: 114 days Regulatory review time: 92 days	Jun. 22, 2015 No clinical study results	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets, and who are unable to undergo surgery. The application was submitted to add raw materials for the capsule, shaft and in-line sheath of the delivery catheter system. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Sep. 7, 2017 Total review time: 106 days Regulatory review time: 100 days	- No clinical study results	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing a high-frequency current to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to modify the specifications for the performance and safety, in association with the change of the upper limit of the preset temperature for “SATAKE HotBalloon Generator” (Approval No. 22700BZX00356000), add a stirring tube different in length , and confirm the conformance to the latest specifications for leakage current. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Oct. 27, 2017 Total review time: 231 days Regulatory review time: 183 days	— No clinical study results	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted to correct discrepancies in descriptions of the shape, structure, and principles, raw materials, and specifications for performance and safety in the approval document. (A "partial change" application submitted during the reexamination period)
Cardiopulmonary Circulation	Oct. 31, 2017 Total review time: 368 days Regulatory review time: 222 days	May 10, 2016 Foreign and Japanese clinical study results	MitraClip NT System (Abbot Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	The system is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The results of a foreign clinical study comparing the percuntaneous reduction by this system with surgery in operable patients, and Japanese and foreign clinical studies in patients with severe MR who have been determined to be at high risk for mitral valve surgery were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Nov. 8, 2017 Total review time: 167 days Regulatory review time: 104 days	Jul. 8, 2016 No clinical study results	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add activation of the remote monitoring function and adjust the descriptions on details of approved items. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Nov. 28, 2017 Total review time: 298 days Regulatory review time: 118 days	— No clinical study results	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system used to improve circulation until heart transplant in patients who are considered difficult to survive without heart transplant. The application was submitted to add another type of the device with a blood pump that has been downsized and made lighter in weight and a driveline with reduced diameter, and to adjust the descriptions in the approval document. (A "partial change" application submitted during the reexamination period)
Cardiopulmonary Circulation	Dec. 7, 2017 Total review time: 252 days Regulatory review time: 100 days	— No clinical study results	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist system is a device which is intended to support the blood circulation in end-stage heart failure patients who cannot survive without receiving heart transplantation. This application was submitted to add a self management kit of cool seal fluid which enables patients to refill the reservoir with cool seal fluid at home by themselves. (A "partial change" application submitted during the reexamination period)
Cardiopulmonary Circulation	Dec. 15, 2017 Total review time: 228 days Regulatory review time: 179 days	— No clinical study results	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted to add double portable batteries to the methods of battery usage at night. (A "partial change" application submitted during the reexamination period)
Cardiopulmonary Circulation	Feb. 5, 2018 Total review time: 129 days Regulatory review time: 36 days	Jun. 22, 2015 No clinical study results	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets, and who are unable to undergo surgery. The application was submitted to add raw materials for the flush tube of the delivery catheter system. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Mar. 9, 2018 Total review time: 343 days Regulatory review time: 151 days	Jun. 22, 2015 Foreign clinical study results	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets, and who are unable to undergo surgery. The application was submitted to add a new indication, valve implantation in an implanted surgical bioprosthetic aortic valve with failure (stenosis, insufficiency, or combined). The results of a foreign clinical study in patients with failure of an implanted surgical valve and who are unable to undergo surgery, were submitted. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 22, 2018 Total review time: 146 days Regulatory review time: 76 days	May 30, 2008 No clinical study results	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51 Implantable pump catheter for ventricular support	The catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery and placed in the left ventricle. This device pulls blood directly from the left ventricle and expels the blood from the catheter into the ascending aorta. The application was submitted to add raw materials for the motor housing part, and to change the specification of the maximum discharge performance. (A "partial change" application submitted during the post-market performance review period)

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Products Approved in FY 2017: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Nov. 16, 2017 Total review time: 324 days Regulatory review time: 179 days	— Japanese clinical study results	Hemodynamic Monitor HDM-3000 (Nihon Kohden Corporation)	Approval	Instrument & apparatus 21 Multi-item patient monitor	A multi-item monitor intended to display patient's vital signs (e.g. electrocardiogram, blood pressure, and oxygen saturation) on a screen, generate alarms, and provide continuous cardiac output estimated by a non-invasive parameter, pulse wave transit time under conditions of relatively stable hemodynamics. It is a device that is based on "Bedside Monitor: BSM-3000 Series, Life Scope VS," the previous generation device (Certification No. 22300BZX00245000), and has the added feature that it can calculate and display estimated continuous cardiac output (esCCO). esCCO is calculated by continuous pulse waves obtained by electrocardiography and pulse oximetry measurement, and calibrated by blood pressure and cardiac output known or calculated based on patient data such as body weight. The results of a clinical comparative study of the approved product, "Vigileo Monitor" (Approval No. 21700BZY00328000), as the control were submitted as materials to evaluate the clinical safety and efficacy of the function of calculating esCCO.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 4, 2017 Total review time: 187 days Regulatory review time: 18 days	Apr. 13, 2017 Clinical evaluation report	Philips IntelliSite Pathology Solution (Philips Japan, Ltd.)	Approval	Instrument & apparatus 21 Diagnostic auxiliary equipment for whole-slide imaging in pathology	A system for preparation and storage of whole-slide images in pathology and assisting pathological diagnosis, consisting of a scanner for image reading and an image management system. In addition, remote pathological diagnosis is feasible by connecting to an external network. A clinical assessment report summarizing the results of foreign clinical studies was submitted to confirm the equivalenece between the diagnositic result using this product and existing light microscope.
Robotic, ICT, and other devices (not classified as other categories)	Feb. 19, 2018 Total review time: 265 days Regulatory review time: 148 days	Sep. 28, 2016 Foreign clinical study results	Medtronic MiniMed 600 Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 74 Portable insulin infusion pump	An insulin infusion pump for display and storage of data on glucose levels in interstitial fluids and continuous subcutaneous insulin infusion. The application was submitted to add the feature of being able to temporarily stop insulin infusion ("Suspend on low" and "Suspend before low") if the glucose level in the interstitial fluid has decreased or is anticipated to decrease below a pre-specified value. The results of a foreign clinical study showing the efficacy and safety of the features by comparing the area under the blood glucose level curve at the onset of nocturnal hypoglycemia in the presence and the absence of the features, were submitted. The results of a clinical single-arm study performed outside Japan to confirm the safety of the "Suspend before low" feature, were also submitted.
Orthopedic and Plastic Surgery	May 30, 2017 Total review time: 967 days Regulatory review time: 203 days	— Japanese clinical study results	4-U CLS Hip Prosthesis (Teijin Nakashima Medical Co., Ltd.)	Approval	Medical products 4 Total hip prosthesis	An acetabular cup and a sleeve to be used exclusively with femoral stem of hip prosthesis to replace or reconstruct the hip joint. Both components can be fixed without bone cement and are manufactured by Electron-beam additive manufacturing using Ti-15Zr-4Nb-4Ta alloy powder. The results of a Japanese clinical study were submitted to evaluate the efficacy of the new surface treatment using GRAPE Technology, which gives bone conductivity to this device.
Orthopedic and Plastic Surgery	Jun. 27, 2017 Total review time: 256 days Regulatory review time: 176 days	Sep. 17, 2010 Japanese clinical study results	V.A.C. Ulta Wound Therapy System (KCI KK)	Approval	Medical products 4 Negative pressure wound therapy system	V.A.C. Ulta Therapy System is a negative pressure wound therapy (NPWT) system with wound cleaning function to be used for patients with refractory wounds which have not responded to and/or are considered unlikely to respond to the conventional NPWT. This device can also be used for wounds with local infection using its function to instill wound-cleansing solutions automatically and periodically to optimize the wound surface environment and clean wounds. Furthermore, it can also be used as a local NPWT without using the function of periodic and automatic instillation. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety in patients with refractory wounds associated with contamination or local infection.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Aug. 21, 2017 Total review time: 263 days Regulatory review time: 110 days	Jan. 23, 2009 Japanese clinical study results	BC Corkscrew FT Anchor (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament fixation made of poly-L-lactic acid/β-tricalcium phosphate composite used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. There have been no Japanese approvals of medical devices using the raw material. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using this device and “BC SwiveLock Screw” for which an application was made simultaneously, were submitted as clinical study data.
Orthopedic and Plastic Surgery	Aug. 22, 2017 Total review time: 264 days Regulatory review time: 125 days	Jan. 7, 2011 Japanese clinical study results	BC SwiveLock Screw (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament fixation used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. As a raw material for the absorbable screw, poly-L-lactic acid/β-tricalcium phosphate composite is adopted. Until now, there have been no approvals of products for which β-tricalcium phosphate is added to poly-L-lactic acid. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using this device and “BC Corkscrew FT Anchor” for which an application was made simultaneously, were submitted as clinical study data.
Orthopedic and Plastic Surgery	Aug. 31, 2017 Total review time: 125 days Regulatory review time: 91 days	Sep. 15, 2011 Japanese clinical study results	BC SwiveLock Tenodesis Screw (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament anchor made of poly-L-lactic acid/β-tricalcium phosphate composite used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. There have been no Japanese approvals of medical devices using the raw material. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using the company’s similar devices “BC SwiveLock Screw” and “BC Corkscrew FT Anchor” which use the raw material, were submitted as clinical study data.
Orthopedic and Plastic Surgery	Oct. 16, 2017 Total review time: 108 days Regulatory review time: 79 days	Aug. 5, 2005 Clinical evaluation report	Compress System (Zimmer Biomet G.K.)	Approval	Medical products 4 Artificial material for lower limb reconstruction	An artificial material for lower limb reconstruction intended to reconstruct lower limb function with prosthesis of the defective part of the bone, in patients who had undergone extensive bone resection, due to conditions such as malignant tumor. The structure of the system provides compressive stress on the bone-implant interface, and reduces stress shielding which is caused by the placement of implant. The device does not include a stem, and is therefore available for use in patients where necessary length of the stem for bone implant cannot be ascertained. A clinical assessment report including the results of a clinical study with follow-up in the U.S., and reports from foreign clinical literature, were submitted to demonstrate similar efficacy and safety of the product to existing artificial joints for cancer patients.
Orthopedic and Plastic Surgery	Dec. 7, 2017 Total review time: 90 days Regulatory review time: 55 days	Mar. 2, 2015 Clinical evaluation report	Mpact DM Acetabular Component (Medacta Japan Co., Ltd.)	Approval	Medical products 4 Artificial hip joint, acetabular component	The acetabular component for an artificial hip intended to replace or restore the acetabulum during hip replacement (including reimplantation), consisting of a stainless steel cup and liner made of ultra-high molecular weight polyethylene. The contact surface of the cup and acetabular roof is treated with pure titanium flame spray, and the liner is treated with crosslinking. Since the device is the first double mobility system of this company with sliding surfaces both on the in- and outside of the liner, a clinical assessment report based on a foreign clinical study of the device and foreign clinical literature on the previous generation of the product, demonstrating equivalence to this device, were submitted to confirm that the product has similar efficacy and safety to a conventional artificial hip.

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Orthopedic and Plastic Surgery	Total review time: 364 days Regulatory review time: 75 days	Clinical evaluation report	CO2RE Carbon Dioxide Laser with Fractional Mode (Syneron Candela K.K.)		Carbon dioxide laser	A carbon dioxide laser intended for ablation of soft tissue for skin resurfacing. The device has a computer-controlled scanner by which uniform ablation is feasible based on the pattern that is selected by the physician in advance. It also has a mode of fine fractional laser irradiation. Improved points include improved safety compared to the conventional laser scalpel by smaller spots ablation instead of larger area ablation on the skin, to expand its applications to various purposes including cosmetic improvement. The product is equipped with a mode that allows its use for other purposes as a laser scalpel, similarly to conventional carbon dioxide lasers. A clinical assessment report, consisting of the results of a foreign clinical study of the device and clinical papers of similar products was submitted to evaluate that the performance of the product on skin resurfacing as well as complications due to the product are acceptable for a medical device for cosmetic use.
Orthopedic and Plastic Surgery	Feb. 2, 2018 Total review time: 310 days Regulatory review time: 114 days	May 17, 2009 Foreign clinical study results	Prontosan (B. Braun Medical AG)	Approval	Medical products 4 Antibacterial wound dressing	Antibacterial gel dressing for wounds reaching the subcutaneous adipose tissue (excluding third-degree burns) to "protect wounds," "moisten wound bed," "accelerate healing," and "alleviate pain." Ingredients of the product include polyhexanide, which has been used as a disinfectant in clinical practice, in expectation of the effect of preventing bacterial infection and diffusion in the wounds. The results of a foreign clinical study were submitted to confirm the efficacy and safety of the product as a wound dressing consisting of new raw materials, and the absence of delayed healing due to the polyhexanide content.
Orthopedic and Plastic Surgery	Feb. 28, 2018 Total review time: 258 days Regulatory review time: 178 days	Aug. 24, 2012 Clinical evaluation report	Trabecular Metal Ankle System (Zimmer Biomet G.K.)	Approval	Medical products 4 Total ankle prosthesis	A hinge-type titanium bridge made of titanium is used to fix the thyroid cartilage with the incision gap made during type II thyroplasty to improve symptoms of adductor spasmodic dysphonia. While there has been no relatively less invasive and permanent treatment for adductor spasmodic dysphonia, the product realized the treatment based on a novel principle and its development for early commercialization was anticipated in Japan ahead of the rest of the world. Therefore, the product has been designated as an item to be reviewed under the sakigake designation fast-track review system. The results of an investigator-initiated clinical study conducted in Japan were submitted to evaluate the safety and clinical efficacy of the product. [SAKIGAKE designation, Orphan device]
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 26, 2017 Total review time: 270 days Regulatory review time: 181 days	Jul. 9, 2015 Foreign clinical study results	SCS External Stimulation Device (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Stimulation device for pain relief	A stimulation device used in Spinal Cord Stimulation which allows physicians to locate stimulus and patients to subjectively evaluate the therapeutic effect. The application was submitted to establish a new stimulation mode (A "partial change" application). The results of a foreign clinical study using a similar product, “Prodigy MRI Dual 8 Neurostimulator” designed to demonstrate the non-inferiority to the existing stimulation mode were submitted to evaluate the efficacy and safety of the new stimulation mode which is not included in the existing system.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Total review time: 209 days Regulatory review time: 108 days	Foreign clinical study results	Proclaim Elite MRI Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)		Implantable stimulator for pain relief	An implantable stimulator for pain relief used in patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. The patients implanted with the device can conditionally undergo an MRI scan. The application was submitted to add a stimulation mode, namely “Surgical mode,” which is provided as one of safety measures when the patient has to have whole-body MRI with electrosurgical units (A "partial change" application). The results of a foreign clinical study using a similar product, “Prodigy MRI Dual 8 Neurostimulator” designed to demonstrate the non-inferiority to the existing stimulation mode were submitted to evaluate the efficacy and safety of the new stimulation mode which is not included in the existing system.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 27, 2017 Total review time: 231 days Regulatory review time: 161 days	None Foreign clinical study results	Vascular Stent-1 (Covidien Japan, Inc.)	Approval	Instrument & apparatus 7 Stent for iliac artery	An iliac arterial stent system available in nominal stent sizes of 6, 7 and 8 mm diameters for maintaining vascular patency of atherosclerotic lesions in the iliac arteries. The results from foreign clinical studies were submitted to evaluate the efficacy and safety of this device.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 27, 2017 Total review time: 231 days Regulatory review time: 188 days	Jan. 21, 2015 Foreign clinical study results	Vascular Stent-2 (Covidien Japan, Inc.)	Approval	Instrument & apparatus 7 Stent for iliac artery	An iliac arterial stent system available in nominal stent sizes of 9, 10 and 12 mm diameters for maintaining vascular patency of atherosclerotic lesions in the iliac arteries. The results from foreign clinical studies were submitted to evaluate the efficacy and safety of this device.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 15, 2017 Total review time: 267 days Regulatory review time: 203 days	Jan. 27, 2017 Foreign clinical study results	GORE VIABAHN VBX Balloon Expandable Endoprosthesis (W. L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Stent graft with heparin for central circulatory system	A stent graft system which consists of a balloon expandable stent graft made of stainless steel and delivery catheter used to treat de novo or restenotic lesions found in iliac arteries. The inside and outside of the stent are fused with a PTFE film which has a heparin bonding layer. The results from a foreign clinical study using this product were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 10, 2017 Total review time: 477 days Regulatory review time: 233 days	Sep. 15, 2015 Global clinical trial	COOK Zenith Alpha Thoracic Endovascular Graft (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for endovascular treatment of thoracic aortic aneurysm, consisting of the stent graft and the delivery system. Based on the structure of the company's approved product, "COOK Zenith TX2 TAA Endovascular Graft" (Approval No. 22300BZX00147000), the raw material of the stent was changed from stainless steel to nitinol, the flexibility of the stent graft was increased by thinning the graft material, and the external diameter of the delivery catheter was reduced. The results of a global clinical trial were submitted to evaluate the efficacy and safety of the product for thoracic aortic aneurysm.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 8, 2017 Total review time: 161 days Regulatory review time: 71 days	— Clinical evaluation report	TMP Occlusion (Tokai Medical Products, Inc.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	An emboli-capturing catheter for carotid artery stenting and acute cerebral revascularization and so forth prevent distal embolization of cerebrovascular vessels, and the catheter has a balloon at its tip. A clinical assessment report prepared based on clinical literature reports of the device and similar products, was submitted to indicate the equivalence of the device to approved products.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 6, 2018 Total review time: 224 days Regulatory review time: 52 days	May 6, 2011 Clinical evaluation report	AFX Endovascular AAA System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for endovascular treatment of infrarenal abdominal aortic aneurysms. The application was submitted mainly to add a cuff extension with a large diameter and another type of delivery catheter. To complement the performance evaluation of the cuff extension of the additional size, a clinical assessment report summarizing the clinical results of the cuff extension of the applicable size was submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 9, 2018 Total review time: 266 days Regulatory review time: 60 days	Oct. 1, 2001 Clinical evaluation report	Bactiseal Shunt Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cerebrospinal catheter	A cerebrospinal catheter intended to be placed in the body as a component of a shunt system for treatment of hydrocephalus by leading excessive cerebrospinal fluid from the central nervous system to other absorptive sites in the body using a cerebrospinal fluid shunt. The device is impregnated with rifampicin and clindamycin hydrochloride to inhibit colonization of bacteria that stick to the catheter surface. It was selected as an item for early introduction at the "Japanese Ministry of Health, Labour and Welfare's Panel of experts meeting on early introduction of highly needed medical devices" on August 9, 2013. A clinical evaluation report summarizing such materials as foreign literature was submitted for safety evaluation.
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 24, 2017 Total review time: 269 days Regulatory review time: 117 days	— Japanese clinical study results	Toray Filtryzer BK (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow-fiber dialyzer used to remove fluid and uremic substances stored in the body due to uremia. This device is indicated for patients with extremely impaired renal function caused by chronic or acute kidney failure. The improved points are the addition of some materials to the raw materials of hollow fiber used for the approved product, "Filtryzer BK," (Approval No. 15900BZZ01740000) and myoglobin clearance as a specification for performance. Since equivalence of the raw materials of dialysis membranes for the device and those for the approved product was not confirmed, the results of a Japanese clinical study for safety evaluation were submitted in accordance with PFSB Notification No. 0301-5 dated on March 1, 2013.
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 24, 2017 Total review time: 269 days Regulatory review time: 117 days	— Japanese clinical study results	Toray Filtryzer BG (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow-fiber dialyzer used to remove fluid and uremic substances stored in the body due to uremia. This device is indicated for patients with extremely impaired renal function caused by chronic or acute kidney failure. The improved points are the addition of some materials to the raw materials of hollow fiber used for the approved product, "Filtryzer BG," (Approval No. 20700BZZ00293000) and myoglobin clearance as a specification for performance. Since equivalence of the raw materials of dialysis membranes for the device and those for the approved product was not confirmed, the results of a Japanese clinical study for safety evaluation were submitted in accordance with PFSB Notification No. 0301-5 dated on March 1, 2013.
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 29, 2017 Total review time: 184 days Regulatory review time: 138 days	Mar. 20, 2015 Clinical evaluation report	AirSeal Intelligent Flow System (Conmed Japan KK)	Approval	Instrument & apparatus 25 Air and water supply device for endoscopy	An air and water supply device for endoscopy intended to secure adequate space and visualization of the surgical field required for examination and surgery by insufflating CO2 gas into the peritoneal cavity, or retroperitoneal space and rectum to extend the space in the applicable area while eliminating smoke during endoscopy and surgery or transanal rectal surgery. The insufflation of CO2 gas into the retroperitoneal space or rectum to aid surgery by securing the visual field has been added to the intended use or effects, and thereby makes the product available for transanal total mesorectal excision (taTME) of all layers of rectal cancer or transanal minimally invasive surgery (TAMIS) for some procedures such as mucosal stripping from the gut lumen using a rigid endoscope. A clinical assessment report summarizing the foreign literature was submitted to evaluate the efficacy and safety of insufflation into the retroperitoneal space and rectum at the implementation of taTME or TAMIS.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Dentistry and Oral Medicine	Jul. 6, 2017 Total review time: 267 days Regulatory review time: 154 days	Sep. 13, 2011 Foreign clinical study results	Episil Oral Liquid (Solasia Pharma K.K.)	Approval	Medical products 4 Wound dressing and protecting hydrogel material for topical management	The product is used for management and relief of oral pain by covering and protecting lesions/stomatitis associated with chemotherapy and/or radiotherapy. The bioadhesive oral liquid consists of lipid components such as glycerol dioleate and soy phosphatidylcholine wituout "active medicinal (pharmacuetical) components. The liquid forms a protective bioadhesive layer by the uptake of aqueous fluid i.e saliva. The results from a foreign clinical study were submitted to evaluate the efficacy and safety of the product.
Dentistry and Oral Medicine	Dec. 14, 2017 Total review time: 212 days Regulatory review time: 125 days	— Japanese clinical study results	GC Cytrans Granules (GC Corporation)	Approval	Medical products 4 Resorbable dental bone reconstruction implant material	The device is a resorbable dental implant material for bone reconstruction consisting of granular carbonate apatite used for compensation of a bone defect of the maxilla, mandible, and alveolar bone. The results of a Japanese clinical study of the efficacy and safety of the product when concurrently used with a dental implant fixture were submitted.
Ophthalmology and Otorhinolaryngology	Jun. 28, 2017 Total review time: 184 days Regulatory review time: 102 days	- Japanese clinical study results	2week Menicon PremiO (Menicon Co., Ltd.)	Change	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored soft contact lenses for correcting visual acuity. This silicone lens is to be replaced periodically in 2-week intervals. The application was submitted to add a progressive toric lens, which is a combination of the existing progressive design and toric design (A "partial change" application). Since the progressive toric lens has a new design, a Japanese clinical study was conducted to evaluate its efficacy and safety.
Ophthalmology and Otorhinolaryngology	Jul. 24, 2017 Total review time: 270 days Regulatory review time: 165 days	Aug. 14, 2015 Foreign clinical study results	Naída CI (Nihon Kohden Corporation)	Approval	Medical products 4 Cochlear implant system	A sound processor that constitutes the cochlear implant system used in patients with bilateral severe hearing loss who have not responded sufficiently to wearing hearing aids. The basic performance of the product is equivalent to that of the approved Auria harmony sound processor for “HiRes Auria Sound Processor” (Approval No. 22000BZY00009000). A power saving method based on the approved method of audio signal processing was added to this device. The results from a clinical study conducted in the United States were submitted to evaluate the efficacy and safety of this device.
Ophthalmology and Otorhinolaryngology	Nov. 2, 2017 Total review time: 133 days Regulatory review time: 100 days	— Foreign clinical study results	Tecnis Symfony Toric VB (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye with corneal astigmatism. The shape and structure of the device are similarly designed as "Tecnis Symfony Toric", which has a diffractive multifocal mechanism and toric structure (Approval No. 22900BZX00359000), and ultraviolet and violet light-absorbing agents were added to the raw materials.
Ophthalmology and Otorhinolaryngology	Nov. 2, 2017 Total review time: 258 days Regulatory review time: 209 days	Jul. 15, 2016 Foreign clinical study results	Tecnis Symfony Toric (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye with corneal astigmatism. The posterior optical zone has the same diffractive multifocal mechanism as the company's approved product, "Tecnis Symfony" (Approval No. 22900BZX00006000). The anterior optical zone has an aspherical surface similar to the company's approved product, "Tecnis Toric One-piece" (Approval No. 22500BZX00363000). The improved point is that it has combined optical functions of the company's approved products.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Nov. 24, 2017 Total review time: 269 days Regulatory review time: 107 days	— Japanese clinical study results	Noninvasive Transtympanic Pressure Device EFET01 (Daiichi Medical Co., Ltd.)	Approval	Instrument & apparatus 12 Transtympanic pressure device	A device intended to inhibit vertiginous attacks due to Meniere's disease and delayed endolymphatic hydrops by non-invasively adding pressure to the middle ear cavity through the external auditory canal to facilitate excretion of endolymphatic fluid that has accumulated in the inner ear, consisting of an air pressure generating device, a tube with ear plugs to add pressure and a power supply. The improved point is increased reproducibility of the waveform by detailed specification of the parameters of the air pressure wave to efficiently add pressure to the middle ear space, compared to certified tympanum massagers.
Ophthalmology and Otorhinolaryngology	Nov. 27, 2017 Total review time: 262 days Regulatory review time: 199 days	— Japanese clinical study results	Clareon Aspherical Hydrophobic Acryl Intraocular Lens (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A monofocal posterior chamber lens to be inserted as a substitute for a crystalline lens in the posterior chamber to correct visual acuity of an aphakic eye. The shape of the product is a one-piece type, consisting of the same raw materials in the optic and haptic. The product is a cross-linked acrylic copolymer containing the same ultraviolet and blue light-absorbing agents as the company's approved product, "Alcon AcrySof Natural Single Piece" (21800BZY10066000). The improved point is that flexibility and maneuverability are increased by changing the composition of the major component monomers.
Ophthalmology and Otorhinolaryngology	Dec. 7, 2017 Total review time: 261 days Regulatory review time: 141 days	— Clinical evaluation report	Menicon Rose K-T (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	An oxygen-transmissible daily wear hard contact lens intended to correct visual acuity in patients with keratoconus and associated myopia and hyperopia. The improved points are that the lens blanks of products made of the same raw materials as the company's approved product, "Menicon Tinu," (21800BZZ10125000) are formed to enable patients with keratoconus to wear the lenses, and that indications are made clear in the intended use.
Ophthalmology and Otorhinolaryngology	Feb. 27, 2018 Total review time: 263 days Regulatory review time: 212 days	— Japanese clinical study results	Aktis Toric (Nidek Co., Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The product is a single-piece-type monofocal posterior chamber lens intended to be inserted into the aphakic eye of patients with corneal astigmatism after cataract surgery. The shape other than the optic is similar to the company's approved product, "Nex-Acri AA 1P" (Approval No. 22100BZX00945000). The improved points are the change of raw material compositions and the addition of cylindrical power for the correction of corneal astigmatism. The results of a Japanese clinical study were submitted to evaluate the clinical efficacy, including an astigmatism correction function, and safety of the device.
Cardiopulmonary Circulation	Jun. 9, 2017 Total review time: 221 days Regulatory review time: 107 days	Apr. 28, 2017 Foreign clinical study results	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a zotarolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm and a delivery catheter to place the stent at the site of stenosis. The deliverability was improved by reducing the thickness of the stent strut to lower crossing profile as compared to that of the previous product “Resolute Integrity Coronary Stent System (Approval No. 22400BZX00176000)”. To maintain radiopacity, platinum-iridium alloy was used for inner core of the strut. The results of clinical studies conducted in the United States were submitted to evaluate the efficacy and safety in patients with symptomatic ischemic cardiac disease.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 1, 2017 Total review time: 412 days Regulatory review time: 277 days	- Foreign clinical study results	BioFreedom Drug-Coated Stent (Biosensors Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a biolimus-coated stent and a delivery catheter for the treatment of patients with symptomatic ischemic heart disease, with de novo coronary lesions of a lesion length of 33 mm or less, and with a reference vessel diameter of 2.25-4.0 mm in size. Without the use of polymer, biolimus A9 is directly coated to the stainless steel which has a selectively micro-structured surface. The drug is absorbed in about 1 month, after which becomes a bare metal stent. This stent was developed to allow discontinuation of dual antiplatelet therapy in one month, similarly to bare metal stents. The results from Japanese and foreign clinical studies were submitted to evaluate the efficacy and safety of this device.
Cardiopulmonary Circulation	Aug. 14, 2017 Total review time: 255 days Regulatory review time: 98 days	Jul. 1, 2014 Nov. 12, 2014 Clinical evaluation report	COOK Evolution RL Controlled-Rotation Dilator Sheath Set (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Pacemaker/ defibrillator lead removal kit	A pacemaker/defibrillator lead removal kit used for transvenous lead removal of implantable pacemaker leads, implantable defibrillator leads, etc. It was developed based on the approved product “COOK Lead Extraction System” (Approval No. 22700BZX00054000). Changes were made to unidirectional or bidirectional rotation of the inner sheath by handle operation and to a stainless-steel tip on the end of the inner sheath. A clinical evaluation report summarizing foreign literatures reporting this device or the previous generation device was submitted to evaluate the efficacy and safety of this device.
Cardiopulmonary Circulation	Aug. 31, 2017 Total review time: 262 days Regulatory review time: 72 days	Jul. 31, 2017 Foreign clinical study results	Avalus Bioprosthesis (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve to be used to substitute for the function of a malfunctioning native or prosthetic aortic valve. The biological valve has a frame made of polyetheretherketone and a valve leaflet treated with alpha-amino oleic acid for anticalcification. It was developed aiming at the safety of MRI and reductions of permanent deformations and corrosion risk when assuming future valve in valve procedures are performed, by using non-metallic components. The results of clinical studies conducted in EU, US, and Canada were submitted to evaluate the efficacy and safety of this product in patients with aortic valve stenosis requiring aortic valve replacement.
Cardiopulmonary Circulation	Nov. 2, 2017 Total review time: 247 days Regulatory review time: 135 days	Oct. 25, 2016 Foreign clinical study results	Claria MRI CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. It is a higher-end model of the company's approved product, "Amplia MRI CRT-D Series" (Approval No. 22800BZX00219000). The major differing point is an additional feature whereby the device evaluates the efficacy of pacing with CRT during atrial fibrillation (AF), and adjusts the pacing rate based on the evaluation results (EffectivCRT during AF feature). The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the EffectivCRT during AF feature.
Cardiopulmonary Circulation	Jan. 19, 2018 Total review time: 374 days Regulatory review time: 157 days	— Global clinical trial	Orsiro Sirolimus Eluting Coronary Stent System (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 26 mm or less) with a reference vessel diameter of 2.25 mm to 4.0 mm and a delivery catheter to place the stent at the site of stenosis. The stent platform made of cobalt chromium is coated with hydrogenated amorphous silicon carbide that inhibits metal ion release. The drug coating layer is composed of sirolimus and bioabsorbable PLLA. The results of Japanese and foreign clinical studies were submitted to evaluate the efficacy and safety of this device.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Jan. 24, 2018	Dec. 21, 2017	BSC OI Ablation Catheter (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51	A catheter designed to be inserted percutaneously into the heart through a blood vessel to deliver radiofrequency energy to the electrophysiologically identified target site of arrhythmia to treat drug-refractory recurrent symptomatic paroxysmal atrial fibrillation as well as sustained or recurrent type I atrial flutter. The device is intended for the treatment of arrhythmia by an increase in tissue temperature due to the delivery of radiofrequency energy, leading to ablation in the myocardial tissue. The application was submitted to expand the indication to drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. The results of a foreign clinical study that evaluated the efficacy and safety of the device on drug-refractory recurrent symptomatic paroxysmal atrial fibrillation were submitted.
	Total review time: 239 days Regulatory review time: 140 days	Foreign clinical study results			Cardiovascular ablation catheter	

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Products Approved in FY 2016: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Oct. 25, 2016 Total review time: 848 days Regulatory review time: 298 days	- Domestic clinical study results and global clinical study results	1	Neuraceq Automated Synthesizer Synthera (SCETI K.K.)	Approval	Instrument & apparatus 10 Radiopharmaceutical synthesizer	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound, florbetaben (^{18}F) injection, by remote control system indicated for the visualization of beta-amyloid plaques in the brain of patients with cognitive impairment suspected to be Alzheimer's disease. Results from non-clinical and global clinical studies were submitted as evaluation data on the efficacy and safety of this product and florbetaben (^{18}F) injection.
Orthopedic and Plastic Surgery	Jun. 29, 2016 Total review time: 43 days Regulatory review time: 28 days	Dec. 19, 2005 No clinical study results	2	Trabecular Metal Reverse Shoulder System (Zimmer Biomet G.K.)	Change	Medical products 4 Total shoulder prosthesis	A reverse shoulder prosthesis used in cases of rotator cuff dysfunction such as rotator cuff tear arthropathy or massive rotator cuff tear. The application was submitted to add the use of the product in combination with the approved product, "Comprehensive Reverse Shoulder System" (Approval No. 22700BZX00232000). (A ”partial change” application submitted during the reexamination period)
Orthopedic and Plastic Surgery	Oct. 25, 2016 Total review time: 512 days Regulatory review time: 219 days	- Domestic clinical study results	3	DARTS Wrist Prosthesis (Teijin Nakashima Medical Co., Ltd.)	Approval	Medical products 4 Total wrist prosthesis	A total wrist prosthesis that functions as a substitute of a natural wrist, by replacing a severely destroyed and impaired wrist due to underlying diseases such as rheumatoid arthritis, etc. The improvement of joint function and elimination of pain can be expected by replacing the dysfunctional wrist with the device. The device is designed as a semi-constrained surface replacement type, in order to closely mimic the natural joint surface shapes, forming a structure that induces dart thrower's motion, which is more natural physiological motion of the wrist. Results from an investigator-initiated clinical study conducted in Japan were submitted to evaluate the efficacy and safety of the device.
Orthopedic and Plastic Surgery	Dec. 15, 2016 Total review time: 359 days Regulatory review time: 213 days	Dec. 26, 2013 Clinical evaluation report	4	Long-Pulsed Alexandrite Laser GentleLase Pro (Syneron Candela K.K.,)	Approval	Instrument & apparatus 31 Alexandrite laser	The device is intended to achieve long-term hair reduction by selective photothermolysis. The device is equipped with a dynamic cooling device, which sprays cryogen to prevent skin damage caused by laser irradiation. A clinical evaluation report, which summarized the results from foreign clinical studies for the previous-generation products, was submitted to evaluate the long-term efficacy of hair reduction and the risk of complications after laser treatment.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 11, 2016 Total review time: 57 days Regulatory review time: 24 days	- No clinical study results	5	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of cross-linked polyvinyl alcohol polymer. This product is used for vascular embolization in patients with hypervascular tumors or arteriovenous malformations. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 9, 2016 Total review time: 105 days Regulatory review time: 55 days	- No clinical study results	6	Revive SE Thrombectomy device (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system to restore blood flow by removing clots from blood vessels in the brain in patients with acute-phase cerebral infarction (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 14, 2016 Total review time: 114 days Regulatory review time: 66 days	ICY Catheter: Oct. 23, 2003 Quattro Catheter: Feb. 15, 2007 No clinical study results	7	Quattro・ICY IVTM Catheter (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A central venous catheter with a balloon for heat exchange used for body temperature management (temperature management therapy) in patients under cardiac arrest or after return of (spontaneous) circulation. The catheter is designed to be connected to the console of the approved "Thermogard System" (Approval No. 22400BZI00010000). The application was submitted for the changes in the shape and material of the luer part for connecting the catheter and start-up kit, as well as the changes in the values for specification of flow rate which are related to the performance and safety of the heat-exchange catheter. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 15, 2016 Total review time: 118 days Regulatory review time: 67 days	Jun. 12, 2015 No clinical study results	8	Trevo Pro Clot Retriever (Stryker Japan K.K.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system intended to restore blood flow by removing thrombus for patients with acute-phase cerebral infarction (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application was submitted for an additional size variation in the length of the stent. (A ”partial change” application submitted during the reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 15, 2016 Total review time: 359 days Regulatory review time: 283 days	Oct. 5, 2015 Foreign clinical study results	9	NovoTTF-100A System (NovoCure Ltd.)	Change	Instrument & apparatus 12 Alternating electric field tumor treatment system	This non-invasive medical device delivers alternating electric fields referred to as Tumor Treating Fields (TTField) - that disrupt cancer cell division - through insulated transducer arrays (INE transducer array) placed on the scalp. The application was submitted to change the indication so that the device can be used regardless of the status of glioblastoma (indicated for both newly-diagnosed and recurrent glioblastoma). Data from a clinical study conducted to demonstrate the efficacy and safety of the device in patients with newly-diagnosed glioblastoma after receiving all possible surgeries and radiation therapies were submitted. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 15, 2016 Total review time: 364 days Regulatory review time: 266 days	Jul. 11, 2016 Foreign clinical study results	10	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)	Approval	Instrument & apparatus 12 Focused Ultrasound System	The device is a focused ultrasound surgery system intended for focally heating and ablating targeted brain tissues by irradiating focused ultrasound to the target in the thalamus from outside the skull. By connecting to an MR device, the device can be used to alleviate essential tremor which does not respond sufficiently to drug therapies. The cell necrosis is induced at the heated temperature of target region by focusing the ultrasound beam emitted from the transducer helmet on the central intermediate nucleus of the thalamus. Results from foreign clinical studies were submitted to evaluate the efficacy and safety of the device in patients with essential tremor who were refractory to drug therapies.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 15, 2017 Total review time: 257 days Regulatory review time: 232 days	Jul. 13, 2016 No clinical study results	11	NovoTTF-100A System (NovoCure Ltd.)	Change	Instrument & apparatus 12 Alternating electric field tumor treatment system	A non-invasive medical device delivers alternating electric fields referred to as Tumor Treating Fields (TT Field) - that disrupt cancer cell division - through insulated transducer arrays (INE transducer array) placed on the scalp. The application was submitted for an additional product type with a downsized TT Field generator. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 31, 2017 Total review time: 102 days Regulatory review time: 51 days	- No clinical study results	12	Bronchial Spigot EWS (Harada Corporation)	Change	Instrument & apparatus 7 Bronchial blocker	A silicone resin bronchial spigot that is used to fill the bronchi and close fistula in patients who have refractory and inoperable secondary pneumothorax, prolonged air leak following pneumectomy or other fistula. The application was submitted to change the raw materials and manufacturing method of the bronchial spigot. (A "partial change" application submitted during the reexamination period) [Orphan device]

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Gastroenterology, Genitourinary and Reproductive Medicine	Sep. 16, 2016 Total review time: 322 days Regulatory review time: 241 days	Jun. 30, 2006 Clinical evaluation report	13	InterStim II Neurostimulator for Sacral Neuromodulation (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Implantable stimulator for bladder and bowel control	An implantable nerve stimulation system to be used in sacral nerve stimulation therapy for fecal incontinence and overactive bladder. The application was submitted for an additional indication of overactive bladder (A "partial change" application). A clinical evaluation report summarizing data from foreign clinical studies was submitted to demonstrate that treatment using the device improves the symptom of overactive bladder as compared to conservative treatment. (A "partial change" application submitted during the reexamination period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Mar. 27, 2017 Total review time: 136 days Regulatory review time: 89 days	- No clinical study results	14	PD Laser (Meiji Seika Pharma Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A photodynamic therapy (PDT) semiconductor laser to be used in combination with an oncotropic photo-sensitizer, "Laserphyrin 100 mg for Injection (R)" (Approval No. 21500AMZ00509000; generic name, talaporfin sodium), for the treatment of early lung cancer that can be treated with laser irradiation, or recurrent esophageal cancer associated with local persistence after chemotherapy or radiotherapy. The application was submitted for the changes to comply with the amendments of JIS specifications on electric safety and electromagnetic compatibility of medical devices, design changes, and addition of components. (A "partial change" application submitted during the post-market performance review period)
Ophthalmology and Otorhinolaryngology	Mar. 14, 2017 Total review time: 104 days Regulatory review time: 35 days	Sep. 30, 2016 No clinical study results	15	iStent Trabecular Micro-Bypass Stent System (Glaukos Corporation)	Change	Medical products 4 Heparin using intraocular drain	A device consisting of the iStent, a titanium-alloy glaucoma implant designed to maintain a patent outflow of aqueous humor through the trabecular meshwork facilitating its drainage from anterior chamber to the Schlemm's canal and its subsequent natural outflow. This device accompanies its inserter. The surface of the iStent is coated with porcine-derived heparin. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Sep. 27, 2016 Total review time: 2007 days Regulatory review time: 641 days	May 30, 2008 Foreign clinical study results	16	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Approval	Instrument & apparatus 51 Implantable Pump Catheter for Ventricular Support	The catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery and placed in the left ventricle. This device pulls blood directly from the left ventricle and expels the blood from the catheter into the ascending aorta. The catheter pump, (two models are available: Impella 2.5 and Impella 5.0), is a catheter based blood pump equipped with a small axial flow pump. The blood is unloaded from an inlet placed in the left ventricle and pumped to an outlet placed in the aorta by the pump-unit of the catheter pump. The device is used with "Impella Controller" (Approval No. 22800BZI00031000). Data from a foreign clinical studies, which demonstrated that using the device is beneficial in patients with cardiogenic shock or other acute heart failure, were submitted.
Cardiopulmonary Circulation	Sep. 27, 2016 Total review time: 2007 days Regulatory review time: 628 days	Jul. 8, 2010 Foreign clinical study results	17	Impella Controller (Abiomed, Inc.)	Approval	Instrument & apparatus 7 Controller of Implantable Pump Catheter for Ventricular Support	The device is an extermal controller for "Impella Circulatry Assist Pump Catheter" (Approval No. 22800BZI00032000) (hereinafter referred to the Catheter Pump). The device controls the performance and monitors the catheter position of the Catheter Pump, and controls the flow rate of the purge cassette, which is a component of the Catheter Pump. Data from foreign clinical studies, which demonstrated that this device is capable of controlling the Catheter Pump when used for circulatory support in patients with cardiogenic shock or other acute heart failure, were submitted.
Cardiopulmonary Circulation	Oct. 25, 2016 Total review time: 186 days Regulatory review time: 123 days	Aug. 8, 2016 No clinical study results	18	S-ICD Pulse Generator (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is a subcutaneous implantable cardioverter-defibrillator (S-ICD) used in patients at high risk of sudden cardiac death caused by ventricular tachyarrhythmias. The application was submitted to add the functions of SMART Pass and AF Monitor, respectively, and to allow patients with the device to undergo MRI scans under predefined conditions. (A "partial change" application submitted during the post-market performance review period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Oct. 25, 2016 Total review time: 186 days Regulatory review time: 123 days	Aug. 8, 2016 No clinical study results	19	S-ICD Lead (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Implantable defibrillator /pacemaker lead	The device is a subcutaneous implantable cardioverter-defibrillator (S-ICD) lead used in patients at a high risk of sudden cardiac death caused by ventricular tachyarrhythmias. The application was submitted to allow patients with the device to undergo MRI scans under predefined conditions. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Nov. 2, 2016 Total review time: 552 days Regulatory review time: 250 days	Jul. 5, 2016 Domestic clinical study results Foreign clinical study results	20	Absorb GT1 Bioresorbable Vascular Scaffold System (Abbot Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Absorbable coronary stent	A stent system consisting of an everolimus-eluting bioresorbable scaffold used for the treatment of patients with symptomatic ischemic heart disease due to de novo native coronary artery lesions (length ≤24 mm) with a reference vessel diameter ranged from ≥2.5 mm to ≤3.75 mm, and a delivery catheter to place the stent at the site of stenosis. Results of domestic and foreign clinical studies using the previous generation model of the device were attached to show that the efficacy and safety of the device are equivalent to those of the previously approved coronary stent.
Cardiopulmonary Circulation	Nov. 8, 2016 Total review time: 288 days Regulatory review time: 161 days	Jun. 22, 2015 Foreign and domestic clinical study results	21	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with symptomatic severe aortic valve stenosis attributed to sclerosis and degeneration of the cusp of the native valve, for whom surgery cannot be performed. This device has been improved in the diameter of outflow area and the length, etc. from those of the previously approved "CoreValve" (Approval No. 22700BZX00100000), for the purpose of reducing deformation caused by interference with the ascending aorta. In addition, the device includes a 23-mm-diameter size variation, which is not available in "CoreValve" system. Furthermore, the delivery system also has been improved to enhance the safety and allow the valve to be recaptured, repositioned, or retrieved, etc. Results of domestic clinical study were submitted to evaluate the efficacy and safety of the 23-mm-diameter product in Japanese patients, in addition to the results of foreign clinical studies in patients with symptomatic severe aortic valve stenosis whose risks for surgical aortic valve replacement were estimated as "High risk" or "Extreme risk."
Cardiopulmonary Circulation	Nov. 14, 2016 Total review time: 634 days Regulatory review time: 523 days	Nov. 26, 2014 Foreign clinical study results	22	HeartFlow FFR_{CT} (HeartFlow Japan G.K.)	Approval	Program 1 Circulatory dynamics analysis program	A diagnosis support program that calculates the fractional flow reserve (FFRCT) by computational fluid dynamics analysis based on the data of coronary computed-tomography angiography in clinically stable patients suspected of having coronary artery diseases. Results from foreign clinical studies were submitted to evaluate the diagnostic performance pertaining to sensitivity and specificity of FFRCT values against FFR values measured with a pressure wire.
Cardiopulmonary Circulation	Feb. 14, 2017 Total review time: 365 days Regulatory review time: 88 days	Apr. 6, 2016 Global clinical trial	23	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	A single-chamber transcatheter implantable cardiac pacemaker designed to periodically deliver artificial electrical impulses to the heart of the patients with bradycardia. Results from global clinical trial including Japan were submitted to evaluate the efficacy and safety of the device in the treatment of bradyarrhythmia.
Cardiopulmonary Circulation	Feb. 17, 2017 Total review time: 241 days Regulatory review time: 97 days	- No clinical study results	24	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for patients with severe cardiac failure who are qualified to receive heart transplant presenting continuous decompensation in spite of drug therapy or circulation assist techniques such as an external ventricular assist system and considered difficult to survive without heart transplant. This application was submitted to correct errors in the product information of the approved device. (A "partial change" application submitted during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Specified partial change	Apr. 5, 2016 Total review time: 55 days Regulatory review time: 21 days	- No clinical study results	25	PD Laser (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A photodynamic therapy (PDT) semiconductor laser to be used in combination with "Laserphyrin 100 mg for Injection" (approval No. 21500AMZ00509000; generic name, talaporfin sodium), an oncotropic photo-sensitizer, for the treatment of early lung cancer that can be treated with laser irradiation, or recurrent esophageal cancer associated with local persistence after chemotherapy or radiotherapy. This application was submitted to change the raw material used for the cover of the lateral firing tip in the lateral firing probe, falling under a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the post-market performance review period)
Specified Partial Change	Nov. 25, 2016 Total review time: 88 days Regulatory review time: 73 days	Aug. 18, 2016 No clinical study results	26	GORE CTAG Thoracic Endoprosthesis (W. L. GORE & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for intravascular treatment of thoracic aorta, consisting of the stent graft and the delivery system. The application was submitted to change the raw materials for parts of the delivery catheter. It is a partial change during the post-market performance review period, falling under a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the post-market performance review period)

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Products Approved in FY 2016: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	May 25, 2016 Total review time: 614 days Regulatory review time: 304 days	- Foreign clinical study results	1	Freestyle Libre (Abbott Japan Co., Ltd.)	Approval	Instrument & apparatus 20 Glucose monitoring system	A glucose monitoring system to continuously measure and record glucose levels in the interstitial fluid. When the user scans the Reader over the sensor, fluctuation patterns of the interstitial fluid glucose level are displayed on the screen. In addition, the Reader also has the function of measuring blood glucose and blood ketone levels, as a glucose meter for self-testing. Results from clinical studies were submitted to compare the correlation between glucose level in blood or plasma and that in the interstitial fluid in order to evaluate the accuracy of the interstitial glucose levels measured by the product and the safety.
Robotic, ICT, and other devices (not classified as other categories)	Jun. 13, 2016 Total review time: 570 days Regulatory review time: 419 days	- Foreign clinical study results	2	Freestyle Libre Pro (Abbott Japan Co., Ltd.)	Approval	Instrument & apparatus 20 Glucose monitoring system	A glucose monitoring system for professional use to continuously measure and record glucose levels in the interstitial fluid. When the healthcare professional scans the Reader over the sensor, the fluctuation patterns of the interstitial fluid glucose level are displayed on the screen. Results from clinical studies were submitted to compare the correlation between glucose level in blood or plasma and that in the interstitial fluid in order to evaluate the accuracy of the interstitial glucose levels measured by the product and the safety.
Orthopedic and Plastic Surgery	May 9, 2016 Total review time: 1075 days Regulatory review time: 434 days	Sep. 17, 2012 Clinical evaluation report	3	KMC Kyphoplasty System (Nihon Americare Co.,Ltd.)	Approval	Instrument & apparatus 58 Single-use vertebral body restoration device	A single-use device used in balloon kyphoplasty (BKP) for restoration of fractured vertebral body. The system is used to create a cavity in the fractured vertebral body for patients in acute phase of compression fracture in one vertebral body due to primary osteoporosis, whose pain has not relieved after receiving sufficient conservative treatment. Improvements are made to enable: restoration of vertebral height using an expandable balloon; and reduction of the risk of cement leakage outside the vertebral body by creating a cavity for bone cement injection.
Orthopedic and Plastic Surgery	May 9, 2016 Total review time: 1075 days Regulatory review time: 411 days	Jun. 9, 2005 Clinical evaluation report	4	Mendec Spine Bone Cement Kit (Nihon Americare Co.,Ltd.)	Approval	Medical products 4 Orthopedic bone cement	Orthopedic bone cement for percutaneous vertebroplasty (PVP) in patients with vertebral fracture accompanying pain due to malignant vertebral tumor, or balloon kyphoplasty (BKP) in patients in acute phase of compression fracture in one vertebral body due to primary osteoporosis. Following improvements are made: enhancement of the visibility under fluoroscopy by increasing the amount of barium sulfate; and extension of the curing time as compared with that of the approved product, "KYPHON BKP Bone Cement HV-R" (Approval No. 22200BZX00119000) in order to enhance its operability.
Orthopedic and Plastic Surgery	May 25, 2016 Total review time: 299 days Regulatory review time: 253 days	- Clinical evaluation report	5	Sorbact Foam Dressing (ABIGO Medical AB)	Approval	Medical products 4 Secondary foam dressing for wound healing	A secondary foam dressing for wound healing to be used for wounds reaching subcutaneous adipose tissue (excluding third-degree burns) to protect wounds, maintain a moist wound environment, accelerate curing, and alleviate pain. The following improvement is made in the product: cellulose acetate fabric, which was made hydrophobic-by a covalent bond with dialkyl carbamoyl chloride (DACC), is used in the product surface coming into contact with the wound.
Orthopedic and Plastic Surgery	Aug. 4, 2016 Total review time: 478 days Regulatory review time: 249 days	- Domestic clinical study results	6	Renerve (Nipro Corporation)	Approval	Medical products 4 Collagen-using absorbent nerve regeneration-inducing material	An absorbent nerve regeneration-inducing material which is to be placed into the torn or deficit part of peripheral nerve, except the inside of dura mater, to induce neurotization. Pig skin collagen is used as a raw material. Japanese clinical study results were submitted to evaluate the recovery rate of sensory function after treatment with the product.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Orthopedic and Plastic Surgery	Sep. 9, 2016 Total review time: 260 days Regulatory review time: 78 days	Oct. 22, 2013 Foreign clinical study results	7	Juvederm Vista Voluma XC (Allergan Japan K.K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material to soft-tissue using hyaluronic acid injected into a subcutaneous or a supraperiosteal deep tissue to correct volume loss in the midface, chin or temple in adults. The product contains 0.3 wt% of lidocaine hydrochloride to alleviate pain at the time of injection. Results from foreign clinical studies were submitted to evaluate the effect of volume correction in the midface.
Orthopedic and Plastic Surgery	Oct. 19, 2016 Total review time: 807 days Regulatory review time: 81 days	Jul. 18, 1997 Clinical evaluation report	8	Titanium Elastic Nail (Sterilized) (Johnson & Johnson K.K.)	Approval	Medical products 4 Intramedullary nail for internal fixation of femoral fracture	An intramedullary nail made of titanium alloy used for fracture fixation of the femur, tibia, humerus, radius, and ulna in pediatric patients, and the humerus, radius, and ulna in adult patients. The nailing system is used for the elastic stable intramedullary nailing technique, which allows fixation in the medullary cavity without damaging the epiphyseal line, for diaphyseal fractures in pediatric patients. A clinical evaluation report summarizing foreign clinical study results on the device was submitted to verify that fracture healing can be achieved without any serious complication.
Orthopedic and Plastic Surgery	Dec. 22, 2016 Total review time: 155 days Regulatory review time: 37 days	Jan. 3, 2007 Clinical evaluation report	9	Smart Curette (Medical U&A, Inc.)	Approval	Instrument & apparatus 12 Ultrasonic surgical instrument	The device is an ultrasonic surgical instrument used for wound debridement. It sprays physiological saline from the tipping of the probe and dissects necrotic tissue, etc. by vibrating the probe tip. A clinical evaluation report summarizing results from domestic and foreign clinical studies on the device and similar products was submitted to demonstrate that debridement by ultrasonic surgical instruments is effective in wound therapy.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 31, 2016 Total review time: 407 days Regulatory review time: 238 days	Feb. 13, 2009 Foreign clinical study results Domestic clinical study results Clinical evaluation report	10	Lifestent Solo Vascular Stent System (Medicon, Inc.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A self-expanding vascular stent used for the treatment of symptomatic arterial disease with a lesion length up to 200 mm in the region from native superficial femoral artery (SFA) to proximal popliteal artery with reference vessel diameter of 4.0-6.5mm, and for the treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The following data was submitted: results from the foreign pivotal study to evaluate the performance of the product in lesion lengths up to 150 mm and a domestic study conducted to investigate whether the data can be extrapolated to Japanese population; a clinical evaluation report compiling the data from a foreign clinical study conducted to evaluate the performance of the product in lesion lengths up to 200 mm and literature reports on the results of surgical and endovascular treatments for lesions up to 200 mm in length.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 2, 2016 Total review time: 267 days Regulatory review time: 148 days	- Domestic clinical study results	11	DURAWAVE (GUNZE LIMITED)	Approval	Medical products 4 Synthetic artificial dura mater	The device is an artificial dura mater, primarily composed of polyglycolic acid, and identical to the previously approved product "NEOVEIL" (Approval No. 20400BZZ00322000). This application was submitted to newly obtain the indication of prosthetic dura mater, which is listed as a contraindication in the package insert for the already approved product. With the use of biological tissue adhesive, suturing is not necessary and the functioning as a prosthesis for dura mater deficit is easily and successfully achieved. Clinical study results on the device examining the sealing capability as well as effectiveness in prevention of cerebrospinal fluid leakage and subcutaneous cerebrospinal fluid retention were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 17, 2016 Total review time: 266 days Regulatory review time: 151 days	Feb. 29, 2016 Foreign clinical study results	12	Gore Excluder AAA Endoprosthesis (W. L. GORE & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	The device consists of a stent graft and delivery system used for endovascular treatment of abdominal aortic aneurysm and aortic aneurysms extending from the abdominal aorta to the iliac artery (hereinafter referred to as "aortoiliac aneurysms"). The application was submitted to add an iliac branch endoprosthesis used for common iliac artery aneurysms (aortoiliac aneurysms and isolated common iliac artery aneurysms) (A "partial change" application). Results of foreign clinical studies were submitted to evaluate the performance of the device in the treatment of common iliac artery aneurysms.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 13, 2016 Total review time: 300 days Regulatory review time: 178 days	Jul. 30, 1993 Clinical evaluation report	13	Mini-BAL Sampling Catheter (Halyard Healthcare, Inc.)	Approval	Instrument & apparatus 51 Bronchoalveolar lavage (BAL) catheter	A single-use catheter used to collect specimens by bronchoalveolar lavage (BAL) without bronchoscope to diagnose pneumonia. The device is used in adult patients with an artificial airway created by procedures such as tracheal intubation or tracheotomy. Although the catheter is inserted without visualization, the tip of the catheter is curved so that the catheter can be smoothly inserted into the right and left bronchi. In addition, the area of catheter tip coming in contact with the bronchial wall is round-shaped. A clinical evaluation report based on the information collected from the literatures on the device and the similar products was submitted as the clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 27, 2016 Total review time: 641 days Regulatory review time: 425 days	Apr. 16, 2014 Foreign clinical study results	14	TruePath Chronic Total Occlusion (CTO) Device (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Oscillating peripheral artery recanalization catheter system	The device is used for chronic total occlusion that is difficult to be penetrated with a guidewire during percutaneous transluminal angioplasty. Using mechanical rotation, the device penetrates the lesion to secure the passage for a guidewire. Results of foreign clinical study using this device were submitted to verify the status of penetration through lesions in peripheral vessels and the presence or absence of blood vessel perforation after the procedure.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 27, 2016 Total review time: 224 days Regulatory review time: 156 days	May 15, 2013 Foreign clinical study results	15	Denali IVC Filter (Medicon, Inc.)	Approval	Instrument & apparatus 51 Inferior vena cava filter	The device, consisting of an inferior vena cava filter and the delivery system, is used to prevent pulmonary embolism. The device was developed based on the concept of risk reduction for blood vessel penetration, enhancement of resistance to migration and fracture, and secure retrieval of the devices after a long-term implantation, etc., and characterized by addition of an anchor and penetration limiter to the legs and the one-piece body by laser cutting. Data of foreign clinical studies conducted to evaluate the success rates of placement and retrieval of the devices were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 9, 2017 Total review time: 232 days Regulatory review time: 202 days	May 4, 2015 Clinical evaluation report	16	ERBE CRYO2 (Amco Inc.)	Approval	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgery unit used for tissue biopsy or removal of foreign matters by cooling/freezing the bronchus, bronchial peripheral tissue, or foreign matters in the bronchus by touching with the probe tip cooled by high pressure carbon dioxide. It was judged that clinical evaluation was necessary because its indications differ from those of existing cryosurgery equipment.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 9, 2017 Total review time: 178 days Regulatory review time: 132 days	- Foreign clinical study results Domestic clinical study results	17	Misago 3 (Terumo Corporation)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent and a delivery system to deliver the stent to the lesion site, used for the treatment of symptomatic artery diseases with reference vessel diameters of 4-7 mm and target lesion length of 40-150 mm in the superficial femoral artery region by dilatation of the artery and maintenance of the lumen, and for the treatment of acute or impending occlusions associated with unsuccessful intervention treatments in the same lesion. The system uses the same stent as the company's approved product, "Misago" (Approval No. 22400BZX00463000), but differs from the approved product in that its delivery system is specialized in placing the stent to the target lesion by the ipsilateral approach. The results of clinical studies using the original product "Misago" were provided as clinical evaluation material and the rationale for its extrapolation was explained.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 23, 2017 Total review time: 226 days Regulatory review time: 186 days	Oct. 3, 2016 Foreign clinical study results	18	Prodigy MRI Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator that generates electrical stimulation and its accessories used in spinal stimulation therapy for patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. Results of foreign clinical studies using this product were submitted to demonstrate that efficacy and safety of the new stimulation mode not included in conventional products were not inferior to those of the conventional stimulation mode.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 29, 2017 Total review time: 300 days Regulatory review time: 238 days	May 29, 2015 Foreign clinical study results	19	Vagus Nerve Stimulation Device Aspire SR (Cyberonics, Inc.)	Approval	Instrument & apparatus 12 Vagus nerve stimulation device with anti-seizure effects	An electrical stimulation device to stimulate vagus nerve as an adjuvant therapy to reduce the frequency of seizures for patients with drug-resistant epilepsy who have refractory epileptic seizures (excluding those responding to craniotomy procedure). This device was developed based on the "Vagus Nerve Stimulation Device VNS System" (Approval No. 22600BZI00008000) and equipped with an additional automatic stimulation mode to automatically deliver electrical stimulation triggered by the sudden increase in heart rate before and after epilepsy seizure. Results from foreign clinical studies were submitted to evaluate the efficacy and safety of the automatic stimulation mode.
Gastroenterology, Genitourinary, and Reproductive Medicine	Jun. 21, 2016 Total review time: 365 days Regulatory review time: 268 days	- Domestic clinical study results	20	AdSpray (Terumo Corporation)	Approval	Medical products 4 Bioresorbable adhesion barrier	An adhesion barrier applied to the surgical wound to prevent surgical adhesions after surgery of abdomen or pelvic cavity. A spray style was adopted to improve the workability and to enable the use in areas of complex structures. When sprayed, gel is formed in the applied area and works as a physical barrier to prevent adhesion. The results of a pharmacokinetics study in humans demonstrate that gel remains for about 24 hours, and subsequently undergoes breakdown and absorption. Results from a Japanese clinical trial were submitted, in which the product was applied right under a midline incision following laparoscopic surgery, to evaluate the product's effects to reduce the incidence rate, size, and the severity of adhesion.
Gastroenterology, Genitourinary and Reproductive Medicine	Oct. 14, 2016 Total review time: 198 days Regulatory review time: 156 days	- Domestic clinical study results	21	Toraylight HDF (Toray Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia in patients with extremely impaired renal function caused by chronic or acute kidney failure. Based on the previously approved "Toraylight NV" (Approval No. 22200BZX00871000), a light-weight, hollow-fiber dialyzer without filling fluid, this device was developed to improve the operability in hemodiafiltration with increased surface area of the membrane. Results from a domestic clinical study were submitted to evaluate safety and efficacy of the device, in accordance with the PFSB Notification No. 0301-5 dated March 1, 2013.
Gastroenterology, Genitourinary, and Reproductive Medicine	Feb. 13, 2017 Total review time: 250 days Regulatory review time: 188 days	- Domestic clinical study results	22	Asahi Hollow Fiber Hemodiafilter ABH-PA (Asahi Kasei Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. This device is indicated for patients with extremely impaired renal function caused by chronic or acute kidney failure. The device differs in the composition of hollow fiber polymer from that of the approved "Asahi Hollow Fiber Hemodiafilter" (Approval No. 22200BZX00577000), using a wavy hollow fiber to reduce transmembrane pressure difference during hemodiafiltration.
Gastroenterology, Genitourinary, and Reproductive Medicine	Feb. 23, 2017 Total review time: 265 days Regulatory review time: 137 days	- Domestic clinical study results	23	IRIS Monitor (Atom Medical Corporation)	Approval	Instrument & apparatus 21 Heart rate monitor	A heart rate monitor designed to non-invasively measure, display, and save fetal heart rate through the mother's abdomen. Unlike the approved similar medical devices using the ultrasonic or direct induction method, this device detects bioelectric signals via the electrode placed on the mother's abdominal wall and thereby determing the fetal heart rate based on the extracted signals.
Ophthalmology and Otorhinolaryngology	Apr. 25, 2016 Total review time: 1060 days Regulatory review time: 789 days	Jun. 13, 2002 Domestic clinical study results	24	Paragon Ortho-K (Eyemed Co., Ltd.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	Orthokeratology contact lens with a specially shaped inner surface intended to reshape the corneal surface by wearing it during sleep and to correct and maintain the unaided vision during daytime after removal of the lens. A domestic clinical study was conducted to evaluate the efficacy such as how precisely the eyesight is corrected, etc. and the safety such as harm to the cornea, etc.
Ophthalmology and Otorhinolaryngology	Jun. 13, 2016 Total review time: 593 days Regulatory review time: 79 days	Sep. 11, 2013 Foreign clinical study results	25	Bausch + Lomb Aqualox (B.L.J. Company, Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable tint-colored contact lenses with vision correction which may be worn whole day for maximum two weeks. The lens is made of samfilcon A, a silicone hydrogel material with a water content of 46% and an oxygen permeability (Dk) of 114. Because of the novelty in the raw materials, a clinical study was conducted to confirm the efficacy and safety in wearing the lenses to correct visual acuity.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Ophthalmology and Otorhinolaryngology	Jan. 10, 2017 Total review time: 218 days Regulatory review time: 166 days	- Foreign clinical study results	26	Tecnis Symfony VB (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision in patients with aphakia. The raw material and basic structure of this device are identical to those of the company's approved product, "Tecnis 1-Piece VB" (Approval No. 22400BZX00172000), but with the same diffractive multifocal function as "Tecnis Symfony" (Approval No. 22900BZX00006000) at the posterior optic zone. Results of foreign clinical studies using "Tecnis Symfony" (Approval No. 22900BZX00006000) to evaluate clinical efficacy and fundamental safety, including visual function as a multifocal posterior chamber lens, were submitted, and the rationale for its extrapolation was explained.
Ophthalmology and Otorhinolaryngology	Jan. 10, 2017 Total review time: 263 days Regulatory review time: 175 days	Jul. 15, 2016 Foreign clinical study results	27	Tecnis Symfony (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision in patients with aphakia. The raw material and basic structure of this device are identical to those of the company's approved product "Tecnis Multifocal 1-Piece" (Approval No., 22300BZX00277000), but this device differs in light distribution, focused mainly from far to intermediate distance by improving the diffractive multifocal function such as the number of diffractive rings and step heights. Results of foreign clinical studies using an approved monofocal posterior lens as a control to evaluate the clinical efficacy and fundamental safety, including visual function as a multifocal posterior lens, were submitted.
Cardiopulmonary Circulation	Apr. 26, 2016 Total review time: 403 days Regulatory review time: 223 days	- Clinical evaluation report	28	Optisure Single Screw-In (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead that is connected to an automatic implantable cardioverter-defibrillator, a dual-chamber automatic implantable cardioverter-defibrillator, or an implantable biventricular pacing pulse generator with defibrillator function used for the treatment of ventricular tachycardia and other condition. The application was submitted to allow patients to undergo an MRI scan under predefined conditions (A "partial change" application). To evaluate the safety of the device under MRI scans, a clinical evaluation report summarizing the results from foreign clinical studies relating to the product was submitted.
Cardiopulmonary Circulation	Apr. 26, 2016 Total review time: 403 days Regulatory review time: 223 days	- Clinical evaluation report	29	Optisure Dual Screw-In (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead that is connected to an automatic implantable cardioverter-defibrillator, a dual-chamber automatic implantable cardioverter-defibrillator, or an implantable biventricular pacing pulse generator with defibrillator function used for the treatment of ventricular tachycardia and other condition. The application was submitted to allow patients to undergo an MRI scan under predefined conditions (A "partial change" application). To evaluate the safety of the device under MRI scans, a clinical evaluation report summarizing the results from foreign clinical studies relating to the product was submitted.
Cardiopulmonary Circulation	Apr. 26, 2016 Total review time: 362 days Regulatory review time: 191 days	- Clinical evaluation report	30	Fortify Assura (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an automatic implantable defibrillator used in patients at a high risk of sudden death due to ventricular tachyarrhythmia. The application was submitted to allow patients to undergo an MRI scan under predefined conditions (A "partial change" application). To evaluate the safety of the device under MRI scans, a clinical evaluation report summarizing the results from foreign clinical studies relating to the product was submitted.
Cardiopulmonary Circulation	Jun. 8, 2016 Total review time: 229 days Regulatory review time: 112 days	- Global clinical trial results	31	Ultimaster (Terumo Corporation)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease, and a delivery catheter used to implant the stent at stenotic lesions. The application was submitted for an additional stent size of 4.0 mm in diameter (A "partial change" application). To expand the size variation from the range of 2.5-3.5 mm to 2.5-4.0 mm of vessel diameter, the results from the global clinical trials conducted to evaluate the efficacy and safety of the product were submitted.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Jun. 24, 2016 Total review time: 84 days Regulatory review time: 64 days	Aug. 11, 2016 Foreign clinical study results	32	Thermocool Smarttouch SF (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An ablation catheter to be used for conducting cardiac ablation with high-frequency current and cardiac electrophysiologic technique for the treatment of patients with drug refractory symptomatic paroxysmal or persistent atrial fibrillation, atrial flutter, and patients with ventricular tachycardia who have not responded to other therapies. This product is an ablation catheter with the irrigation function of "Navistar Thermocool SF" (Approved No. 22300BZX00453000) with additional contact force-sensing function of the "Thermocool Smarttouch" (Approval No. 22400BZX00163000). The results of SMART-AF study, conducted outside Japan were submitted as clinical evaluation data, in order to demonstrate the safety and efficacy of "Thermocool Smarttouch," as an irrigation catheter with contact force-sensing function, in the treatment of patients with drug refractory symptomatic paroxysmal atrial fibrillation.
Cardiopulmonary Circulation	Aug. 22, 2016 Total review time: 280 days Regulatory review time: 208 days	Dec. 17, 2011 Clinical evaluation report	33	Kodama Catheter (ACIST Medical Systems)	Approval	Instrument & apparatus 51 Central circulation system intravascular ultrasound catheter	An intravascular ultrasound catheter for imaging of the vascular lumen and wall of the central circulatory system using ultrasound. The device is connected to the previously certified device "HD-IVUS System" (Certification No. 226ADBZX00178000) to irradiate the observation target site with ultrasonic wave from the sensor in the tip, and display images by processing the reflected signals. Majority of approved intravascular ultrasound catheters can be set at 40 MHz of ultrasonic frequency only; in contrast, the device can be set at either 40 or 60 MHz to improve the distance resolution and azimuth resolution. A clinical evaluation report summarizing foreign clinical studies was submitted to evaluate the ability to distinguish vascular lesions.
Cardiopulmonary Circulation	Oct. 25, 2016 Total review time: 403 days Regulatory review time: 222 days	Dec. 4, 2015 Foreign clinical study results	34	Stingray System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter used to treat coronary chronic total occlusion (CTO) during percutaneous transluminal coronary angioplasty (PTCA). The device is used in the difficult cases to pass the guidewire through a lesion, assisting the guidewire inserted into the subintimal space to re-enter into the true lumen and securing the passage. The catheter and the guidewire with a projected tip allow the guidewire to re-enter into the true lumen. Results from foreign clinical studies, which confirmed that the guidewire of this system was able to be placed in the true lumen crossing the CTO in patients unsuccessfully treated with the existing guidewire, were submitted.
Cardiopulmonary Circulation	Oct. 27, 2016 Total review time: 706 days Regulatory review time: 291 days	Oct. 24, 2014 Foreign clinical study results	35	TactiCath Quartz Ablation System (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A device consisting of an electrode catheter and the dedicated system components. The device system is intended to treat drug treatment resistant, symptomatic paroxysmal atrial fibrillation and common atrial flutter, and is capable of percutaneous transluminal myocardial ablation with a high-frequency current as well as cardiac electrophysiological study. The device also allows real-time monitoring of the contact force. Data related to foreign clinical study were submitted to show the efficacy and safety of the device used in the treatment of paroxysmal atrial fibrillation.
Cardiopulmonary Circulation	Oct. 27, 2016 Total review time: 80 days Regulatory review time: 64 days	Oct. 24, 2014 Foreign clinical study results	36	TactiCath Quartz Ablation System N (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A device consisting of an electrode catheter and the dedicated system components. The device system is intended to treat drug treatment resistant, symptomatic paroxysmal atrial fibrillation and common atrial flutter, and is capable of percutaneous transluminal myocardial ablation with a high-frequency current as well as cardiac electrophysiological study. This device was developed based on the approved "TactiCath Quartz Ablation System" (Approval No. 22800BZX00394000), with modifications of the adhesive at the tip of the catheter and image sensor. Data related to foreign clinical study were submitted to show the efficacy and safety of the device used in the treatment of paroxysmal atrial fibrillation.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Nov. 29, 2016 Total review time: 343 days Regulatory review time: 124 days	May 10, 2011 Foreign clinical study results	37	CrossBoss Coronary CTO Crossing Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter used to treat coronary chronic total occlusion (CTO) during percutaneous transluminal angioplasty (PTCA). The device is used in the difficult cases to pass the guidewire through the lesion for the purpose of securing the passage. The device may be moved toward the target lesion along the guidewire or precede the guidewire. Results from foreign clinical studies, which confirmed that the guidewire was able to be placed in the true lumen crossing the CTO in patients unsuccessfully treated with the existing guidewire, were submitted.
Cardiopulmonary Circulation	Nov. 29, 2016 Total review time: 152 days Regulatory review time: 128 days	- Domestic clinical study results	38	Ultimaster (Terumo Corporation)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease, and a delivery catheter used to implant the stent at stenotic lesions. The application was submitted for an additional stent size of 2.25 mm in diameter (A "partial change" application). To expand the size variation from the range of 2.5-4.0 mm to 2.25-4.0 mm of vessel diameter, the results from the domestic clinical study conducted to evaluate the efficacy and safety of the product were submitted.
Cardiopulmonary Circulation	Dec. 15, 2016 Total review time: 244 days Regulatory review time: 112 days	- Foreign clinical study results	39	FlexAbility SE Irrigated Catheter (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An ablation catheter intended to treat common atrial flutter, diagnosing arrhythmia by pacing and mapping during percutaneous transluminal myocardial ablation. The device was developed based on "FlexAbility Irrigated Catheter" (Approval No. 22500BZX00096000). The approval application was submitted for the major changes such as additions of a magnetic sensor to acquire position information and an indication for paroxysmal atrial fibrillation, and a change in raw materials. To demonstrate the efficacy and safety of the device in the treatment of paroxysmal atrial fibrillation, data from foreign clinical studies using the devices different from this product was submitted. However, the results of the study could not be extrapolated for the examination of this device. Therefore, paroxysmal atrial fibrillation was removed from the indication.
Cardiopulmonary Circulation	Feb. 14, 2017 Total review time: 365 days Regulatory review time: 115 days	Sep. 27, 2013 Global clinical trial	40	Micra Introducer (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiac catheter introducer kit	A kit composed of an introducer sheath and dilator used to transdermally insert the treatment or diagnostic device including the "Micra Transcatheter Pacing System" (Approval No. 22900BZX00047000) into a vein. The results of global clinical studies including Japan conducted to evaluate the efficacy and safety when using the Micra Transcatheter Pacing System with this product in the treatment of bradyarrhythmia were submitted.
Cardiopulmonary Circulation	Feb. 17, 2017 Total review time: 262 days Regulatory review time: 129 days	- Foreign clinical study results	41	INSPIRIS RESILIA Aortic Valve (Edwards Lifesciences Limited)	Approval	Instrument & Bovine pericardial valve	A bovine pericardial valve intended to function as a substitute for a malfunctioning cardiac valve. The product structure is based on the approved product "Carpenter-Edwards Bovine Pericardial Biological Valve Magna EASE ThermaFix Process" (Approval No. 22300BZX00320000) and it has a specially-processed leaflet tissue to enhance anticalcification and enable storage without glutaraldehyde solution. The results of US and EU clinical studies were submitted to evaluate the efficacy and safety of this product in patients with aortic valve disease requiring aortic valve replacement.
Cardiopulmonary Circulation	Mar. 3, 2017 Total review time: 403 days Regulatory review time: 230 days	Feb. 12, 2016 Foreign clinical study results	42	Quadra Assura MP (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with a defibrillator function (CRT-D) for cardiac resynchronization therapy (CRT). A multi-point pacing (MPP) function of this product allows the user to choose 2 electrodes as the left ventricular pacing positions while similar CRT-Ds can provide only one out of 4 electrodes (hereinafter referred to as BiV pacing). The MPP function is used in patients who do not respond to BiV pacing. Results from a non-clinical study ensuring the required function for CRT and safety in MRI and foreign clinical study evaluating the efficacy and safety of the MPP function were submitted.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Mar. 21, 2017 Total review time: 264 days Regulatory review time: 93 days	Mar. 19, 2017 Global clinical trial and foreign clinical study results	43	Diamondback 360 Coronary Orbital Atherectomy System Micro Crown (Cardiovascular Systems, Inc.)	Approval	Instrument & apparatus 51 Angioplasty catheter for ablation atherectomy	An atherectomy device used to remove calcified plaques in severely calcified lesions of new stenotic lesions caused by coronary arteriosclerosis using high speed rotation of diamond coated crown and diamond coated tip at end of shaft thereby facilitating postoperative coronary intervention. The product controls the eccentricity of the crown by the speed of rotations and therefore can be used for large or small lumen diameter vessels without changing the size of the product in contrast to approved similar products whose size must be changed to the larger size depending on the diameter of the target lumen. The results of non-clinical studies demonstrating the ability of this device to cut calcified plaques in the coronary artery as an atherectomy device and those of foreign clinical studies and Japan-US global clinical trial performed to evaluate the efficacy and safety of the adjuvant therapy for stent placement using the product for severely calcified lesions were submitted.
Cardiopulmonary Circulation	Mar. 27, 2017 Total review time: 234 days Regulatory review time: 155 days	Feb. 24, 2016, Jul. 7, 2016, Mar. 2, 2017 Foreign clinical study results	44	BSC OI Ablation Catheter (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A catheter for the treatment of arrhythmia. It is designed to be inserted percutaneously to the heart through a blood vessel to apply a radiofrequency current to the target site of arrhythmia identified electrophysiologically, in order to treat persistent or recurrent type I atrial flutter. The improvement from the company's approved product is an irrigation function of this product to deliver saline from the irrigation holes at the electrode tip. Results from foreign clinical studies that evaluated the efficacy and safety of the irrigation function were submitted.

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Products Approved in FY 2015: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Ophthalmology and Otorhinolaryngology	Feb. 15, 2016 Total review time: 228 days Regulatory review time: 112 days	- Domestic clinical study results	1	Suncon Kyoto-CS (Sun Contact Lens Co., Ltd.)	Approval	Instrument & apparatus 72 Limbal-supported contact lens for abnormal corneal shape	A limbal-supported, rigid contact lens for patients with ocular sequelae of Stevens-Johnson syndrome or toxic epidermal necrolysis, to alleviate symptoms associated with severe dry eye, etc. as well as to correct visual acuity. An investigator-initiated clinical trial was conducted in Japan to evaluate the efficacy and safety of the product in patients with ocular sequelae for whom the product is indicated. [Orphan device]
Ophthalmology and Otorhinolaryngology	Mar. 25, 2016 Total review time: 564 days Regulatory review time: 203 days	Jun. 25, 2012 Foreign clinical study results	2	iStent Trabecular Micro-Bypass Stent System (Glaukos Corporation)	Approval	Medical products 4 Heparin using intraocular drain	A device consisting of the iStent, a titanium-alloy glaucoma implant designed to maintain patency of an outflow canal passing through the trabecular meshwork so that aqueous humor drains from the anterior chamber into Schlemm's canal and is directed naturally to the normal outflow canal, and its inserter. The surface of the iStent is coated with porcine-derived heparin. Results from foreign clinical studies were submitted to evaluate the efficacy and safety of the device in patients with mild-to-moderate glaucoma requiring cataract surgery, for whom the device is indicated.
3-1	Apr. 17, 2015 Total review time: 219 days Regulatory review time: 123 days	Jan. 26, 2015 Foreign and domestic clinical study results	3	Pipeline Flex Flow Diverter System (Covidien Japan, Inc.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system used for endovascular therapy for large or giant wide-neck intracranial aneurysm in internal carotid artery from petrous through superior hypophyseal, except for the acute phase of aneurysm that are at risk of rupture. Results from foreign clinical studies conducted to evaluate the efficacy and safety of this product in the treatment of intracranial aneurysm and domestic clinical studies conducted to confirm the compatibility of this product with the domestic medical environment were submitted. [Priority review product]
3-1	Apr. 21, 2015 Total review time: 63 days Regulatory review time: 60 days	Sep. 3, 2014 Domestic clinical study results	4	XIENCE Alpine Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-3.75 mm and a delivery catheter used to implant a stent to the site of stenosis. This application is for a partial change of approval application for medical device to add a stent size of 2.25 mm diameter. The added drug-eluting stent of this product is identical to the company’s existing approved product "XIENCE PRIME SV Drug Eluting Stent" (Approval No. 22500BZX00070000) and "XIENCE Xpedition Drug Eluting Stent" (Approval No. 22500BZX00309000). The stent delivery system is identical to that of this product of 2.5 mm diameter except for the balloon size. Results from clinical studies on “XIENCE PRIME SV Drug Eluting Stent,” the stent part of which is identical to this product, were submitted to evaluate the efficacy and safety of this product. (The original product is in a reexamination period)
3-1	Jul. 23, 2015 Total review time: 56 days Regulatory review time: 42 days	- No clinical study results	5	Promus Premier Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion of 34 mm or less in length with a reference vessel diameter of 2.25-3.50 mm. The application was submitted for an extension of expiration period from the previously approved 18 months to 24 months. (A "partial change" application submitted during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-1	Aug. 28, 2015 Total review time: 113 days Regulatory review time: 99 days	Feb. 17, 2012 No clinical study results	6	Resolute Integrity SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a zotarolimus-eluting stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The application was submitted to change the specified test method related to the drug that was previously approved. (A "partial change" application submitted during the reexamination period)
3-1	Sep. 17, 2015 Total review time: 353 days Regulatory review time: 268 days	- Domestic clinical study results	7	SeQuent Please Drug Eluting Balloon Catheter (Nipro Corporation)	Change	Instrument & apparatus 51 Balloon-dilating catheter for coronary angioplasty	A balloon-dilating catheter for coronary angioplasty with a paclitaxel-coated balloon. The drug can be delivered to the vascular intima by dilating this catheter at the lesion site after predilation by a regular balloon used for percutaneous coronary intervention. The application was submitted for an additional indication of new coronary lesions with a reference vessel diameter of less than 3.0 mm. (A "partial change" application). Results from domestic clinical studies were submitted for the evaluation of the efficacy and safety of this product in patients with the additional indication compared to the intervention with balloon angioplasty.
3-2	Apr. 17, 2015 Total review time: 359 days Regulatory review time: 201 days	Jan. 13, 2012, Sep. 10, 2013 Foreign clinical study results	8	GORE CTAG Thoracic Endoprosthesis (W.L. GORE & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	The product consists of a stent graft used for treatment of thoracic aorta and delivery system used to deliver and implant the stent graft in the target site. The application is for a partial change to add the indications of traumatic thoracic aortic injury and acute complicated Stanford B aortic dissection in the item of intended use or indications. Results from clinical studies conducted to verify the efficacy and safety for traumatic thoracic aortic injury and acute complicated Stanford B aortic dissection were submitted.
3-2	Apr. 17, 2015 Total review time: 361 days Regulatory review time: 283 days	Jul. 15, 2014 (LVIS and LVIS Jr.3.5) Oct. 14, 2014 (LVIS Jr. 2.5) Domestic clinical study results	9	LVIS Stent (Terumo Corporation)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system to prevent the protrusion and/or dislodgement of embolic coils into/from the parent artery during coil embolization in patients who have a wide-neck cerebral aneurysm (defined as that with a neck part of 4 mm or greater, or dome/neck ratio of less than 2) in the parent artery with a diameter of 2.0 to 4.5 mm, among the patients who have an unruptured aneurysm (with a maximum diameter of 5 mm or greater) which is difficult to treat surgically (including surgical clipping) or by coil embolization using an embolization coil alone. This product is a stent formed with woven nitinol wire, which is expected to improve the tracking of vessel shape and is a closed-cell stent with characteristic of no cell opening or no protrusion into cerebral aneurysm. Results from domestic clinical studies conducted to evaluate the efficacy and safety of this product in treatment of aneurysm were submitted. (The original product is in a reexamination period)
3-2	Jun. 8, 2015 Total review time: 94 days Regulatory review time: 78 days	Nov. 30, 2012 No clinical study results	10	Solitaire FR Revascularization Device (Covidien Japan, Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system to restore blood flow in patients in the acute phase of cerebral infarction (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application is for a partial change to add a new type catheter with a modified junction between push wire and multi-cell retriever in order to make the structure less liable to crack. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-2	Aug. 28, 2015 Total review time: 70 days Regulatory review time: 35 days	- No clinical study results	11	GORE CTAG Thoracic Endoprosthesis (W.L. GORE & Associates, Co.,Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system consisting of a polytetrafluoroethylene (PTFE) graft and a self-expanding nitinol stent to keep the graft extended, and a delivery catheter to deliver and implant the stent graft in the target site. The application was submitted for addition of raw materials used for the soft tip at the end of delivery catheter due to termination of raw material supply which was previously approved. (A "partial change" application submitted during the post-market performance review period)
3-2	Sep. 18, 2015 Total review time: 357 days Regulatory review time: 160 days	Dec. 16, 2002 Domestic clinical study results	12	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microbead used for vascular embolization, composed of cross-linked polyvinyl alcohol polymer (Approval No. 22500BZX00182000). The application was submitted for an additional indication of vascular embolization therapy for hypervascular tumors and arteriovenous malformations to the approved indication of transcatheter arterial embolization therapy for patients with hepatocellular carcinoma. Results from a domestic clinical study were submitted for the evaluation of the efficacy and safety of this device for patients with the additional indication. (A "partial change" application submitted during the reexamination period)
3-2	Sep. 18, 2015 Total review time: 779 days Regulatory review time: 264 days	Feb. 20, 2007 Clinical evaluation report	13	Cook Spectrum M/R Impregnated Central Venous Catheter Kit (Cook Japan Inc.)	Approval	Instrument & apparatus 51 Antimicrobial central venous catheter introducer kit	This product is a central venous catheter impregnated with minocycline and rifampin to reduce catheter-related bloodstream infections (CRBSIs). A clinical evaluation report was submitted to evaluate the effectiveness in reducing CRBSI and the safety of the device.
4	Apr. 6, 2015 Total review time: 206 days Regulatory review time: 151 days	- No clinical study results	14	Activa SC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa SC is an implantable electrical stimulation device used for deep brain stimulation to improve various symptoms associated with movement disorders by delivering an electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). The application is for a partial change to enable MRI tests to be performed only when the patient's condition meets imaging criteria. Results from nonclinical studies evaluating the safety under MRI conditions were submitted. (A partial change during the reexamination period)
4	Apr. 6, 2015 Total review time: 206 days Regulatory review time: 151 days	- No clinical study results	15	Activa RC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa RC is a rechargeable and implantable electrical stimulation device used for deep brain stimulation to improve various symptoms associated with movement disorders by delivering an electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). The application is for a partial change to enable MRI tests to be performed only when the patient's condition meets imaging criteria. Results from nonclinical studies evaluating the safety under MRI conditions were submitted. (A partial change during the reexamination period)
4	Apr. 17, 2015 Total review time: 322 days Regulatory review time: 117 days	Sep. 28, 2012 Foreign clinical study results	16	S-ICD Lead (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable defibrillator /pacemaker lead	The device is a subcutaneous implantable cardioverter-defibrillator (S-ICD) lead used in patients at high risk of sudden cardiac death caused by ventricular tachycardia. Foreign clinical study reports were submitted to evaluate the efficacy and safety of the device for treatment of lethal arrhythmia.

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4	Apr. 17, 2015 Total review time: 322 days Regulatory review time: 134 days	Sep. 28, 2012 Foreign clinical study results	17	S-ICD Pulse Generator (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	The device is a subcutaneous implantable cardioverter-defibrillator (S-ICD) used in patients at high risk of sudden cardiac death caused by ventricular tachycardia. Foreign clinical study reports were submitted to evaluate the efficacy and safety of the device for treatment of lethal arrhythmia.
4	May 26, 2015 Total review time: 158 days Regulatory review time: 48 days	- No clinical study results	18	PD Laser BT (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device designed for photodynamic therapy. This device is to be used in combination with "Laserphyrin 100 mg for Injection" (Approval No. 21500AMZ00509000) as an oncotropic photo-sensitizer, targeting primary malignant brain tumor as an additional treatment to the surgical resection. The application is for a partial change to change the site of manufacture. (A partial change during the reexamination period)
4	Jun. 15, 2015 Total review time: 175 days Regulatory review time: 148 days	Oct. 12, 2010 No clinical study results	19	Thermogard System (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheter balloon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. The application is for a partial change to correct the error in the approved product information. (A partial change during the reexamination period)
4	Jun. 18, 2015 Total review time: 212 days Regulatory review time: 52 days	Dec. 16, 2011 Domestic and foreign clinical study results	20	EXCOR Pediatric Ventricular Assist Device (Cardio Incorporated)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	The device is an external ventricular assist system used for improving circulation of pediatric severe heart failure patients. Foreign clinical study reports to evaluate the survival rate, survival period, adverse events, etc. in pediatric patients using the device and a Japanese clinical study report to confirm the compatibility of the device with the domestic medical environment were submitted. [Orphan device]
4	Sep. 9, 2015 Total review time: 292 days Regulatory review time: 197 days	Apr. 17, 2003 Clinical evaluation report	21	Freezor Cryoablation Catheter Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A catheter used in cryoablation of cardiac tissue for treatment of atrioventricular nodal reentry tachycardia (AVNRT). A clinical evaluation report summarizing results of foreign clinical studies and published literatures was submitted for evaluation of the efficacy and safety in treatment of AVNRT. (The original product is in a reexamination period)
4	Sep. 9, 2015 Total review time: 292 days Regulatory review time: 197 days	Dec. 10, 2010 Clinical evaluation report	22	Medtronic CryoConsole (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical unit to be used for treatment of arrhythmia. The device is for the exclusive use with cryoablation catheters. The application was submitted for addition of a function "the cryomapping mode", which is available when used in combination with the “Freezor Cryoablation Catheter Series” (Approval No. 22700BZX00252000) . (A "partial change" application submitted during the reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 22, 2015 Total review time: 160 days Regulatory review time: 94 days	Oct. 15, 2014 No clinical study results	23	Libra Single 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An implantable stimulator for tremor used for deep brain stimulation (DBS), with the purpose of relieving various symptoms associated with Parkinson's disease, dystonia symptoms, or symptoms of essential tremor, by stimulating the deep brain. The application was submitted for an additional pocket adapter model used for connecting this device and the company’s own approved DBS stimulator to other manufacturer’s extension/lead. (A "partial change" application submitted during the reexamination period)

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 24, 2015 Total review time: 137 days Regulatory review time: 107 days	- No clinical study results	24	LVIS Stent (Terumo Corporation)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system to prevent the protrusion and/or dislodgement of embolic coils into/from the parent artery during coil embolization in patients who have a wide-neck cerebral aneurysm (defined as that with a neck of 4 mm or greater, or dome/neck ratio of less than 2) in the parent artery with a diameter of 2.0 to 4.5 mm, among the patients who have an unruptured aneurysm (with a maximum diameter of 5 mm or greater) which is difficult to treat surgically (including surgical clipping) or by coil embolization using an embolization coil alone. The application was submitted to add a LVIS stent (type 2) in which the stent weave density was changed to realize easier operability at the curvature of the vessels and in which the flare shape was changed for improved manufacturing efficiency. (A "partial change" application) (The original product is in a reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 2, 2015 Total review time: 341 days Regulatory review time: 200 days	Jan. 22, 2014 Foreign clinical study results	25	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system consisting of a stent graft for treatment of the thoracic aorta and a delivery catheter used to deliver and implant the stent graft in the target site. The application was submitted for an additional indication of acute complicated Stanford type B aortic dissection (A "partial change" application). Results from clinical studies conducted in the United States to verify the efficacy and safety of the product for acute complicated Stanford type B aortic dissection were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 2, 2015 Total review time: 56 days Regulatory review time: 29 days	- No clinical study results	26	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of cross-linked polyvinyl alcohol polymer. This product is used for vascular embolization in patients with hypervascular tumors or arteriovenous malformations. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 4, 2015 Total review time: 94 days Regulatory review time: 12 days	- No clinical study results	27	PD Laser BT (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device designed for photodynamic therapy. This device is to be used in combination with "Laserphyrin 100 mg for Injection" (Approval No. 21500AMZ0050900) as an oncotropic photo-sensitizer, targeting primary malignant brain tumor as an additional treatment to surgical resection. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2015 Total review time: 266 days Regulatory review time: 138 days	- No clinical study results	28	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Change	Instrument & apparatus 7 Aortic stent graft	A device consisting of a stent graft for treatment of thoracic aortic aneurysm and a delivery system used to deliver and implant the stent graft in the target site. The application was submitted for an additional type of delivery catheter with an effective sheath length of 950 mm and a compatible guidewire diameter of 0.035 inch. (A "partial change" application submitted during the reexamination period)

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 5, 2016 Total review time: 292 days Regulatory review time: 155 days	- Domestic clinical study results	29	Revive SE Thrombectomy device (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system to restore blood flow by removing clots from blood vessels in the brain in patients in the acute phase of cerebral infarction (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. Results from a single-arm clinical study conducted in Japan to confirm that the efficacy and safety of the device is practically equivalent to those of the approved medical device "Merci Retriever (Approval No. 22200BZX00596000) were submitted. (The original product is in a reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 29, 2016 Total review time: 304 days Regulatory review time: 176 days	Jan. 13, 2014 No clinical study results	30	Trevo Pro Clot Retriever (Stryker Japan K.K.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system intended to restore blood flow by removing thrombus for patients with acute-phase cerebral infarction (generally, within 8 hours of symptom onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. The application was submitted for an additional model (Type 3) with the tip structure at end of the retriever being removed and for additional size variations in effective length and diameter of the stent that are within the range of other approved devices. (A ”partial change” application submitted during the reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 15, 2016 Total review time: 152 days Regulatory review time: 113 days	Jan. 22, 2007 No clinical study results	31	Thermogard System (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A system for heat exchange with the blood using a central venous catheter accompanying a heat exchange balloon placed inside a blood vessel intended for the use in patients requiring body temperature management. Temperature-controlled physiological saline circulates within the balloon of the central venous catheter, which allows heat exchange between the balloon surface and the blood in contact with the surface, thereby controlling the temperature of the whole body. The application was submitted for an additional component, Quattro･ICY IVTM Catheter, and an additional indication of body temperature management (temperature management therapy) in patients under cardiac arrest or after return of (spontaneous) circulation. (A "partial change" application)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 15, 2016 Total review time: 257 days Regulatory review time: 144 days	Jun. 14, 2005 Clinical evaluation report Domestic clinical study results	32	Gore Viabahn Stent Graft (W. L. Gore & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft and delivery catheter, used for the treatment for arterial injury in the chest, abdomen, or pelvis, or for maintenance of arterial patency of the superficial femoral artery. A clinical evaluation report and results of the domestic clinical study were submitted to evaluate the efficacy and safety of the device in vascular injury treatment, and vascular patency treatment, respectively. [Priority review product]
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 15, 2016 Total review time: 452 days Regulatory review time: 225 days	ICY Catheter: Oct. 23, 2003 Quattro Catheter: Feb. 15, 2007 Domestic clinical study results	33	Quattro・ICY IVTM Catheter (ZOLL Circulation, Inc.)	Approval	Instrument & apparatus 12 Central venous placement temperature management system	A central venous catheter with a balloon for heat exchange used for body temperature management (temperature management therapy) in patients under cardiac arrest or after return of (spontaneous) circulation. The catheter is designed to be connected to the console of the approved "Thermogard System" (Approval No. 22400BZI00010000). Temperature-controlled physiological saline circulates within the balloon of the central venous catheter, which allows heat exchange between the balloon surface and the blood in contact with the surface, thereby controlling the temperature of the whole body. A clinical study was conducted in Japan in patients who are under cardiac arrest suspected to be caused by intrinsic cardiac dysfunction or who are after return of (spontaneous) circulation, to evaluate whether body temperature of these patients can be managed appropriately enabling therapeutic hypothermia, and to evaluate the safety.

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Cardiopulmonary Circulation	Nov. 18, 2015 Total review time: 357 days Regulatory review time: 215 days	- Domestic clinical study results	34	SATAKE･HotBalloon Catheter (Toray Industries, Inc.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing a high-frequency current to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. Results from domestic clinical studies using the previous product as an investigational device were submitted to verify the efficacy and safety in patients with drug-resistant symptomatic paroxysmal atrial fibrillation in comparison with control groups receiving antiarrhythmic drugs.
Cardiopulmonary Circulation	Dec. 18, 2015 Total review time: 232 days Regulatory review time: 177 days	Sep. 28, 2012 No clinical study results	35	S-ICD Pulse Generator (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is a subcutaneous implantable cardioverter-defibrillator (S-ICD) used in patients at high risk of sudden cardiac death caused by ventricular tachycardia. The application was submitted for addition of a device which is thinner than the existing one. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Dec. 24, 2015 Total review time: 182 days Regulatory review time: 114 days	- No clinical study results	36	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	A ventricular assist device used to improve circulation until heart transplantation in patients showing continuous decompensation in spite of drug therapy or circulation assist techniques such as an external ventricular assist system, and for whom it is considered difficult to survive without a heart transplant. The application was submitted for addition of surgical accessories and nonsterile supply of the existing surgical accessories. (A "partial change" application) [Orphan device]
Cardiopulmonary Circulation	Mar. 11, 2016 Total review time: 301 days Regulatory review time: 146 days	Jun. 17, 2015 Foreign clinical study results	37	Edwards Sapien 3 (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic heart valve system used for transcatheter valve implantation for patients with severe symptomatic aortic valve stenosis and for whom surgical aortic valve replacement cannot be performed due to their general condition and comorbidities. Foreign clinical study results were submitted to demonstrate that the efficacy and safety of the new device are equivalent to those of the existing approved model, Sapien XT. (The original product is in a reexamination period)
5	May 26, 2015 Total review time: 244 days Regulatory review time: 140 days	- Domestic clinical study results	38	EC-PDT Probe (Panasonic Healthcare Co., Ltd.)	Approval	Instrument & apparatus 31 Single-use probe for PDT semiconductor laser	A probe for laser irradiation used for photodynamic therapy using talaporfin sodium for recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy. This probe is connected to PD Laser to irradiate the target lesion from the esophageal lumen with laser light oscillated from PD Laser. Results from a domestic phase II study (an investigator-initiated clinical trial) conducted to evaluate the efficacy and safety of photodynamic therapy using talaporfin sodium, PD Laser, and this product for recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy were submitted. [Orphan device]
5	May 26, 2015 Total review time: 237 days Regulatory review time: 133 days	- Domestic clinical study results	39	PD Laser (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device used for photodynamic therapy using talaporfin sodium. The application is for a partial change to add recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy to the target diseases. This device irradiates the target lesion with laser light from the esophageal lumen when an exclusive EC-PDT probe for the device is connected. Results from a domestic phase II study (an investigator-initiated clinical trial) conducted to evaluate the efficacy and safety of photodynamic therapy using talaporfin sodium, this device, and the EC-PDT probe for recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy were submitted. [Orphan device]

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Gastroenterology, Genitourinary, and Reproductive Medicine	Mar. 9, 2016 Total review time: 82 days Regulatory review time: 9 days	- No clinical study results	40	EC-PDT Probe (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 Single-use probe for PDT semiconductor laser	A probe for laser irradiation used for photodynamic therapy using talaporfin sodium for recurrent esophageal cancer associated with local persistence after chemoradiotherapy or radiotherapy. This probe is connected to PD Laser to irradiate the target lesion from the esophageal lumen with laser light oscillated from PD Laser. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
6-1	Aug. 13, 2015 Total review time: 360 days Regulatory review time: 98 days	Jul. 9, 2008 Clinical evaluation report	41	Comprehensive Reverse Shoulder System (Biomet Japan, LLC)	Approval	Medical products 4 Total shoulder prosthesis	A reverse shoulder prosthesis used in cases of rotator cuff dysfunction such as rotator cuff tear arthropathy or massive rotator cuff tear. The device consists of humeral and glenoid components, and is used in combination with the approved humeral stem. A clinical evaluation report summarizing clinical data on foreign clinical literatures and foreign post-marketing surveillance was submitted to show the clinical equivalence of the product to overall reverse shoulder prostheses used in foreign countries. (The original product is in a reexamination period)
6-1	Aug. 13, 2015 Total review time: 104 days Regulatory review time: 55 days	May. 12, 2014 No clinical study results	42	Trabecular Metal Reverse Shoulder System Vivacit-E Polyethylene Liner (Zimmer K.K.)	Approval	Medical products 4 Humeral component for shoulder prosthesis	An insert consisting of humeral components of a reverse shoulder prosthesis used in cases of rotator cuff dysfunction such as rotator cuff tear arthropathy or massive rotator cuff tear. The insert adopts vitamin E blended highly crosslinked polyethylene as the raw material, which has already been used for the approved device. The device is used in combination with the humeral stem or other components of the company's own approved products, “Trabecular Metal Reverse Shoulder System” (Approval No. 22500BZX00475000). (The original product is in a reexamination period)
6-1	Aug. 28, 2015 Total review time: 147 days Regulatory review time: 47 days	Dec. 19, 2005 No clinical study results	43	Trabecular Metal Reverse Shoulder System (Zimmer K.K.)	Change	Medical products 4 Total shoulder prosthesis	A reverse shoulder prosthesis used in cases of rotator cuff dysfunction such as rotator cuff tear arthropathy or massive rotator cuff tear. The application was submitted for addition of manufacturing conditions of a component, “TM Reverse Base Plate”, and addition and deletion of the sterile manufacturing facilities. (A "partial change" application submitted during the reexamination period)
6-1	Sep. 2, 2015 Total review time: 306 days Regulatory review time: 104 days	Feb. 2, 2007 Clinical evaluation report	44	DELTA XTEND Reverse Shoulder System (Modular) (Johnson & Johnson K.K.)	Approval	Medical products 4 Total shoulder prosthesis	A reverse total shoulder prosthesis used in cases of rotator cuff dysfunction to replace the shoulder joint function. The part of the components to be implanted within bones is applied with surface roughening by grit blasting and plasma spray coating of hydroxyapatite, allowing cementless fixation. A clinical evaluation report summarizing clinical data on foreign clinical literatures and foreign post-marketing surveillance was submitted to show the clinical equivalence of the product to overall reverse shoulder prostheses used in foreign countries. (The original product is in a reexamination period)

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6-1	Sep. 2, 2015 Total review time: 306 days Regulatory review time: 108 days	Feb. 2, 2007 Clinical evaluation report	45	DELTA XTEND Reverse Shoulder System (Monobloc) (Johnson & Johnson K.K.)	Approval	Medical products 4 Humeral component for shoulder prosthesis	The humeral stem of a reverse shoulder prosthesis used in cases of rotator cuff dysfunction, to replace shoulder joint function. The devise is used in combination with the components of the “DELTA XTEND Reverse Shoulder System (Modular)” which have been filed simultaneously, and is fixed to bone with cement. A clinical evaluation report summarizing clinical data on foreign clinical literatures and foreign post-marketing surveillance was submitted to show the clinical equivalence of the product to overall reversed shoulder prostheses used in foreign countries. (The original product is in a reexamination period)
6-1	Sep. 14, 2015 Total review time: 297 days Regulatory review time: 89 days	Jun. 5, 2010 No clinical study results	46	Aequalis Reversed Cementless (Tornier S.A.S.)	Approval	Medical products 4 Humeral component for shoulder prosthesis	The humeral component of a reverse shoulder prosthesis used in cases of rotator cuff dysfunction such as rotator cuff tear arthropathy or massive rotator cuff tear. The component includes a stem and a metaphysis of which surfaces are treated of grit blasting and plasma spraying of hydroxylapatite, allowing cementless fixation. The device is used in combination with the components of the company's own approved product, “Aequalis Reversed Shoulder Prosthesis” (Approval No. 22500BZI00021000). (The original product is in a reexamination period)
8	May 19, 2015 Total review time: 425 days Regulatory review time: 239 days	- Domestic and foreign clinical study results	47	Radioactive Pharmaceutical Synthesizer FASTlab (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 10 Radiopharmaceutical synthesizer	A radioactive pharmaceutical synthesizer used for the automated preparation of a radioisotope labeled compound, flutemetamol (^{18}F) injection by remote control system indicated for the visualization of beta-amyloid plaque in the brain in patients with cognitive impairment who are suspected of having Alzheimer's disease. Results from domestic and foreign clinical studies were submitted as evaluation data on the efficacy and safety of this product and flutemetamol (^{18}F) injection.
8	Sep. 28, 2015 Total review time: 546 days Regulatory review time: 161 days	- Domestic and foreign clinical study results	48	Radiopharmaceutical Synthesis Device MPS200Aβ (Sumitomo Heavy Industries, Ltd.)	Approval	Instrument & apparatus 10 Radiopharmaceutical synthesizer	Radiopharmaceutical Synthesis Device used for the semi-automated preparation of a radioisotope labeled compound, florbetapir (^{18}F) injection, by a remote control system indicated for the visualization of beta-amyloid plaque in the brains in patients with cognitive impairment who are suspected of having Alzheimer's disease. Results from non-clinical studies, and domestic and foreign clinical studies were submitted as evaluation data on the efficacy and safety of this product and florbetapir (^{18}F) injection.
Robotic, ICT, and other devices (not classified as other categories)	Nov. 25, 2015 Total review time: 245 days Regulatory review time: 107 days	- Domestic clinical study results	49	HAL For Medical Use (Lower Limb Type) (CYBERDYNE Inc.)	Approval	Instrument & apparatus 58 Biosignal-responsive motor function improvement device	The device is composed of components that are to be attached to a patient, including a base component, battery pack, upper and lower leg cuff, and sensor shoes, and is used to improve walking function in patients with impaired ambulation caused by slowly progressive neurologic or muscular disease (spinal muscular atrophy, spinobulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal myopathy, sporadic inclusion body myositis, congenital myopathy, muscular dystrophy). Results from a domestic clinical trial (an investigator-initiated clinical trial) conducted to confirm the safety and effect in the improvement of walking function were submitted. [Orphan device]

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Robotic, ICT, and other devices (not classified as other categories)	Dec. 22, 2015 Total review time: 777 days Regulatory review time: 193 days	Feb. 18, 2009 Foreign and domestic clinical study results	50	da Vinci Si Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeon's manipulation in endoscopic surgery in areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology. The application was submitted for an additional indication for cardiac surgery (limited to intracardiac surgical operations under cardiac arrest) (A "partial change" application). In the United States and Japan, studies on mitral valve repair and atrial septal defect closure were conducted using the similar approved device “da Vinci Surgical System” (approval No. 22100BZX01049000). By extrapolating these results, the success rate of surgery and safety of this device were demonstrated.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 22, 2015 Total review time: 804 days Regulatory review time: 222 days	Mar. 19, 2008 Foreign and domestic clinical study results	51	da Vinci Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeon's manipulation in endoscopic surgery in areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology. The application was submitted for an additional indication for cardiac surgery (limited to intracardiac surgical operations under cardiac arrest) (A "partial change" application). In the United States and Japan, studies on mitral valve repair and atrial septal defect closure were conducted, and the success rate of surgery and safety of this device were demonstrated.
Specified partial change	Sep. 2, 2015 Total review time: 29 days Regulatory review time: 19 days	- No clinical study results	52	Promus Premier Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion of 34 mm or less in length, with a reference vessel diameter of 2.25-3.50 mm. The application was submitted for addition of the colorant raw material used for the tip of the monorail delivery catheter, falling under a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the reexamination period)
Specified partial change	Mar. 22, 2016 Total review time: 92 days Regulatory review time: 65 days	- No clinical study results	53	COOK Zenith Dissection Endovascular System (Cook Japan Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of acute complicated Stanford type B aortic dissection. The application was submitted to add a graft material as a "specified partial change" based on "Acceleration of Procedure for Specified Change for Medical Devices" (PFSB/ELD/OMDE Notification No. 1110001 dated on November 10, 2008). (A "partial change" application submitted during the reexamination period)
Cellular and tissue-based products	Apr. 28, 2015 Total review time: 224 days Regulatory review time: 144 days	- No clinical study results	54	Jace (Japan Tissue Engineering Co.,Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	An autologous cultured epidermis manufactured with epidermal cells indicated for use in patients with severe and extensive burn when sufficient donor sites for autologous skin grafts are not available and the total area of deep dermal and full-thickness burns is 30% or more of the total body surface area. This application is for a partial change in the manufacturing process to add the available culture media in each cell culture process. Results of comparing characteristics of product before and after the change in the manufacturing process were submitted.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Cellular and tissue-based products	May 22, 2015 Total review time: 196 days Regulatory review time: 96 days	- No clinical study results	55	Jacc (Japan Tissue Engineering Co.,Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	An autologous cultured cartilage indicated for use in patients with a cartilage deficiency area of 4 cm^2 or more without other standard surgical treatment options, in order to improve clinical symptoms of traumatic cartilage deficiency and osteochondritis dissecans. This application is for a partial change related to the addition of a sub-component, which is to measure the shape and size of cartilage deficiency site in knee joints, for the final product. Results of evaluation based on the sterilization and biological safety testing of sub-component were submitted.
Bio-derived Device (Quality)	Aug. 13, 2015 Total review time: 97 days Regulatory review time: 41 days	Jan. 17, 2014 No clinical study results	56	CoreValve (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A self-expanding biological percutaneous aortic valve (porcine pericardial valve) system used for transcatheter valve implantation in the native aortic valve for patients with symptomatic severe aortic stenosis attributed to sclerosis and degeneration of the cusp of the native aortic valve, for whom surgery cannot be performed. The application was submitted to change the manufacturing process of this device (viral inactivation process). (A "partial change" application submitted during the post-market performance review period)

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Products Approved in FY 2015: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	Jun. 3, 2015 Total review time: 239 days Regulatory review time: 96 days	Dec. 17, 2014 Foreign clinical study results	1	Tecnis Multifocal 1-Piece (AMO Japan K.K.)	Change	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near and/or far vision in patients with aphakia. This application is for a partial change to mainly add a low ADD model to the current models. Results of comparative studies using an existing approved monofocal posterior chamber lens as controls to evaluate clinical efficacy and fundamental safety, including visual function of the additional model as a multifocal posterior chamber lens, were submitted.
1	Jul. 8, 2015 Total review time: 265 days Regulatory review time: 104 days	Dec. 21, 2011 Foreign clinical study results	2	Catalys Precision Laser (AMO Japan K.K.)	Approval	Instrument & apparatus 31 Ophthalmic pulsed laser surgical instrument	An ophthalmic pulsed laser surgical instrument used for the anterior capsulotomy, the lens fragmentation, and creation of corneal incisions in cataract surgery. A foreign clinical study was conducted to confirm that this device has no particular issues as compared with the conventional standard technique used in cataract surgery.
1	Aug. 28, 2015 Total review time: 423 days Regulatory review time: 203 days	Jun. 27, 2003 Domestic clinical study results	3	MED-EL Middle Ear Implant VSB (MED-EL Elektro-Medizinische Ger äte GmbH)	Approval	Medical products 4 Middle Ear Implant	A middle ear implant system that processes signals incorporated from a microphone and vibrates a floating mass transducer implanted in the middle ear. Domestic clinical studies were conducted to confirm improved hearing in patients with conductive hearing loss or with mixed conductive-sensorineural hearing loss.
1	Sep. 16, 2015 Total review time: 266 days Regulatory review time: 143 days	Jan. 29, 2014 Foreign clinical study results	4	Air Optix Colors (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Daily wear, two-week replacement, reusable colored contact lenses with vision correction, and reusable colored contact lenses without vision correction. These contact lenses have additional feature of colored ring-shaped regions to the previously approved two-week replacement, silicone hydrogel contact lenses, “Air Optix (22000BZX00109000)”. Novelty was recognized in clear coat which directly contacts with the cornea. Results from multicenter, randomized, open clinical studies conducted in the United States were submitted to confirm efficacy and safety in wearing the lenses to correct visual acuity.
1	Sep. 16, 2015 Total review time: 266 days Regulatory review time: 143 days	Jan. 29, 2014 Foreign clinical study results	5	Air Optix Bright (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Daily wear, two-week replacement, reusable colored contact lenses with vision correction, and reusable colored contact lenses without vision correction. These contact lenses have additional feature of colored ring-shaped regions to the previously approved two-week replacement, silicone hydrogel contact lens “Air Optix (22000BZX00109000)”. The application was submitted for obtaining multiple brand names for “Air Optix Colors.”
Ophthalmology and Otorhinolaryngology	Oct. 19, 2015 Total review time: 263 days Regulatory review time: 159 days	- Domestic clinical study results	6	1 Day Menicon PremiO (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Daily wear, single-use, colored contact lenses for correction of visual acuity. The lens is composed of silicone hydrogel with a water content of 56% and an oxygen permeability (Dk) of 64, and is wholly colored in pale blue, containing ultraviolet absorber. Plasma treatment on the surface of the lens improves the wetness of the lens surface at the time of wearing. Novelty was recognized in the raw material. Results from single-arm, open-label, clinical studies conducted in Japan were submitted to confirm efficacy and safety in wearing the lenses to correct visual acuity.
Ophthalmology and Otorhinolaryngology	Oct. 28, 2015 Total review time: 188 days Regulatory review time: 91 days	Aug. 30, 2013 Domestic clinical study results	7	MyDay (CooperVision Japan, Inc.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Daily wear, single-use, colored contact lenses for correction of visual acuity. The lens is composed of stenfilcon A, a silicone hydrogel material with a water content of 54% and an oxygen permeability (Dk) of 80, and is wholly colored in pale blue, containing ultraviolet absorber. Novelty was recognized in the raw material. Results from single-arm, open-label, clinical studies conducted in Japan were submitted to confirm efficacy and safety in wearing the lenses to correct visual acuity.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
2	Jul. 17, 2015 Total review time: 263 days Regulatory review time: 82 days	Aug. 20, 2014 Foreign clinical study results	8	Straumann Implant (Roxolid SLActive) BLT (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	A bone level dental implant, which is to be placed into the jawbone and has an apically tapered root apex. Similar to the approved device “Straumann Implant (SLActive) BL” (Approval No. 22600BZX00257000), this device is supplied in a sealed vial filled with normal saline to keep hydrophilic nature of titanium until just before use, which accelerates the osseointegration and enables the early loading. This device has the identical shape and roughened surface treatment to the previously approved device “Straumann Implant (Ti SLA) BLT” (Approval No. 22700BZX00167000). However, this device adopts a titanium alloy with zirconium as a raw material to improve strength as compared with the approved device made of pure titanium. Results from multicenter, randomized, comparative studies conducted in foreign countries were submitted to demonstrate that the device has a bone bonding ability equivalent to that of the approved device made of pure titanium.
2	Aug. 26, 2015 Total review time: 413 days Regulatory review time: 189 days	Feb. 26, 2009 Foreign clinical study results	9	Straumann Implant (Roxolid SLActive) BL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	A bone level dental implant, which is placed into the jawbone and has a straight root apex. Similar to the approved device “Straumann Implant (SLActive) BL” (Approval No. 22600BZX00257000), this device is supplied in a sealed vial filled with normal saline to keep hydrophilic nature of titanium until just before use, which accelerates the osseointegration and enables the early loading. This device adopts a titanium alloy with zirconium as a raw material to improve strength as compared with the approved device made of pure titanium. Results from multicenter, randomized, comparative studies conducted in foreign countries were submitted to demonstrate that the device has a bone bonding ability equivalent to that of the approved device made of pure titanium.
Dentistry and Oral Medicine	Dec. 25, 2015 Total review time: 540 days Regulatory review time: 315 days	Feb. 26, 2009 Foreign clinical study results	10	Straumann Implant (Roxolid SLActive) TL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	A tissue level dental implant, which is partially or wholly placed into the jawbone. The device has the identical shape and surface treatment to the previously approved device “Straumann Implant (SLActive) TL” (Approval No. 22600BZX00016000). The point of improvement is that the device adopts a titanium alloy with zirconium as a raw material to improve strength. Results from foreign clinical studies were submitted for the evaluation of the efficacy and safety of this raw material.
3-1	Jul. 31, 2015 Total review time: 189 days Regulatory review time: 92 days	Sep. 3, 2014 Foreign clinical study results	11	XIENCE Alpine Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-4.25 mm and a delivery catheter used to implant a stent to the site of stenosis. The application was submitted for an additional stent size of 4.0 mm diameter. The added stent of 4.0 mm diameter is identical to the approved stent of 3.5 mm diameter. The stent delivery system is identical to the approved product except for the balloon size. (A "partial change" application) Results from clinical studies conducted using the company's own approved product with a stent identical to this product were submitted for evaluation of the efficacy and safety of this added size in clinical use.
3-1	Aug. 7, 2015 Total review time: 346 days Regulatory review time: 135 days	- Global clinical trial results	12	Ultimaster (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease and a delivery catheter used to implant the stent at stenotic lesions. The coating layer of the stent is composed of sirolimus and bioabsorbable polymer only, so that the stent behaves as a bare-metal stent in the late phase after the stent implantation. Results from the global clinical trials conducted to evaluate the efficacy and safety of this device for patients with symptomatic ischemic heart disease were submitted.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 9, 2015 Total review time: 412 days Regulatory review time: 234 days	May 6, 2011 Foreign clinical study results	13	AFX Stent Graft System (Cosmotec Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	AFX Stent Graft System consists of a stent graft and delivery system for the endovascular treatment of infrarenal abdominal aortic aneurysms. The device has the basic structure of the company's own approved product “Powerlink Stent Graft System” (Approval No. 22000BZX00110000) (hereinafter referred to as “Powerlink”) with thinner outer diameter of the delivery catheter achieved by thinning the graft material. The indications for this device are the same as those for the Powerlink. In addition, a suprarenal cuff extension, which was not included in the Powerlink, was added as a component. Results from foreign clinical studies were submitted for the evaluation of the efficacy and safety of the cuff extension.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 22, 2015 Total review time: 269 days Regulatory review time: 156 days	- Domestic clinical study results	14	LSO1470 Laser (Medico's Hirata Inc.)	Approval	Instrument & apparatus 31 Diode laser	A laser surgical device for treatment of varicose veins of lower extremities by guiding the laser light oscillated from semiconductor laser element into a fiber and irradiating a vein of lower extremities to occlude the saphenous vein. The wavelength of the laser is 1470 nm. In order to verify the efficacy and safety of the product, a single-arm clinical study was conducted to compare the clinical study results of the approved product of 980 nm “ELVeS Laser” (Approval No. 22200BZX00660000).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 8, 2016 Total review time: 326 days Regulatory review time: 158 days	Jul. 21, 2015 Global clinical trial results	15	Innova Vascular Stent (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A self-expanding vascular stent used for the treatment of symptomatic vascular disease in superficial femoral artery or proximal popliteal artery, with reference vessel diameters from 4 mm to 7 mm, lesion lengths up to 150 mm on each limb, and for treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. Results from global clinical trial were submitted to evaluate the efficacy and safety of the device in the treatment of symptomatic vascular diseases.
3-2	Jul. 6, 2015 Total review time: 684 days Regulatory review time: 483 days	Dec. 3, 2001 Domestic clinical study results Foreign clinical study results	16	Bioglue Surgical Adhesive (Century Medical, Inc.)	Change	Medical products 4 Albumin-use adhesive	A surgical adhesive consisting of two solutions: glutaraldehyde and bovine serum albumin. The product has already been approved (approval No. 22200BZY00003000) for the use for adhesion and hemostasis at the suture site of an artificial blood vessel associated with closure of aortic dissection and a false lumen (including dissecting aneurysm of the aorta) as its intended use. The application was submitted to expand the indications to “assistance in adhesion and hemostasis at the resection/suture site of the aorta and at the suture site of the heart.” (A "partial change" application) Results from domestic and foreign clinical studies on cardiovascular surgeries, etc. were submitted for evaluation of the efficacy and safety of this product.
3-2	Jul. 23, 2015 Total review time: 266 days Regulatory review time: 169 days	- Foreign clinical study results Domestic clinical study results	17	Cook Zenith AAA-LP Endovascular Graft (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft system for abdominal aortic aneurysms which has the basic structure of the company's own approved product “Cook Zenith AAA Endovascular Graft” (Approval No. 21800BZY10175000) with the smaller outer diameter of the delivery catheter achieved by thinning the graft material. Results from domestic and foreign clinical studies were submitted for the evaluation of the efficacy and safety of this device for patients with abdominal aortic aneurysm.
3-2	Aug. 28, 2015 Total review time: 184 days Regulatory review time: 104 days	- Clinical evaluation report	18	Inoue Balloon for Aortic Valve (Toray Industries, Inc.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for valvuloplasty	A balloon catheter used for percutaneous transluminal aortic valvuloplasty (PTAV) for aortic valve stenosis. The device has identical shape and structure to those of the approved product, Inoue Balloon for mitral valve (Approval No. 16300BZZ01718000). A clinical evaluation report was submitted to demonstrate the safety and efficacy on use of this product in PTAV.

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Cardiopulmonary Circulation	Oct. 19, 2015 Total review time: 174 days Regulatory review time: 104 days	Jun. 24, 2014 Foreign clinical study results	19	Solo Stentless Biological Valve (Sorin Group Italia S.r.l.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	A stentless biological valve made of bovine pericardial membrane to replace the malfunctioning aortic valve due to disease or injury. The device is designed to be implanted in the supra annular position with a single suture line, which was impossible with conventional stentless biological valves. Results from foreign clinical studies conducted based on ISO 5840 were submitted for the evaluation of the efficacy and safety of this product.
Cardiopulmonary Circulation	Nov. 6, 2015 Total review time: 329 days Regulatory review time: 214 days	- Foreign clinical study results	20	Accolade MRI (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	An implantable cardiac pacemaker used to treat bradycardia. Patients implanted with the device can have an MRI scan only when the condition meets imaging criteria. A clinical evaluation report was submitted to demonstrate the safety of this device in MRI scans. In addition, results from foreign clinical studies were submitted for evaluation of the efficacy and safety of a function that automatically regulates the pulse amplitude in atrial pacing.
Cardiopulmonary Circulation	Nov. 6, 2015 Total review time: 329 days Regulatory review time: 214 days	- Clinical evaluation report	21	Ingevity AFx (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker lead	A pacemaker lead used when connected to an implantable cardiac pacemaker, etc. Patients implanted with the device can have an MRI scan only when the condition meets imaging criteria. A clinical evaluation report summarizing the clinical data on the product in foreign countries was submitted for the evaluation of the safety of this device in MRI scans.
Cardiopulmonary Circulation	Nov. 6, 2015 Total review time: 329 days Regulatory review time: 214 days	- Clinical evaluation report	22	Ingevity (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker lead	A pacemaker lead used when connected to an implantable cardiac pacemaker, etc. Patients implanted with the device can have an MRI scan only when the condition meets imaging criteria. A clinical evaluation report summarizing the clinical data on the product in foreign countries was submitted for the evaluation of the safety of this device in MRI scans.
Cardiopulmonary Circulation	Nov. 18, 2015 Total review time: 357 days Regulatory review time: 279 days	- Domestic clinical study results	23	SATAKE･HotBalloon Generator (Toray Industries, Inc.)	Approval	Instrument & apparatus 29 Electronic surgical unit for percutaneous ablation	A high-frequency generator used for percutaneous catheter ablation to treat tachyarrhythmia. The device was developed as a high-frequency generator used exclusively with the “SATAKE HotBalloon Catheter” (Approval No. 22700BZX00355000). Results from domestic clinical studies using the previous product as an investigational device were submitted to verify the efficacy and safety in patients with drug-resistant symptomatic paroxysmal atrial fibrillation in comparison with control groups receiving antiarrhythmic drugs.
Cardiopulmonary Circulation	Nov. 27, 2015 Total review time: 245 days Regulatory review time: 153 days	Oct. 2, 2015 Domestic and foreign clinical study results	24	Synergy Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 34 mm or less) with a reference vessel diameter of 2.25-4.00 mm and a delivery catheter used to implant a stent at the site of stenosis. Results from domestic and foreign clinical studies with the use of previous products were attached to demonstrate that this device has efficacy and safety equivalent to those of the approved coronary stents.
Cardiopulmonary Circulation	Dec. 9, 2015 Total review time: 230 days Regulatory review time: 130 days	- Domestic clinical study results	25	Kaneka Bare Metal Stent CO-R1 (Kaneka Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent used for the treatment (including treatment of acute or impending occlusion associated with failure of intervention therapy) of patients with symptomatic ischemic heart disease who have a new or recurrent coronary lesion (a lesion length of 28 mm or less) with a reference vessel diameter of 3.0-4.0 mm. Results from domestic clinical studies were submitted for evaluation of the efficacy and safety of this device.

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Cardiopulmonary Circulation	Jan. 12, 2016 Total review time: 817 days Regulatory review time: 179 days	Jun. 10, 2010 Foreign clinical study results	26	AtriCure Left Atrial Appendage Clip (Century Medical, Inc.)	Approval	Instrument & apparatus 30 Clip for cardiac tissue	A device used to occlude the left atrial appendage in patients with a risk of thromboembolism including atrial fibrillation and other conditions during an open-heart cardiovascular surgery. Results from foreign clinical studies conducted to evaluate the efficacy and safety of the device were submitted.
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	27	Durata ICD Screw-in Lead (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device consists of an implantable defibrillator/pacemaker lead and accessories that are connected to a pulse generator for use in the treatment of tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	28	Durata ICD Lead Single Coil (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device consists of an implantable defibrillator/pacemaker lead and accessories that are connected to a pulse generator for use in the treatment of tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	29	Ellipse ICD (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device consists of an implantable defibrillator and accessories. It is intended to be used for patients at high risk of sudden death due to ventricular tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	30	Ellipse Limited ICD (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device consists of an implantable defibrillator and accessories. It is intended to be used for patients at high risk of sudden death due to ventricular tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 108 days	- Clinical evaluation report	31	Assurity MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by delivering the electrical stimulus to myocardium for a long period. The patients implanted with the device can have an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies related to the device was submitted to evaluate the safety of the device on MRI scan.
4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 118 days	- Clinical evaluation report	32	Gore Viabahn Stent Graft (W. L. Gore & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	The device is an implantable cardiac pacemaker to regulate the heart rhythm by delivering the electrical stimulus to myocardium for a long period. The patients implanted with the device can have an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies related to the device was submitted to evaluate the safety of the device on MRI scan.

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4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 120 days	- Clinical evaluation report	33	Tendril STS (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable cardiac pacemaker lead. The patients implanted with the specific model of the leads can have an MRI scan under specific conditions. The application is for a partial change for the leads that can be labeled as MR conditional. A clinical evaluation report summarizing the results of the foreign clinical studies related to the device was submitted to evaluate the safety of the device on MRI scan.
4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 120 days	- Clinical evaluation report	34	Tendril STS J (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable cardiac pacemaker lead. The patients implanted with the specific model of the leads can have an MRI scan under specific conditions. This application is submitted in relation to the partial change application for "Tendril STS" (Approval No. 22200BZX00085000), which is identical to this device and has obtained the approval for multiple trade names.
5	Jun. 24, 2015 Total review time: 1470 days Regulatory review time: 215 days	Sep. 4, 2007 Clinical evaluation report	35	ERBE JET2 (AMCO Inc.)	Approval	Instrument & apparatus 12 Hydraulic knife	A hydraulic knife used for incision, ablation, or resection of liver tissue. This knife incises, ablates, or resects the liver tissue using the hydraulic pressure energy of a high pressure water jetting from the tip of hand-held applicator. A clinical evaluation report was provided in order to evaluate that the safety of the technique using this product was not inferior to the conventional technique.
5	Aug. 5, 2015 Total review time: 390 days Regulatory review time: 185 days	Mar. 26, 2007 Clinical evaluation report	36	Revolix 120 (Takai Hospital Supply Co,. Ltd.)	Approval	Instrument & apparatus 31 Thulium YAG laser	A thulium YAG laser used for incision, hemostasis, coagulation and vaporization of soft biological tissue under direct vision or endoscopy. This device is also used for treatment of prostatic hyperplasia. Laser light irradiated from this device (wavelength of 2.0 μm, continuous wave) has a similar wavelength of the approved product, the holmium YAG laser (wavelength of 2.1 μm, pulse wave). However, this device irradiates a continuous wave and has increased maximum output as compared with that of the approved device. A clinical evaluation report was submitted to compare and evaluate the treatment outcomes between this device and existing therapies for transurethral prostate treatment, in which the high output is utilized.
5	Aug. 13, 2015 Total review time: 371 days Regulatory review time: 166 days	- Domestic clinical study results	37	Surefilter (Nipro Corporation)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter used for elimination of unnecessary metabolites and excess fluid in the blood of patients with renal failure complicated by cardiovascular diseases such as multiple organ failure, severe complications, and edema. This device has novelty in that the material of the hollow fiber membrane is polyether sulfone. Clinical studies were conducted to evaluate the usefulness of this device in patients with acute renal failure, etc., for whom slow continuous hemofiltration is indicated.
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 24, 2015 Total review time: 378 days Regulatory review time: 235 days	- Clinical evaluation report	38	Electrohydraulic Lithotripter Lithotron EL 27 (Century Medical, Inc.)	Approval	Instrument & apparatus 12 Intracorporeal electrohydraulic shock wave lithotripter	An intracorporeal electrohydraulic shock wave lithotripter that crushes gallstones using shock waves generated by a high-voltage discharge between electrodes exposed at the tip of probe. Test results on electrical safety, electromagnetic compatibility, biological safety, stability, durability, and performance of this device were submitted. In addition, clinical results on electrohydraulic shock wave lithotripsy (hereinafter referred to as “EHL”) of this device for gallstones were evaluated. A clinical evaluation report was submitted to compare the treatment outcomes of EHL for gallstones between by this device and by other devices employing the same principle as this device (including the approved devices).

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Gastroenterology, Genitourinary, and Reproductive Medicine	Dec. 21, 2015 Total review time: 360 days Regulatory review time: 235 days	- Clinical evaluation report	39	Modulith (Sumire Medical Corporation)	Change	Instrument & apparatus 12 Extracorporeal lithotripter	An extracorporeal lithotripter used to generate shock waves and irradiate from outside the body to fragment and crush calculi formed in the body. The application was submitted to add the treatment of pancreatolithiasis to the previously approved intended use or indications. (A "partial change" application) In order to add the treatment of pancreatolithiasis, the efficacy equivalent to that of the approved device used for the treatment of pancreatolithiasis was assessed based on a clinical evaluation report. Since the safety of treatment of pancreatolithiasis by focal pressure exceeding that of the approved device was difficult to evaluate with the clinical evaluation report, the safety was guaranteed through restrictions with the contraindications and prohibitions listed in the package insert.
Gastroenterology, Genitourinary, and Reproductive Medicine	Feb. 24, 2016 Total review time: 462 days Regulatory review time: 232 days	Sep. 15, 2010 Domestic clinical study results	40	Ceralas HPD Laser (Integral Corporation)	Approval	Instrument & apparatus 31 Diode laser	A diode laser with a central wavelength of 980 nm (continuous wave) used in laser vaporization for benign prostatic hyperplasia. The device differs from existing approved medical devices indicated for benign prostatic hyperplasia in that the use of continuous wave laser with a wavelength of 980 nm and the maximum output power 300 W emitted from the oscillator. Domestic clinical study results were submitted to evaluate the efficacy and safety of the device in the treatment of benign prostatic hyperplasia.
Gastroenterology, Genitourinary, and Reproductive Medicine	Mar. 11, 2016 Total review time: 268 days Regulatory review time: 128 days	- Domestic clinical study results	41	P (LA/CL) Suture (Kono Seisakusho Co., Ltd.)	Approval	Medical products 2 Synthetic absorbable suture	Synthetic monofilament absorbable sutures prepared from lactide-caprolactone copolymer fibers. New raw materials were used to improve the suture workability. Therefore, domestic clinical study results were attached to evaluate the efficacy and safety of the device in procedures such as suturing, anastomosis, and ligation in general surgery.
6-1	Sep. 17, 2015 Total review time: 269 days Regulatory review time: 161 days	- Domestic clinical study results	42	AG-PROTEX HIP System (KYOCERA Medical Corporation)	Approval	Medical products 4 Total hip prosthesis	A product containing a small amount of silver in the hydroxyapatite coating of the company's own approved acetabular cup, "SQRUM HA Shell" (Approval No. 22500BZX00152000) and femur stem " KYOCERA PerFix HA Stem Fullcoat" (Approval No. 22100BZX01118000), in anticipation of an antibacterial effect. Results from a domestic clinical study were submitted to confirm that the device has equivalent efficacy to the approved hip prosthesis and that no serious malfunction occurs.
6-2	Apr. 21, 2015 Total review time: 299 days Regulatory review time: 110 days	Jan. 7, 2010 Foreign clinical study results	43	Juvederm Vista Ultra XC (Allergan Japan KK)	Approval	Medical Products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft-tissue using hyaluronic acid used to correct facial wrinkles and folds. The product is "Juvederm Vista Ultra" (22600BZX00108000), an existing approved product of Allergan Japan KK, with added lidocaine hydrochloride to relieve pain at the time of treatment. Results from randomized, within-subject controlled studies conducted in the United States were submitted to verify the effect of pain relief compared to that of the existing approved product.
6-2	Apr. 21, 2015 Total review time: 299 days Regulatory review time: 110 days	Jan. 7, 2010 Foreign clinical study results	44	Juvederm Vista Ultra Plus XC (Allergan Japan KK)	Approval	Medical Products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft-tissue using hyaluronic acid used to correct facial wrinkles and folds. The product is "Juvederm Vista Ultra Plus" (22600BZX00109000), an existing approved product of Allergan Japan KK, with added lidocaine hydrochloride to relieve pain at the time of treatment. Results from randomized, within-subject controlled studies conducted in the United States were submitted to verify the effect of pain relief compared to that of the existing approved product.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
6-2	Jun. 9, 2015 Total review time: 473 days Regulatory review time: 64 days	Jan. 29, 2010 Foreign clinical study results	45	Restylane Lido (Galderma KK)	Approval	Medical Products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft-tissue made of hyaluronic acid designed to improve appearance of facial wrinkles and folds, which is indicated for injection into the mid to deep dermis. Lidocaine hydrochloride is added to relieve pain at the time of injection. A report on prospective, randomized, within-subject controlled study conducted in the United States, and 3 additional clinical study reports were submitted in order to verify the effects on correction of nasolabial fold and pain relief.
6-2	Jun. 9, 2015 Total review time: 473 days Regulatory review time: 64 days	Jan. 29, 2010 Foreign clinical study results	46	Restylane Perlane Lido (Galderma KK)	Approval	Medical Products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft-tissue made of hyaluronic acid designed to improve appearance of facial wrinkles and folds, which is indicated for injection into the deep dermis to superficial subcutis. Lidocaine hydrochloride is added to relieve pain at the time of injection. A report on prospective, randomized, within-subject controlled study conducted in Europe, and 5 additional clinical study reports were submitted in order to verify the effects on correction of nasolabial fold and pain relief.
Orthopedic and Plastic Surgery	Dec. 2, 2015 Total review time: 383 days Regulatory review time: 173 days	- Domestic clinical study results	47	Biohesive Ag Light (Alcare Co., Ltd.)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	A hydrocolloid dressing containing silver sulfadiazine in anticipation of an antibacterial effect. The device is intended to be used for wounds reaching into dermis, which is the limited-use purpose of the company's own approved antibacterial wound dressing and protecting material “Biohesive Ag” (Approval No. 22300BZX00001000). Results from clinical studies previously submitted for application of the above approved product and data on those results with new analyzation using a stratified analysis were submitted to confirm the efficacy and safety of this product in wounds reaching into dermis.
Orthopedic and Plastic Surgery	Mar. 9, 2016 Total review time: 217 days Regulatory review time: 111 days	- Clinical evaluation report	48	Lima Delta Ceramic Liners (Lima Japan K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	The device is an acetabular component for a hip prosthesis made of the material "Biolox delta" (manufactured by CeramTec) and is used in combination with the approved Lima's device, "Lima Delta Ceramic Head" (Approval No. 22500BZX00311000), which is made of the same material as the new device. Given that this is the Lima's first liner made of Biolox delta and the novelty exists in the combination of raw materials, a clinical evaluation report based on the post-market performance outside Japan was submitted to confirm the equivalent efficacy and safety of the new combination to those of the conventional combination using different materials.
Orthopedic and Plastic Surgery	Mar. 28, 2016 Total review time: 396 days Regulatory review time: 123 days	Aug. 11, 2014 Foreign clinical study results	49	enLIGHTen (Cutera K.K.)	Approval	Instrument & apparatus 31 Neodymium:YAG laser	Q-switched neodymium (Nd): YAG laser used for the vaporization and removal of benign pigmented lesions on the body surface. The pulse width can be set at 750 psec or 2 nsec, allowing the treatment with high peak powers. Foreign clinical study results were submitted to evaluate the risk of complications or adverse events associated with an increase in peak power.
Orthopedic and Plastic Surgery	Mar. 30, 2016 Total review time: 496 days Regulatory review time: 148 days	Feb. 5, 2004 Clinical evaluation report	50	SmartSet GMV Endurance Gentamicin Bone Cement (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic Bone Cement	This product is orthopedic bone cement containing gentamicin sulfate as antibiotic, and is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared. A clinical evaluation report was submitted to demonstrate that a necessary fixation can be obtained, and the safety of the device is equivalent to that of bone cements without antibiotics.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Mar. 30, 2016 Total review time: 581 days Regulatory review time: 271 days	- Domestic clinical study results	51	Chest Tomosynthesis CAD: Cadviser TS （Shimadzu Corporation)	Approval	Instrument & apparatus 9 Diagnostic x-ray imaging system workstation	An X-ray diagnostic imaging workstation intended to provide imaging information for diagnosis, which is the computer-processed image data of the lung field from thoracic tomosynthesis images produced using an X-ray fluoroscopy system or an X-ray diagnostic system. The device has the computer-aided detection (CAD) functions, in which potential pulmonary nodules are extracted and the information is provided to prevent misdiagnosis that the nodules are overlooked by radiologists. This CAD function is intended to assist in reading images by radiologists, but not to perform screening or definitive diagnosis of lung cancer based only on the results provided by the device. Domestic clinical study results were submitted to evaluate the clinical diagnostic ability of the CAD function.

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Products Approved in FY 2014: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
1	Mar. 10, 2015 Total review time: 126 days Regulatory review time: 80 days	- No clinical study results	1	Hoya CTR (Hoya Corporation)	Change	Medical products 4 Ophthalmic intracapsular ring	An intracapsular ring inserted into a lens capsule is used when surgical difficulty can be expected in a cataract surgery because of the risks associated with completion of the surgery due to a weakness or rupture of Zinn's Zonule. An application for partial changes of approval application for medical device to mainly add the insertion method using an injector in the usage instructions. (A partial change during the reexamination period)
3-1	Apr. 7, 2014 Total review time: 255 days Regulatory review time: 110 days	Nov. 21, 2013 Global clinical trial and foreign clinical study results	2	Promus Premier Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent coated with everolimus to inhibit neointimal proliferation and a delivery catheter. The delivery catheter was improved by adding a link at the proximal end of a stent to produce axial strength to be superior to the original product. Clinical studies were conducted to confirm the efficacy and safety of this product in the treatment of symptomatic ischemic diseases.
3-1	May 20, 2014 Total review time: 110 days Regulatory review time: 76 days	Dec. 21, 2012 Domestic clinical study results	3	XIENCE Xpedition Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-3.75 mm and a delivery catheter used to implant a stent to the coronary stenosis site. This application for partial changes of approval application for medical device to add a stent size of 2.25mm diameter and change a drug release profile determination method. The added stent is identical to the company's approved product "XIENCE PRIME SV Drug-Eluting Stent (22500BZX00070000, hereinafter referred to as XIENCE PRIME SV). The stent delivery system is identical to that of the product of 2.5 mm diameter except for the balloon size. Results from clinical studies on "XIENCE PRIME SV" were submitted to confirm the efficacy and safety of this product in the treatment of symptomatic ischemic diseases.
3-1	Jun. 12, 2014 Total review time: 43 days Regulatory review time: 41 days	- No clinical study results	4	XIENCE PRIME SV Drug-Eluting Stent System (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 22 mm or less) with a reference vessel diameter of 2.25-2.5 mm. This application for a partial change of approval application for medical device to modify inconsistent information provided in the raw material or component field. (A partial change during the reexamination period)
3-1	Jul. 25, 2014 Total review time: 91 days Regulatory review time: 48 days	- No clinical study results	5	Zilver Flex Vascular Stent for SFA (Cook Japan Inc.)	Change	Instrument & apparatus 7 Stent for blood vessel	A vascular stent to be used in patients with symptomatic vascular diseases of the above-the-knee femoropopliteal artery with reference vessel diameter of 4-7 mm. This product is used for the treatment for acute or impending occlusion caused by failure of intervention therapy or for dissection, etc. after the maximum number of "Zilver PTX Drug-Eluting Peripheral Stent" implantations. This application for a partial change of approval application for medical device to add a manufacturing site. (A partial change during the reexamination period)
3-1	Sep. 25, 2014 Total review time: 360 days Regulatory review time: 218 days	Nov. 7, 2012 Domestic clinical study results	6	SMART CONTROL Stent (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for iliac artery	A self-expanding nickel-titanium alloy stent inserted into the site of lesion in the iliac artery and/or the superficial femoral artery to expand/maintain a vascular lumen. This application for a partial change to add an elective therapy for symptomatic vascular diseases to indications for the superficial femoral artery. A clinical study was conducted to evaluate the safety and efficacy of this product in elective patients. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-1	Sep. 25, 2014 Total review time: 360 days Regulatory review time: 218 days	Nov. 7, 2012 Domestic clinical study results	7	SMART Stent (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for blood vessel	A self-expanding nickel-titanium alloy stent inserted into the site of lesion in the superficial femoral artery to expand/maintain a vascular lumen. This application to add an indication of elective therapy for symptomatic vascular diseases. A clinical study was conducted to evaluate the safety and efficacy of this product in elective patients. (A partial change during the reexamination period)
3-1	Jan. 14, 2015 Total review time: 404 days Regulatory review time: 178 days	May 22, 2015 Domestic and global clinical study results	8	Misago (Terumo Corporation)	Change	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent and a delivery system to deliver the stent to the site of lesion, used for the treatment of symptomatic artery disease by dilatation of artery and maintenance of the lumen with target vessel diameter of 4-7 mm and target lesion of 40-150 mm in the superficial femoral artery region, and for the treatment of acute or impending occlusion associated with unsuccessful intervention treatment in the lesion. An application for a partial change to add palliative treatment for symptomatic vascular disease to the indications of this product. Clinical studies were conducted to evaluate efficacy and safety of this product for palliative cases.
3-2	May 29, 2014 Total review time: 358 days Regulatory review time: 172 days	Jun. 12, 2012 Foreign clinical study results	9	AMPLATZER Vascular Plug 4 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	This device is used to occlude blood vessels, and reduce, block, or modify blood flow, by transdermally inserting and placing it in arteries/veins, except blood vessels within the heart and the skull. It was changed to a form with two conical blocks, and improved its components to reduce the profile of the whole plug (the diameter in its closed state) so that the device can be advanced through an imaging catheter, maintaining the same barrier area to blood flow as that of the approved product “AMPLATZER Vascular Plug (approval No.: 22400BZX00361000) (hereinafter referred to as AVP). Results from domestic clinical studies using AVP were submitted as clinical data of this product because several non-clinical studies including design verification and animal studies had shown that the same efficiency of this product is secured as that of AVP.
3-2	Nov. 7, 2014 Total review time: 728 days Regulatory review time: 281 days	- Foreign clinical study results	10	COOK Zenith Dissection Endovascular System (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of acute complicated Stanford type B aortic dissection, consisting of a stent graft that is placed to close the primary entry tear, a bare stent that enlarges compressed or narrowed intravascular lumen due to aortic dissection, and a delivery system that delivers/places them in the lesions. Results from clinical studies were submitted to evaluate efficacy and safety on this product for patients with acute complicated Stanford type B aortic dissection.
3-2	Nov. 14, 2014 Total review time: 135 days Regulatory review time: 81 days	- No clinical study results	11	Codman Enterprise VRD (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system to prevent the protrusion and/or dropout of embolic coils into/from the parent artery during coil embolization. An application for partial changes to add VRD that improves conformability and visibility of the vascular wall, and a delivery system that improves the operability. This product is an orphan medical device. (A partial change during the reexamination period)
3-2	Dec. 24, 2014 Total review time: 398 days Regulatory review time: 146 days	Oct. 26, 2001 Clinical evaluation report	12	BIOPATCH Protective Disk with CHG (Johnson & Johnson K.K.)	Approval	Medical products 4 Protective patch for puncture site	A sterilized disk pad with a slit, which consists of a layer of polyurethane foam impregnated with chlorhexidine gluconate antimicrobial constituent and a covering layer of foam. This product protects the insertion site of various percutaneous devices by covering the site and absorbing the fluids like wound exudate. In patients who are inserted with central venous or arterial catheters, this product also reduces the incidence of catheter-related bloodstream infections and local infections. Clinical evaluation report summarizing the clinical results on this product was submitted to evaluate the reduction of catheter-related bloodstream infections and safety of this product.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-2	Mar. 24, 2015 Total review time: 361 days Regulatory review time: 240 days	Jun. 16, 2014 Domestic and foreign clinical study results	13	Sapien XT (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic heart valve system is used for transcatheter valve implantation for patients with symptomatic severe aortic valve stenosis and for whom surgical aortic valve replacement cannot be performed due to the risks of complications. An application for a partial change of approval application to add the 20 mm- and 29 mm-diameter valves as the variation in size. A clinical study was conducted to confirm the equivalence in efficacy and safety between the new sizes and approved existing sizes. (A partial change during the reexamination period)
3-2	Mar. 25, 2015 Total review time: 357 days Regulatory review time: 198 days	Jan. 17, 2014 Domestic and foreign clinical study results	14	CoreValve (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A self-expanding biological percutaneous aortic valve (porcine pericardial valve) system is used for transcatheter valve implantation in the native aortic valve for patients with symptomatic severe aortic stenosis attributed to sclerosis and degeneration of the cusp of the native aortic valve, for whom surgery cannot be performed. A clinical study was conducted to evaluate the efficacy and safety of this product and to confirm the compatibility to the domestic medical environment.
4	May 30, 2014 Total review time: 287 days Regulatory review time: 144 days	- Clinical evaluation report	15	Entovis MRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	May 30, 2014 Total review time: 287 days Regulatory review time: 144 days	- Clinical evaluation report	16	Safio S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker lead	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 5, 2014 Total review time: 108 days Regulatory review time: 106 days	- Clinical evaluation report	17	Etrinsa 8-T ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 5, 2014 Total review time: 108 days Regulatory review time: 106 days	- Clinical evaluation report	18	Etrinsa 6 ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 30, 2014 Total review time: 271 days Regulatory review time: 95 days	- No clinical study results	19	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom the need for cardiac transplantation is indicated, showing continuous decompensation in spite of drug therapy or circulation assist techniques such as an external ventricular assist system, and for whom it is considered difficult to survive without a heart transplant. An application for a partial change to alter the alarm setting when the automatic restart function of a blood pump (automatic return mechanism) works. (A partial change during the reexamination period) [Orphan device]

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4	Jul. 31, 2014 Total review time: 265 days Regulatory review time: 177 days	- No clinical study results	20	Solia JT (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker lead	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to add a new lead size of 45 cm in length. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 89 days Regulatory review time: 73 days	- Clinical evaluation report	21	Iforia 7 ICD ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	22	Linox Smart Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	23	Linox Smart Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	24	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Sep. 9, 2014 Total review time: 187 days Regulatory review time: 126 days	- Clinical evaluation report	25	Sentus ProMRI OTW BP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A pacemaker lead connected with an implantable pulse generator and implanted in the coronary vein. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Sep. 9, 2014 Total review time: 102 days Regulatory review time: 31 days	Jul. 26, 2013 No clinical study results	26	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A flexible over-the-wire balloon catheter inserted into a blood vessel using a conventional minimally invasive procedure. It is used in cryoablation of cardiac tissue. This application for partial changes of approval application to remove a leak detection wire traveling in an outer lumen, and to add a manufacturing site. (A partial change during the reexamination period)
4	Sep. 17, 2014 Total review time: 265 days Regulatory review time: 158 days	Apr. 27, 2010 Foreign clinical study results	27	Alair Bronchial Thermoplasty System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Bronchial thermoplasty catheter system	A catheter system used to apply high frequency energization to the bronchial wall to reduce asthmatic symptoms in patients aged 18 or older with severe asthma whose asthmatic symptoms are not well controlled with high-dose inhaled steroids and long-acting beta2-agonists. Foreign clinical studies were conducted to demonstrate its relieving effect on asthmatic symptoms.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 154 days	- Foreign clinical study results	28	Evera MRI ICD Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator intended for the treatment of ventricular tachycardia, etc. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company's own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 142 days	- Foreign clinical study results	29	Sprint Quattro MRI Screw-In Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable catheter electrode connected with an implantable defibrillator and a defibrillator with biventricular pacing. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company's own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 142 days	- Foreign clinical study results	30	Sprint Quattro MRI Screw-In Lead S (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable catheter electrode connected with an implantable defibrillator and a defibrillator with biventricular pacing. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company's own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 87 days Regulatory review time: 44 days	Dec. 10, 2010 No clinical study results	31	Medtronic CryoConsole (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical unit to be used for the treatment of arrhythmia. The device is for the exclusive use of cryoablation catheters. This application for a partial change of approval application for medical device to add a manufacturing site. The application falls under "expedited review of changes of manufacturing site" stated in "Acceleration of the Procedure for Changing or Adding Manufacturing Site of Medical Devices and In-vitro Diagnostics" (PFSB/ELD Notification No. 0330004, PFSB/CND Notification No. 0330012 dated on March 30, 2007). (A partial change during the reexamination period)
4	Oct. 9, 2014 Total review time: 164 days Regulatory review time: 95 days	Oct. 13, 2014 Foreign clinical study results	32	CapSureFIX Novus Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an implantable pacing lead used by connecting it to an implantable cardiac pacemaker or defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for requirements for imaging. The application is for a partial change to conditionally allow MRI scan with this device. Data on foreign clinical study results related to this product were submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	2014/10/20 Total review time: 343 days Regulatory review time: 86 days	Oct. 13, 2014 Foreign clinical study results	33	CapSureFIX Novus MRI Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to pulse generators including an implantable cardiac pacemaker or defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. Data on foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)

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4	Nov. 14, 2014 Total review time: 162 days Regulatory review time: 95 days	- Foreign clinical study results	34	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add a single-chamber type which conditionally allows MRI scan to the existing dual-chamber type. Data on foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 130 days Regulatory review time: 83 days	- Clinical evaluation report	35	Iperia 7 ICD DF-1 ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an implantable cardiac defibrillator used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. This product was developed based on the approved product "Ilesto 7 ICD Pro" (Approval No.: 22500BZX00292000). The major improvements from the approved product include the addition of conditions for the strength of static magnetic field used in MRI and an additional function for detecting ventricular tachycardia. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 105 days Regulatory review time: 80 days	- Clinical evaluation report	36	Itrevia 7 CRT-D ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with defibrillator function used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. This product was developed based on the approved product "Ilesto 7 CRT-D Pro" (Approval No.: 22500BZX00293000). The major improvement from the approved product is an additional function of ventricular tachycardia detection. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	37	Linox Smart Pro S (Biotronik Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	38	Linox Smart Pro SD (Biotronik Japan, Inc)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	39	Linox Smart Pro S DX (Biotronik Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- No clinical study results	40	Nuance MRI RF (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. Patients implanted with the device can undergo an MRI scan under specific conditions. The application is for a partial change to add concomitant medical devices to perform MRI scan. (A partial change during the reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- No clinical study results	41	Accent MRI RF (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. Patients implanted with the device can undergo an MRI scan under specific conditions. The application is for a partial change to add concomitant medical devices to perform MRI scan. (A partial change during the reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- Clinical evaluation report	42	IsoFlex Optim J (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead. The patient implanted with the device except for the 46 cm straight lead can undergo an MRI scan under specific conditions. The application is for a partial change to conditionally allow MRI scan with this device. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- Clinical evaluation report	43	IsoFlex Optim (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead. The patient implanted with the device except for the 46 cm straight lead can undergo an MRI scan under specific conditions. The application is for a partial change to conditionally allow MRI scan with this device. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Dec. 22, 2014 Total review time: 115 days Regulatory review time: 59 days	- No clinical study results	44	Ingenio MRI (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term in order to perform the treatment of bradycardia. The application is for a partial change to change the materials of the header part. (A partial change during the reexamination period)
4	Jan. 19, 2015 Total review time: 109 days Regulatory review time: 62 days	- No clinical study results	45	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an axial-flow implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who is are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survival without heart transplant. The application is for partial changes to mainly change the battery cell incorporated into the portable battery. (A partial change during the reexamination period)
4	Jan. 21, 2015 Total review time: 125 days Regulatory review time: 55 days	Jun. 29, 2012 No clinical study results	46	LifeVest Wearable Cardioverter Defibrillator (ZOLL Lifecor Corporation)	Change	Instrument & apparatus 12 Wearable defibrillator	The device is a wearable cardioverter defibrillator intended for the following patients: Patients for whom indication for an implantable cardiac defibrillator (ICD) is unconfirmed despite having a high risk of sudden cardiac death due to ventricular tachycardia or ventricular fibrillation; Patients in whom an ICD cannot be implanted immediately due to their medical conditions although ICD is indicated. This wearable cardioverter defibrillator is used in the period until the propriety of indication of ICD is determined or the implantation is performed. The application is for a partial change to add an attaching method of velocro to electrocardiogram electrodes without an adhesive to the existing direct adhesive method. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Feb. 3, 2015 Total review time: 418 days Regulatory review time: 174 days	- Clinical evaluation report	47	Beflex lead (Sorin CRM SAS)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to an implantable cardiac pacemaker. The application is for a partial change to allow MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Feb. 3, 2015 Total review time: 417 days Regulatory review time: 173 days	- Clinical evaluation report	48	Kora 100 (Sorin CRM SAS)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 4, 2015 Total review time: 132 days Regulatory review time: 87 days	- Clinical evaluation report	49	Itrevia 7 CRT-D QP ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function implanted in the chest or abdomen for the treatment of ventricular tachycardia, etc. by ventricular sensing, pacing and defibrillation. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 4, 2015 Total review time: 132 days Regulatory review time: 87 days	- Clinical evaluation report	50	Sentus ProMRI OTW QP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is a pacemaker lead with four electrodes at its tip used by placing it in the coronary vein and connecting it to an implantable pulse generator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical evaluation report	51	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used for conducting ventricular sensing and pacing, antitachycardia pacing, and defibrillation by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (A partial change during the reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical evaluation report	52	Protego Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used for conducting ventricular sensing and pacing, antitachycardia pacing, and defibrillation by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical study results	53	Iforia 7 ICD ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an implantable defibrillator used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change of approval application to add a model having a different header. (A partial change during the reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical study results	54	Solia S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change of approval application to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (A partial change during the reexamination period)
4	Mar. 26, 2015 Total review time: 125 days Regulatory review time: 97 days	- Foreign clinical study results	55	Sprint Quattro Screw-In Lead S (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable catheter electrode used by connecting it to an implantable defibrillator and a defibrillator with biventricular pacing. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change for some components with which an MRI scan can be conditionally conducted. In order to evaluate the safety of this product in MRI scans, the results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Mar. 26, 2015 Total review time: 125 days Regulatory review time: 97 days	- Foreign clinical study results	56	Sprint Quattro Screw-In Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable catheter electrode used by connecting it to an implantable defibrillator and a defibrillator with biventricular pacing. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change for some components with which an MRI scan can be conditionally conducted. In order to evaluate the safety of this product in MRI scans, the results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
5	Sep. 30, 2014 Total review time: 305 days Regulatory review time: 202 days	Apr. 18, 2014 No clinical study results	57	InterStim II Neurostimulator for Sacral Neuromodulation (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Implantable stimulator for bladder and bowel control	An implantable nerve stimulation system consisting of an electric stimulator and leads to be used in sacral nerve stimulation therapy for fecal incontinence. This application for a partial change of approval application to change a testing stimulator to a new type. A testing stimulator control is changed from a constant voltage control to a constant current control, while an implantable electric stimulator remains to be controlled by a constant voltage. (A partial change during the reexamination period)
6-1	Jun. 5, 2014 Total review time: 160 days Regulatory review time: 40 days	Jul. 20, 2006 Clinical evaluation report	58	Aequalis Reversed Shoulder Prosthesis (Tornier S.A.S.)	Change	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system used in patients with shoulder rotator cuff dysfunction. This application for partial changes to add new components (eccentric or other type of inserts and glenoid sphere, small-diameter and HA-coated base plate, conversion adaptor for anatomical type) and to add usage (fixation of glenoid component with specific bone graft: BIO-RSA). A clinical evaluation report was submitted to demonstrate that this device is equivalent to the approved product and that there is no new unacceptable risk while option for the product is extended by the added components and the usage.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
6-1	Sep. 25, 2014 Total review time: 118 days Regulatory review time: 79 days	Oct. 11, 2012 No clinical study results	59	Trabecular Metal Reverse Shoulder System (Zimmer K.K.)	Change	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system used in patients with shoulder rotator cuff dysfunction including arthropathy with tendon rupture and massive rotator cuff tears. This application for a partial change of approval application to add a new component with a changed base plate (extended post length and off-set model), which is intended to improve suitability to patients' bone shapes. Based on the results of non-clinical studies, it was judged that new additional clinical evaluation is not required, because it is difficult to assume that a new clinical risk is actualized by the difference from the approved product. (A partial change during the reexamination period)
6-1	Oct. 9, 2014 Total review time: 197 days Regulatory review time: 90 days	Aug. 18, 2011 Clinical evaluation report	60	Lima Reverse Shoulder System (Lima Japan K.K.)	Approval	Medical products 4 Total shoulder prosthesis	A shoulder prosthesis having the concept of a reversed shoulder prosthesis system in which the anatomical structure is reversed. It is used for cases of rotator cuff dysfunction such as a massive rotator cuff tears or rotator cuff tear arthropathy. When it is difficult to be combined with a reversed shape, it can be combined with an anatomical shape in humerus or total shoulder joint replacement. A clinical evaluation report was submitted to confirm that the efficacy and safety of this device are equivalent to the existing approved devices based on overseas usage histories and publications of this device and similar devices.
8	Jul. 3, 2014 Total review time: 415 days Regulatory review time: 200 days	- Domestic and foreign clinical study results	61	Radioactive Pharmaceutical Synthesizer NEPTIS Plug-01 (Eli Lilly Japan K.K.)	Approval	Instrument & apparatus 10 Radiopharmaceutical synthesizer	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound, florbetapir (18F) injection by remote control system indicated for the visualization of beta-amyloid plaque in the brain in patients with cognitive impairment who are suspected of having Alzheimer's disease. Results from non-clinical studies, and domestic and foreign clinical studies were submitted as evaluation data on the efficacy and safety of this product and florbetapir (18F) injection.
8	Nov. 7, 2014 Total review time: 322 days Regulatory review time: 180 days	Oct. 18, 2012 Foreign clinical study results	62	MR-Guided Focused Ultrasound Surgery System ExAblate 2000 (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 12 Ultrasound hyperthermia system	The device is a focused ultrosonic surgery system intended for heating and necrotizing target tissues by focusing ultrasound generated using an external transducer on internal targets. The application is for partial changes to (1) add a new indication, "relief of pain due to painful metastatic bone cancer" and (2) make an improvement intended to enhance operability in a previously approved indication, "improvement of symptoms of symptomatic uterine myoma." For (1), results of clinical study conducted to evaluate the efficacy and safety of this device in the new additional indication were submitted. For (2), results of non-clinical study conducted to evaluate efficiency of the additional capability, etc. in previously approved indication were submitted.
8	Dec. 12, 2014 Total review time: 73 days Regulatory review time: 19 days	Jan. 21, 2010 No clinical study results	63	Magnetic Navigation System Niobe (Medix Japan, Inc.)	Change	Instrument & apparatus 51 Cardiac Mapping System Workstation	The device is a guiding system that navigates an exclusive catheter for this system to a target region in the diagnosis of arrhythmia and intervention procedures. This device is used in combination with cardiovascular fluoroscopic X-ray diagnosing apparatus, and consists of a magnetic positioner, a control cabinet, a user interface, a ceiling-suspended monitor and a catheter advancement system. The application is for partial changes to add an image control support device, and to change the monitor size and emergency switch. (A partial change during the reexamination period)
8	Mar. 25, 2015 Total review time: 266 days Regulatory review time: 174 days	Apr. 8, 2011 Foreign clinical study results	64	NovoTTF-100A System (NovoCure Ltd.)	Approval	Instrument & apparatus 12 Alternating electric field tumor treatment system	The medical device is a non-invasive device that delivers alternating electric fields -referred to as Tumor Treating Fields (TTfield) - that inhibit cancer cell replication and cause cancer cell death. TTFields are delivered to the tumor in the brain through insulated transducer arrays (INE transducer array) that are placed on the scalp. A clinical trial was conducted to compare the efficacy and safety of the device to chemotherapy in patients with recurrent glioblastoma multiforme after receiving all possible surgery and radiation therapy options. [Priority review]

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Specified partial change	May 1, 2014 Total review time: 76 days Regulatory review time: 32 days	- No clinical study results	65	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for the treatment of thoracic aortic aneurysm. This application for a partial change of approval application for medical device to add a PFOA-free raw material to a raw material of graft “polytetrafluoroethylene.” The application was submitted as a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008).
Specified partial change	Jul. 25, 2014 Total review time: 121 days Regulatory review time: 36 days	Jan. 4, 2008 No clinical study results	66	NaviStar RMT ThermoCool (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter for the radiofrequency catheter ablation and for the electrophysiological study; it is used to treat symptomatic drug refractory paroxysmal and persistent atrial fibrillation, atrial flutter and ventricular tachycardia which is not treated effectively in other ways. This device is manipulated with a magnetic navigation system. It also has an irrigation system that flows with saline from an irrigation hole at the tip of the electrode. This application for a partial change of approval application for medical device to change a raw material of the hub (polycarbonate). The application was submitted as a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A partial change during the reexamination period)
Specified partial change	Aug. 29, 2014 Total review time: 80 days Regulatory review time: 80 days	- No clinical study results	67	Matsudaito (Sanyo Chemical Industries, Ltd.)	Change	Medical products 4 Non-absorbable local hemostatic material for central circulation system	A non-absorbable local hemostatic material consisting of sealant liquid (main body) filled in a syringe and accessory sheets and spatula. This application for a partial change of approval application for medical device to add a manufacturer of a raw material of sealant liquid, fluorine-containing diisocyanate. The application was submitted as a "specified partial change" based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A partial change during the reexamination period)

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Products Approved in FY2014: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 3, 2014 Total review time: 83 days Regulatory review time: 58 days	- Domestic clinical study results	1	Alcon Acrysof IQ Restor +2.5D Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near and/or far vision in patients with aphakia. The raw materials, basic form and principle of the multifocal mechanism are identical to those of the company's approved product, "Alcon Acrysof IQ Restor Single-Piece" (Approval No.: 22000BZX00970000). However, the diameter of apodized diffraction region, diffraction region number and central refractive region are different from the existing approved product. Domestic clinical study results were submitted to evaluate the efficacy and safety of the multifocal mechanism.
1	Jun. 30, 2014 Total review time: 349 days Regulatory review time: 178 days	Mar. 8, 2012 Clinical evaluation report	2	Advanced Femtosecond Laser (AMO Japan K.K.)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An ophthalmic laser corneal surgical instrument to create lamellar cut/resection of the cornea by irradiating a focused ultrashort pulsed laser beam (wavelength 1053 nm, few hundred femtosecond) on corneal tissue. It is used for creation of a corneal flap in LASIK (laser in-situ keratomileusis) and for corneal resection in keratoplasty. An application for partial changes to mainly add arcuate incisions in the cornea (penetrating incision or intrastromal incision) in ophthalmic surgery to the intended use. A clinical evaluation report was submitted to confirm the safety of intrastromal incision in actual clinical practice because an intrastromal incision cannot be performed with a diamond knife.
1	Aug. 25, 2014 Total review time: 299 days Regulatory review time: 66 days	Oct. 18, 2010 Foreign clinical study results	3	LenSx Laser System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 31 Ophthalmic pulsed laser surgical instrument	An ophthalmic pulsed laser surgical instrument used for incision of anterior lens capsule, split of crystalline lens and corneal incision in cataract surgery. It consists of main body of the laser oscillator and patient interface that sucks and fixes the affected patient's eye. Although in conventional cataract surgery, incision of the anterior lens capsule, split of crystalline lens and corneal incision are performed using a cystotome, ultrasonic shock wave generated by cataract surgery instrument and ophthalmic knife, respectively, this device enables these procedures to be performed consecutively or in arbitrary combinations of each function using a femtosecond laser having a maximum energy of 15 microjoules. A foreign clinical study was conducted to confirm that this product has no particular problems by comparing this method to existing methods in cataract surgery.
2	Jun. 11, 2014 Total review time: 168 days Regulatory review time: 76 days	Jun. 30, 2004 Domestic clinical study result and clinical evaluation report	4	Straumann Implant (SLActive) BL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	Pure titanium dental implant body having the roughened surface by sandblasting and acid etching. This product is a bone level type of the company's approved product "Straumann Implant (SLActive) TL" (Approval No.: 22600BZX00016000), which accelerates osteointegration and enables earlier loading by providing the product sealed into a vial filled with normal saline to keep the hydrophilic nature of titanium until just before use. A domestic clinical study on an implant of 4.1mm in diameter was conducted to evaluate its efficacy and safety in early loading compared to in conventional loading. In addition, results of foreign clinical studies on a thinner implant of 3.3mm in diameter were submitted.
2	Jan. 23, 2015 Total review time: 1488 days Regulatory review time: 319 days	Dec. 14, 2011 Clinical evaluation report	5	Tapered Screw-Vent X (Zimmer K.K.)	Approval	Medical products 4 Intraosseous dental implant	An implant fixture partially or wholly implanted in the jawbone, which supports for the upper structure. In order to confirm the bone fixation performance of the new structure with a porous structure on the surface, a clinical evaluation report created from clinical results in published literatures on this product was submitted to evaluate the clinical performance in addition to the normal performance evaluation test.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	Jul. 25, 2014 Total review time: 512 days Regulatory review time: 183 days	- Domestic clinical study results	6	MOMO Coronary Stent System (Japan Stent Technology Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent consisting of a stent to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion in percutaneous coronary stent placement. This stent is made of a cobalt-chromium alloy and the surface is coated with a diamond-like carbon to reduce in-stent restenosis. A domestic clinical study was conducted to verify the efficacy and safety of this product in patients with symptomatic ischemic heart disease who have a new stenosis or restenosis of a coronary lesion (lesion length is 26 mm or less) with a reference vascular diameter ranging from 3.0 mm to 4.0 mm.
3-1	Aug. 29, 2014 Total review time: 336 days Regulatory review time: 118 days	Jan. 11, 2013 Clinical evaluation report	7	TransForm Occlusion Balloon Catheter (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization of the central circulation system used for temporary interruption of blood flow in percutaneous intravascular surgery or for prevention of a coil mass from protruding into and/or prolapsing into the parent artery as an adjunct of coil embolization for cerebral aneurysms. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Oct. 30, 2014 Total review time: 269 days Regulatory review time: 195 days	Feb. 17, 2012 Foreign clinical study results	8	Resolute Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a zotarolimus-eluting stent to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. An application for a partial change to add a 4.0-mm diameter stent. Foreign clinical study results were submitted to evaluate the efficacy and safety of a stent having a diameter of 4.0 mm.
3-1	Nov. 17, 2014 Total review time: 836 days Regulatory review time: 250 days	- Domestic clinical study results	9	Vival Coronary Stent (Goodman Co., LTD.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be placed at the narrowed or blocked segment of coronary artery to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion and dilate the stent. The raw materials were changed from those of the "Duraflex Coronary Stent" (Approval No.: 21500BZY00516000) to reduce the thickness of the stent, and the delivery catheter was also changed. A domestic clinical study was conducted to evaluate the efficacy and safety of this product in patients with symptomatic ischemic heart diseases who have a new stenosis or restenosis lesion in a coronary artery (a lesion length of 25 mm or less).
3-1	Nov. 28, 2014 Total review time: 246 days Regulatory review time: 164 days	Nov. 21, 2013 Global clinical trial and foreign clinical study results	10	Promus Premier LV Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a everolimus-eluting stent with diameter of 4.0 mm to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The product having a diameter of 2.25 - 3.5 mm was previously approved in Japan as "Promus Premier Stent System" (Approval No.: 22600BZX00181000). A clinical study was conducted to evaluate the efficacy and safety of the stent with a 4.0 mm diameter.
3-1	Jan. 19, 2015 Total review time: 528 days Regulatory review time: 220 days	Jan. 21, 2005 Clinical evaluation report	11	Outback Re-entry Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Vascular recanalization catheter	A catheter consisting of a cannula, an outer shaft, a lure assembly and a handle. It assists recanalization back into the true lumen with a guidewire advanced via the subintimal space during percutaneous angioplasty to treat chronic total occlusion in the region of the femoropopliteal artery. A clinical evaluation report has been created based on the reports that were collected from an adverse-event database with clinical results and published literatures. The clinical report was submitted to confirm the performance and safety of this product to be used for the lesions with chronic total occlusion.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	Feb. 12, 2015 Total review time: 240 days Regulatory review time: 116 days	Oct. 26, 2011 Foreign clinical study results	12	ASSURANT COBALT Stent (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A balloon expandable stent and the delivery system used to maintain the patency of the vessel lumen of de novo and restenotic symptomatic lesions in the common iliac artery and external iliac artery. A clinical study was conducted to evaluate the efficacy and safety of this product in clinical use.
3-2	May 19, 2014 Total review time: 220 days Regulatory review time: 92 days	Scepter C：Sep. 29, 2011, Scepter XC：Jan. 13, 2012 Clinical evaluation report	13	Scepter C (Terumo Corporation)	Change	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	A balloon catheter used for temporary interruption of blood flow in percutaneous intravascular surgery or for prevention of a coil clot protruding into and/or dropping out from the parent artery as an adjunct of coil embolization for cerebral aneurysms. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-2	Aug. 1, 2014 Total review time: 458 days Regulatory review time: 265 days	Feb. 14, 2013 Foreign clinical study results	14	AORFIX AAA Stent Graft System (Medico's Hirata Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system consisting of a stent graft and delivery system used for intravascular treatment of abdominal aortic aneurysms and aortic aneurysms extended from the abdominal aorta to the iliac artery. For the indication of infrarenal aortic aneurysm, although an existing approved stent graft for abdominal aortic aneurysms is limited to treat patients with an aortic neck angle not greater than 60 degrees, this product enable to treat patients with the angles of up to 90 degrees. A foreign clinical study was conducted to evaluate the efficacy and safety of this product in case groups where the aortic neck angles are ranging from 60 degrees to 90 degrees.
3-2	Nov. 20, 2014 Total review time: 262 days Regulatory review time: 181 days	- Domestic clinical study results	15	Steering Microcatheter (Akita Sumitomo Bakelite Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system Microcatheter	An intravascular microcatheter for the central circulation system (except for the cardiac and cerebral [intracranial] vessels) used for selective angiography, drug infusion and embolization. The direction of the catheter tip can be controlled by rotating a dial and thereby the catheter can be inserted selectively into the bent vessels without a guidewire. The results of a domestic clinical study was submitted to confirm the efficacy and safety of this product that enables directional operation of the catheter tip by the dial.
3-2	Jan. 23, 2015 Total review time: 490 days Regulatory review time: 100 days	Apr. 9, 2013 Foreign clinical study results	16	Gore Acuseal Vascular Graft (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel using heparin of the non-central circulation system	An artificial triple-layered blood vessel used for vascular access. The lumen is coated with heparin. A clinical study was conducted to evaluate the efficacy and safety of this product in patients requiring hemodialysis.
4	Aug. 8, 2014 Total review time: 294 days Regulatory review time: 197 days	Oct. 28, 2010 Foreign clinical study results	17	ccNexfin Hemodynamic Monitor (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 21 Monitor of arterial blood pressure and cardiac output	The device is an apparatus for continuously monitoring hemodynamic parameters including systolic/diastolic blood pressures (BP), heart rate (HR), stroke volume (SV), cardiac output (CO) and systemic vascular resistance (SVR). The hemodynamic parameters are calculated from arterial blood pressure waveform at the fingertips measured non-invasively and continuously by using the volume-clamp method. Non-clinical study and foreign clinical study results were submitted as the evaluation data on the efficacy and safety of this product.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
4	Aug. 19, 2014 Total review time: 560 days Regulatory review time: 252 days	Jun. 30, 2010 Foreign clinical study results	18	TVC Imaging System (Nipro Corporation)	Approval	Instrument & apparatus 12 Cardiovascular ultrasonic diagnostic imaging instrument	The device is a device to visualize the form and characteristics of the vascular lumen and wall in the central circulation system and to provide the image data for diagnosis. This device has a function to detect a lipid core plaque using near-infrared light and to provide image data combined with an ultrasonogram. However, the image detected by this function is not intended to diagnose. A clinical study was conducted to evaluate that the device can detect a lipid core plaque using near-infrared light.
4	Aug. 19, 2014 Total review time: 512 days Regulatory review time: 159 days	Jun. 30, 2010 Foreign clinical study results	19	TVC Insight Catheter (Nipro Corporation)	Approval	Instrument & apparatus 51 Central circulation system intravascular ultrasound catheter	The device is a catheter equipped with a transducer for sending and receiving ultrasound on the tip to visualize the form and characteristics of the vascular lumen and wall in the central circulation system. This device is also equipped with an optical mirror and an optical fiber that irradiate and collect near-infrared light to detect a lipid core plaque and to provide image data combined with an ultrasonogram. However, the image detected by near-infrared light is not intended to diagnose. A clinical study was conducted to evaluate that the device can detect a lipid core plaque using near-infrared light.
4	Nov. 26, 2014 Total review time: 299 days Regulatory review time: 115 days	- Foreign clinical study results and clinical evaluation report	20	Vercise DBS System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	The device is an electrical brain stimulation device used to reduce tremors that do not sufficiently respond to drug therapy and symptoms of movement disorder associated with Parkinson's disease by providing an electrical stimulus unilaterally or bilaterally to the deep brain (thalamus, subthalamic nucleus or internal globus pallidus). This device consists of an implantable pulse generator and lead, an external trial stimulator to evaluate presence or absence of effect by test stimulation, and a remote controller to control stimulation parameter. Foreign clinical study results to evaluate the efficacy and safety in patients with Parkinson's disease and a clinical evaluation report summarizing foreign clinical studies and published papers to evaluate the efficacy and safety in patients with tremors were submitted.
4	Dec. 22, 2014 Total review time: 361 days Regulatory review time: 268 days	Jan. 30, 2014 Foreign clinical study results	21	Navvus Catheter (ACIST Medical Systems, Inc.)	Approval	Instrument & apparatus 51 Central circulation system transducer-tipped catheter	The device is a catheter with a pressure sensor at the distal tip. It is used for invasive measuring of intravascular pressure in the central and non-central circulation systems excluding the cerebral blood vessel and carotid artery, and also used for evaluation of hemodynamics. The catheter type was adopted to enhance the operability by comparing with a conventional wire type of a similar medical device. The data on results of clinical study to compare the measurement accuracy with that of a previously approved product "SJM PressureWire Certus" (Approval No.: 22300BZX00247000) was submitted.
5	Jul. 9, 2014 Total review time: 575 days Regulatory review time: 159 days	Jan. 28, 1993 Clinical evaluation report	22	EHL Autolith (AMCO Inc.)	Approval	Instrument & apparatus 12 Intracorporeal electrohydraulic shock wave lithotriptor	An intracorporeal electrohydraulic shock wave lithotriptor used to crush calculuses in the kidney and bladder (urinary calculus) and bileduct stone using an electrohydraulic shock wave. A clinical evaluation report was submitted to evaluate the efficacy and safety of this product in patients with bile duct stone.
5	Sep. 10, 2014 Total review time: 376 days Regulatory review time: 84 days	Mar. 29, 2011 Clinical evaluation report	23	Cook Evolution Duodenal Stent System (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Gastroduodenal stent	A stent system to place a stent by endoscopically inserting a delivery system to maintain patency in gastroduodenal obstruction and duodenal stenosis associated with malignant tumors in patients for whom alleviative gastrectomy is considered difficult to be performed or other treatments is unlikely to have an effect. A clinical evaluation report was submitted to confirm the efficacy and safety of treatment using this stent in patients with malignant gastric outlet obstruction.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
6-2	May 7, 2014 Total review time: 303 days Regulatory review time: 116 days	May 31, 2007 Clinical evaluation report	24	VEPTR II System (Johnson & Johnson K.K.)	Approval	Medical products 4 Internal fixation system	An internal fixation system made of titanium alloy and titanium which corrects thoracic deformity while allowing further growth of thorax by implanting an expandable-metallic rod which is extendable along body axial direction in the thorax of the patients with thoracic insufficiency syndrome. Based on the approved product "VEPTR system (Approved No.: 22000BZX01655000)", and major difference from the approved product is that the usability and compatibility of this device with the patient's thorax were enhanced by adding variations on the components or improving the components. A clinical evaluation was conducted with the literatures on this product and the approved product, overseas safety information and clinical evaluation report based on a use-results survey of the approved product to confirm that efficacy and safety of this device equivalent to or greater than that of the approved product were also maintained by the differences.
6-2	May 26, 2014 Total review time: 124 days Regulatory review time: 91 days	Apr. 11, 2013 Domestic clinical study results	25	HEALICOIL RG Suture Anchor (Smith & Nephew Endoscopy KK)	Approval	Medical products 4 Absorbable ligament fixation	A suture anchor used to fix soft tissues of the tendons and ligaments to the bones of the shoulder, elbow, groin (gluteal tendons), knee and foot/ankle. It consists of an absorbable anchor that adopts the hollow coil configuration of the approved product "HEALICOIL Suture Anchor" (Approval No.: 22500BZX00193000), sutures and an inserter. The point of improvement is that a glycolic acid/L-lactic copolymer and a mixture of calcium sulfate and beta-tricalcium phosphate which are new bioabsorbable materials, were adopted as raw materials. The results of a domestic clinical study on arthroscopic labrum repair in shoulder for traumatic shoulder instability using "Osteoraptor OS Anchor" (Approval No.: 22600BZX00228000) made of the same raw materials as this product were submitted to confirm the efficacy and safety of the new bioabsorbable materials.
6-2	May 26, 2014 Total review time: 180 days Regulatory review time: 119 days	May 18, 2012 Domestic clinical study results	26	PICO Wound Therapy System (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Single-use negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by providing a locally managed negative-pressure for patients with a refractory wound who have not responded to or are considered to be unlikely to respond to existing treatment. This device consists of a negative pressure maintenance unit, dressing and a tube to connect the unit and the dressing. Exudate is retained in the dressing applied to wound area and transpired through the backing film. The point of improvement from the approved product "RENASYS Wound Therapy System" (Approval No: 22400BZX00276000) is a downsizing and weight lightening of the main body of the device which allows the device to be used for outpatient. A clinical study on inpatients and outpatients was conducted to evaluate if the performance of this device was equivalent to that of approved product, and to confirm any defects or adverse events specific to this product.
6-2	May 26, 2014 Total review time: 124 days Regulatory review time: 103 days	Jan. 27, 2011 Domestic clinical study results	27	Osteoraptor OS Anchor (Smith & Nephew Endoscopy KK)	Approval	Medical products 4 Absorbable ligament fixation	A suture anchor used to fix the soft tissues of tendons and ligaments to the bone in the shoulder, elbow, wrist/hand, groin, knee and foot/ankle. It consists of an absorbable anchor, sutures and an inserter. The point of improvement is that a glycolic acid/L-lactic acid copolymer and a mixture of calcium sulfate and beta-tricalcium phosphate which are new bioabsorbable materials, were adopted as raw materials for the anchor. The results of a domestic clinical study on arthroscopic labrum repair in shoulder for traumatic shoulder instability using this device were submitted to confirm the efficacy and safety of the new bioabsorbable materials.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
6-2	Jun. 23, 2014 Total review time: 1242 days Regulatory review time: 281 days	Apr. 30, 1998 Foreign clinical study results	28	OASIS Extracellular Matrix (Cook Japan Inc.)	Approval	Medical products 4 Collagen-based artificial skin	Collagen-based artificial skin for control and treatment of full and partial thickness wounds. Porcine small-intestinal submucosa is used as a raw material. Viral clearance study results were submitted to evaluate the virus safety of this product. In addition, foreign post-marketing clinical study results were submitted to evaluate the efficacy and safety in clinical use for patients with venous ulceration and pressure ulcers (decubitus ulcers).
6-2	Dec. 3, 2014 Total review time: 244 days Regulatory review time: 85 days	Mar. 18, 1998 Clinical evaluation report	29	Orthofix HA Coating Pin (Orthofix S. r. l.)	Approval	Medical products 4 Internal fixation pin	A stainless steel pin used with external fixators. No products such as pins coated with hydroxyapatite to enhance the fixation have been approved in Japan. Therefore, in addition to the results of a tensile strength test, a clinical evaluation report summarizing overseas published papers was submitted to evaluate the efficacy and safety of fixation with this product.
6-2	Feb. 6, 2015 Total review time: 267 days Regulatory review time: 196 days	- Foreign clinical study results	30	Duolith SD1 (Storz Medical AG)	Approval	Instrument & apparatus 12 Extracorporeal shock wave pain therapy system	An extracorporeal shock wave pain therapy system designed to enable adjustment of output by the conventional electromagnetic induction-type extracorporeal shock wave lithotripter to the low power output. It is used for pain relief in patients with refractory plantar aponeurositis. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with refractory plantar aponeurositis.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	31	Leksell Gamma Knife C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	32	Leksell Gamma Knife 4C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	33	Leksell Gamma Knife Model-C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	May. 24, 2012 Clinical evaluation report	34	Leksell Gamma Knife Perfexion (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment in trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	35	Leksell Gamma Knife (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.

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Products Approved in FY 2013: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
1	May 21, 2013 Total review time: 193 days Regulatory review time: 77 days	- (About these changes) No clinical study results	1	Baerveldt Glaucoma Implant (AMO Japan K.K.)	Change	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the anterior or posterior chamber to the episclera to decrease intraocular pressure. Application for a partial change to add raw material to be used in the elbow of pars plana insertion type. (A partial change during the reexamination period)
1	Sep. 20, 2013 Total review time: 245 days Regulatory review time: 161 days	- Foreign clinical study results	2	MED-EL EAS Hearing Implant System (MED-EL Elektro-Medizinische Geräte GmbH)	Approval	Medical products 4 Cochlear implant system	A cochlear implant system for perceiving information such as supporting hearing by acoustic stimulation to the low-frequencies and electric stimulation to the high-frequencies in patients with ski-slope hearing loss, in which there is good hearing for lower frequencies who have not responded sufficiently to wearing hearing aids. This product consists of an audio processor (an audio signal processing device) and an implant (an electrode and a stimulator). Of the sound signals picked up by the microphone embedded the audio processor, the high-frequency sounds are perceived by electric stimulation generated from the electrode in the same way as an existing cochlear implant, while the low-frequency sounds are amplified to be perceived by acoustic stimulation through the ear canal. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with ski-slope hearing loss. [Priority review]
1	Nov. 5, 2013 Total review time: 228 days Regulatory review time: 74 days	- (About these changes) No clinical study results	3	Alcon Ex-PRESS Glaucoma Filtration Device (Alcon Japan Ltd.)	Change	Medical products 4 Intraocular drain	A stainless-steel glaucoma filtration device intended to create an aqueous humor outflow tract between the anterior chamber and extraocular segment and to lower the intraocular pressure by puncture and placement from the limbus into the anterior chamber under the scleral flap with this device. An application for a partial change to change the Ex-PRESS delivery system (EDS) to the improved ESD in which an Ex-PRESS body hardly fall off from the EDS wire during transport. (A partial change during the reexamination period)
1	Dec. 20, 2013 Total review time: 255 days Regulatory review time: 81 days	- Clinical evaluation report	4	HOYA CTR (HOYA Corporation)	Approval	Medical products 4 Ophthalmic intracapsular ring	A blue C-shaped polymethyl methacrylate open ring used for patients whose cataract surgery is expected to carry risks associated with its completion and to be difficult to perform due to a brittleness or rupture of Zinn's Zonule. The ring, inserted into a capsule of crystalline lens, holds the capsule during surgery by making the subluxated capsule produce an extension from the inside. Shape of the ring is a single or a multiple circle. The multiple-circle ring has one or two sewing hooks which is used for anchoring to the sclera by suture thread. The hook is designed to come out from the anterior capsule and a suture thread which passes through the hook is anchored to the sclera. A clinical evaluation report was submitted to confirm that efficacy and safety of this device are equivalent to foreign similar devices, based on domestic and overseas long-term usage histories of the foreign similar devices of which indication and operative procedure had already been established. [Priority review]
1	Mar. 28, 2014 Total review time: 583 days Regulatory review time: 237 days	Nov. 12, 1993 Clinical evaluation report	5	Ahmed Glaucoma Valve (Japan Focus Company, Ltd.)	Approval	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the inside of the eye to decrease intraocular pressure. It consists of a silicone plate and tube, and a polypropylene valve system with silicone membrane sheet. The components include only an anterior chamber insertion type. A major differences from the original product “Baerveldt Glaucoma Implant (Approval No. 22300BZX00370000)” are that this product is smaller and has a valve system. A clinical evaluation report summarizing the results of literature search on overseas clinical studies and experience of this product was submitted to evaluate its safety and efficacy in decreasing intraocular pressure.
3-1	May 1, 2013 Total review time: 418 days Regulatory review time: 116 days	Nov. 7, 2012 Domestic and foreign clinical study results	6	SMART CONTROL Stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A device that is identical to the approved product Smart Stent for Iliac Artery (Approval No.21700BZY00247000). A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in intervention therapy) and a delivery system to deliver the stent to the site of the lesion, for the treatment of stenosis or occlusion of the vessels in the superficial femoral artery region in addition to the treatment of iliac artery which is the applicable scope of the approved product. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out treatment. (The original product is in a reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-1	May 1, 2013 Total review time: 418 days Regulatory review time: 116 days	Nov. 7, 2012 Domestic and foreign clinical study results	7	SMART stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in intervention therapy) and a delivery system to deliver the stent to the site of the lesion, for the treatment of stenosis or occlusion of the vessels in the superficial femoral artery region. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out treatment. (The original product is in a reexamination period)
'3-1	Jun. 26, 2013 Total review time: 425 days Regulatory review time: 329 days	Feb. 17, 2012 Domestic and foreign clinical study results	8	Resolute Integrity SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The stent is coated with zotarolimus with a cytostatic effect to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. A clinical study was conducted to evaluate the efficacy and safety of this product. (The original product is in a reexamination period)
3-1	Jun. 19, 2013 Total review time: 182 days Regulatory review time: 156 days	- (About these changes) No clinical study results	9	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The stent is coated with everolimus with an immunosuppression to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. Application for a partial change to alter the product specification of the kinetic drug release of everolimus. (A partial change during the reexamination period)
3-1	Jul. 23, 2013 Total review time: 400 days Regulatory review time: 250 days	- Domestic clinical study results	10	SeQuent Please Drug Eluting Balloon Catheter (Nipro Corporation)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for coronary angioplasty	The first balloon-dilating catheter for coronary angioplasty with a paclitaxel-coated balloon in Japan to inhibit restenosis during revascularization for restenotic lesion in coronary artery stent. A clinical study was conducted to evaluate the efficacy and safety of this product for coronary in-stent restenosis.
3-1	Dec. 25, 2013 Total review time: 187 days Regulatory review time: 144 days	- Domestic clinical study results	11	Misago (Terumo Corporation)	Change	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in percutaneous angioplasty) and a delivery system to deliver the stent to the site of the lesion, for the treatment of symptomatic arterial diseases in the superficial femoral artery region. An application for a partial change to add longer stents (120 mm and 150 mm) than the approved ones. A domestic clinical study was conducted to evaluate the efficacy and safety of additional lengths of stents. (A partial change during the reexamination period)
3-2	Apr. 12, 2013 Total review time: 848 days Regulatory review time: 356 days	Dec. 16, 2002 Foreign clinical study results	12	DC Bead (Eisai Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of polyvinyl alcohol polymer with a bridged structure. This product is used in transcatheter arterial embolization for patients with hepatocellular carcinoma. A clinical study was conducted to evaluate the efficacy and safety of the transcatheter arterial chemoembolization using this product for patients with unresectable hepatocellular carcinoma.
3-2	May 1, 2013 Total review time: 254 days Regulatory review time: 203 days	· Reperfusion catheter Type 2b, type 3b: Nov. 23, 2011 · Separator Flex (Nitinol) type 1-4: May 21, 2010 Type 2b: Nov. 23, 2011 No clinical study results	13	Penumbra System (Medico's Hirata Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system is used to suck and remove a thrombus in patients with acute-phase cerebral infarction in combination with Penumbra Aspiration Pump (Approval No. 22300BZX00268000). Application for a partial change to add a separator of Nitinol type, a type of reperfusion catheter and a size of aspiration tube. (A partial change during the reexamination period)
3-2	Jun. 21, 2013 Total review time: 478 days Regulatory review time: 287 days	· Hypervascular tumor and arteriovenous malformation: Apr. 26, 2000 · Uterine myoma: Nov. 22, 2002 Domestic and foreign clinical study results	14	Embosphere (Nippon Kayaku Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	Embosphere is a microbead for arterial embolization. It is hydrophilic, non-absorbable, and biocompatible spherical particles, which are impregnated and coated with porcine-derived gelatin to acrylic copolymers. A clinical study was conducted to evaluate the efficacy and safety of this product for patients with hypervascular tumor and arteriovenous malformation.
'3-2	Jun. 21, 2013 Total review time: 357 days Regulatory review time: 189 days	Nov. 7, 2006 Domestic clinical study results	15	Hepasphere (Nippon Kayaku Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	Hepasphere is a microbead for arterial embolization. It is biocompatible, hydrophilic, non-bioabsorbable, swellable, compressible, and deformable spherical particles composed of vinyl alcohol/sodium acrylate copolymers. A clinical study was conducted to evaluate the efficacy and safety of this product for patients with hypervascular tumor and arteriovenous malformation.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
'3-2	Jun. 21, 2013 Total review time: 455 days Regulatory review time: 264 days	ー Domestic and foreign clinical study results	16	Sapien XT (Edwards Lifescience Corporation)	Approval	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic heart valve (balloon expandable bovine pericardial valve) system is used for transcatheter valve implantation for patients with severe symptomatic aortic stenosis attributed to sclerosis and degeneration of the cusp of native aortic valve, for whom surgery cannot be performed and receiving the treatment with this product is considered the best treatment. A clinical study was conducted to evaluate the efficacy and safety of this product and to ensure the feasibility of the procedure.
3-2	Jul. 2, 2013 Total review time: 48 days Regulatory review time: 27 days	- No clinical study results	17	Neuroform Stent (Stryker Japan K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	An intracranial artery stent (for treatment of cerebral aneurysm) used to prevent coil migration in coil embolization for wide-necked cerebral aneurysm. An application for partial changes for addition of a manufacturing site. (A partial change during the reexamination period)
3-2	Jul. 5, 2013 Total review time: 371 days Regulatory review time: 259 days	- Clinical evaluation report	18	Codman Enterprise VRD (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system to prevent the embolic coils from protrude and/or dropout into the parent artery during coil embolization. An application for partial changes to add the jailing technique that is widely used in clinical practice and to add a no-tip type without a distal marker located at the tip of delivery wire. A clinical evaluation report was submitted to evaluate the efficacy and safety of the jailing technique using this device. (A partial change during the reexamination period)
3-2	Jul. 5, 2013 Total review time: 72 days Regulatory review time: 51 days	- No clinical study results	19	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of polyvinyl alcohol polymer with a bridged structure. This product is used in transcatheter arterial embolization for patients with hepatocellular carcinoma. An application for partial changes for addition of a manufacturing site. (A partial change during the reexamination period)
3-2	Nov. 22, 2013 Total review time: 434 days Regulatory review time: 145 days	Aug. 3, 2005 Domestic clinical study results	20	Wingspan stent (Stryker Japan K.K.)	Approval	Instrument & apparatus 7 Cerebral artery stent	A self-expanding cerebral artery stent used in patients who have a dissection of the vessel or acute or impending occlusion caused by failure in percutaneous angioplasty for intracranial arterial stenosis with balloon angioplasty catheter or who require the re-treatment with no other effective treatment option. A domestic clinical study was conducted in patients with drug-resistant transient ischemic attack or cerebral apoplexy caused by intracranial artery stenosis to evaluate the safety and performance under domestic medical environments. [Priority review]
3-2	Dec. 20, 2013 Total review time: 424 days Regulatory review time: 294 days	Mar. 2, 2012 Foreign clinical study results	21	Solitaire FR Revascularization Device (Covidien Japan, Inc.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A multi-cell retriever intended to restore blood flow by removing thrombus for patients in acute phase of ischemic cerebral infarction who are ineligible for intravenous t-PA or who failed to restore blood flow with intravenous t-PA therapy. A clinical study was conducted to evaluate that safety and efficacy of this device substantially equal to the existing approved devices.
3-2	Mar. 28, 2014 Total review time: 456 days Regulatory review time: 175 days	Type I: Aug. 3, 2012, Type II: Oct. 31, 2012 Foreign clinical study results	22	Trevo Pro Clot Retriever (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system intended to restore blood flow by removing thrombus for patients with acute-phase cerebral infarction (generally, within 8 hours of symptom onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with intravenous t-PA therapy. A clinical study was conducted to evaluate that safety and efficacy of this device substantially equal the existing approved device, “Merci retriever” (Approval No. 22200BZX00596000).
4	Apr. 12, 2013 Total review time: 308 days Regulatory review time: 212 days	Mar. 27, 2009 Clinical evaluation report	23	Activa RC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa RC is an implantable electrical stimulation device used to reduce tremor associated with Parkinson's disease, essential tremor, etc. that are adequately controlled with medication. The device stimulates the deep brain (thalamus, subthalamic nucleus or internal globus pallidus), unilaterally or bilaterally. A partial change was applied for additional indications to treat for movement disorder caused by Parkinson's disease and dystonia that are not adequately controlled with medication. A clinical evaluation report summarizing results of foreign clinical studies and literatures, etc. was submitted for evaluating the efficacy and safety of this product for Parkinson's disease and dystonia.

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4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	24	Tendril MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	An implantable defibrillator/pacemaker lead used for long-term the heart rhythm regulation by cardiac stimulation in combination with an implantable cardiac pacemaker, etc. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	25	Accent MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	26	Accent MRI RF (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	27	Nuance MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Application for addition of brand name to "Accent MRI" (Approval No. 22500BZX00241000). (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	28	Nuance MRI RF (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Application for addition of brand name to "Accent MRI RF" (Approval No. 22500BZX00242000). (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	29	Tendril MRI J (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	Application for addition of brand name to "Tendril MRI" (Approval No. 22500BZX00240000). (The original product is in a reexamination period)
4	Jun. 24, 2013 Total review time: 222 days Regulatory review time: 211 days	− Clinical evaluation report	30	Solia JT (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker lead	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as a pacemaker lead which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 28, 2013 Total review time: 59 days Regulatory review time: 47 days	− No clinical study results	31	DuralHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which cardiac transplantation is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. It was revealed after the approval that the electrostatic discharge resistance is not sufficient when using a protect cover (supportive tool that ensures the connection of the power supply to the controller and prevents unintended disconnection); it may cause the occurrence of anomalies. Application for a partial change that the diameter of the speaker hole of the protect cover is expanded and non-conductive coating is included on the surface of the protect cover in order to improve resistance to electrostatic discharge and secure electromagnetic compatibility of the system. (A partial change during the reexamination period) [Orphan device]
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	32	Lumax 740 ICD Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)

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4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	33	Linox Smart Pro S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	34	Linox Smart Pro SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	35	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 364 days Regulatory review time: 239 days	- Clinical evaluation report	36	Lumax 740 CRT-D Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with a defibrillator function intended for the treatment of ventricular tachycardia. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 364 days Regulatory review time: 239 days	- Clinical evaluation report	37	Corox Pro OTW BP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 197 days Regulatory review time: 177 days	- Clinical evaluation report	38	Ilest 7 ICD Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. This product was developed based on the approved product “Lumax 740 ICD” (Approval No.22400BZX00162000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, and MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	39	Ilesto 7 CRT-D Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An Implantable biventricular pacing pulse generator with a defibrillator function intended for the treatment of ventricular tachycardia. This product was developed based on the approved product “Lumax 740 CRT-D” (Approval No.22400BZX00161000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, and MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	40	Ilest 7 ICD DF4 Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. This product was developed based on the approved product “Lumax 740 ICD” (Approval No.22400BZX00162000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, MRI compatibility under specific conditions, and an equipped DF4 connector port. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	41	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. This product was developed based on the company's approved product “Linox Smart SD” (Approval No.22200BZX00751000). The major modifications from the approved product include a change to the DF4 connector port and the MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)

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4	Jul. 2, 2013 Total review time: 81 days Regulatory review time: 79 days	- No clinical study results	42	Protego Pro SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for additional brand name for “Linox Smart Pro DF4 SD”. (The original product is in a reexamination period)
4	Jul. 18, 2013 Total review time: 211 days Regulatory review time: 137 days	- No clinical study results	43	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which cardiac transplantation is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. After the approval, multiple events due to failure to maintain normal rotation mode of the pump (magnetic suspension) were reported in Japan and overseas. A detailed investigation confirmed that some wires in the percutaneous cable were disconnected, which occurred in the connector area close to a pump. This application for partial change to extend a strain relief of the cable as a measure against the failure due to the fracture of the percutaneous cable. (A partial change during the reexamination period) [Orphan device]
4	Jul. 23, 2013 Total review time: 287 days Regulatory review time: 177 days	Aug. 17, 2009 Foreign clinical study results	44	LifeVest Wearable Defibrillator (ZOLL Lifecor Corporation)	Approval	Instrument & apparatus 12 Wearable defibrillator	The first wearable defibrillator in Japan to monitor and analyze electrocardiograms of the patients wearing this device continuously, and to deliver electric shock for defibrillation automatically if ventricular tachycardia or ventricular fibrillation requiring defibrillation is detected. A clinical study was conducted to evaluate the success rate of defibrillation for arrhythmia which requires defibrillation and the risk of inappropriate electric shock delivery due to false detection of arrhythmia. [Priority review]
4	Aug. 7, 2013 Total review time: 156 days Regulatory review time: 147 days	- No clinical study results	45	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for partial changes to alter the cannula (alterations in its surface processing and shape) in hope of inhibition of wedge thrombus formation to reduce the risk of cerebral infarction, which has been frequently reported in ongoing cases in the clinical trials and post-marketing surveillance. (A partial change during the reexamination period) [Orphan device]
4	Aug. 7, 2013 Total review time: 131 days Regulatory review time: 113 days	Jan. 26, 2011 Clinical evaluation report	46	Activa SC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa SC is an implantable electrical stimulation device used for deep brain stimulation to improve various symptoms associated with movement disorders by delivering electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). This device has already been approved for use in reduction of tremors associated with Parkinson's disease, essential tremor, etc. that are not controlled with medication. A partial change has been approved for additional indications to treat movement disorder caused by Parkinson's disease and dystonia that are not adequately controlled with medication. A clinical evaluation report summarizing results of foreign clinical studies and published literatures, etc. was submitted for evaluating the efficacy and safety of this product for Parkinson's disease and dystonia. (The original product is in a reexamination period)
4	Aug. 27, 2013 Total review time: 419 days Regulatory review time: 192 days	- Clinical evaluation report	47	Evia HF-T Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable biventricular pacing pulse generator without a defibrillator function intended for the treatment of bradycardia. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Sep. 6, 2013 Total review time: 205 days Regulatory review time: 51 days	Oct. 12, 2010 No clinical study results	48	Thermogard System (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheter balloon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. An application for partial change to change raw materials of a coating agent for a central venous catheter having a perfusion balloon. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	49	Evia T Series Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	50	Evia Series Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	51	Solia T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	52	Solia S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 17, 2013 Total review time: 116 days Regulatory review time: 59 days	Aug. 24, 2012 No clinical study results	53	Activa RC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa RC is a rechargeable and implantable electrical stimulation device used for deep brain stimulation to improve various symptoms associated with movement disorders by delivering electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). A partial change has been approved for addition of type of a stimulator with no coating applied on its shield case. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	54	Corox Pro OTW BP (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	55	Linox Smart Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	56	Linox Smart Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	57	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	58	Ilest 7 CRT-D Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with a defibrillator function (CRT-D) intended for the treatment of ventricular tachycardia. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)

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4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 60 days	- No clinical study results	59	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 60 days	- No clinical study results	60	Protego Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	61	Ilest 7 ICD DF4 Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator (ICD) intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	62	Ilest 7 ICD Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator (ICD) intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 20 days Regulatory review time: 20 days	Aug. 24, 2012 No clinical study results	63	Activa SC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa SC is an implantable electrical stimulation device used for deep brain stimulation to improve various symptoms associated with movement disorders by delivering electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). A partial change has been approved for addition of type of a stimulator with no coating applied on its shield case. (A partial change during the reexamination period)
4	Sep. 20, 2013 Total review time: 266 days Regulatory review time: 95 days	- Domestic clinical study results	64	PD Laser BT (Panasonic Healthcare Co., Ltd.)	Approval	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device designed for photodynamic therapy. This device is to be used in combination with “Laserphyrin 100mg for Injection” (Approval No. 21500AMZ00509000) as an oncotropic photo-sensitizer, targeting primary malignant brain tumor as an additional treatment to the surgical resection. A clinical trial was conducted to confirm the efficacy and safety of photodynamic therapy for primary malignant brain tumor using this device and the concomitant drug. [Orphan medical device]
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 389 days	- Foreign clinical study results	65	Libra Single 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	A deep brain stimulation device is indicated for patients with essential tremor, various symptoms of Parkinson's disease or dystonia that have not responded sufficiently to drug therapy. This product is used for alleviation of essential tremor, movement disorders associated with Parkinson’s disease, and dystonia symptoms. A clinical study was conducted to evaluate the efficacy and safety of this product for Parkinson’s disease and dystonia. (The original product is in a reexamination period)
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 385 days	- Foreign clinical study results	66	Brio Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	A deep brain stimulation device is indicated for patients with essential tremor, various symptoms of Parkinson's disease or dystonia that have not responded sufficiently to drug therapy. This product is used for alleviation of essential tremor, movement disorders associated with Parkinson’s disease, and dystonia symptoms. A main body of implantable stimulator is rechargeable. A clinical study was conducted to evaluate the efficacy and safety of this product for Parkinson’s disease and dystonia. (The original product is in a reexamination period)
4	Oct. 30, 2013 Total review time: 48 days Regulatory review time: 42 days	- No clinical study results	67	Evia HF-T Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable biventricular pacing pulse generator without a defibrillator function used to improve symptoms of cardiac failure. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Oct. 30, 2013 Total review time: 124 days Regulatory review time: 112 days	- No clinical study results	68	Solia JT (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Nov. 22, 2013 Total review time: 1390 days Regulatory review time: 301 days	- Domestic and foreign clinical study results	69	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	An axial-flow implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which heart transplant is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. A clinical study was conducted in the U.S. to evaluate the efficacy and safety of this product, and a domestic clinical study was conducted to evaluate the efficacy and safety in Japan where healthcare environments are different from those in the U.S. [Orphan device]
4	Nov. 29, 2013 Total review time: 410 days Regulatory review time: 74 days	- Clinical evaluation report	70	Ingenio MRI (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	71	Fineline Ⅱ PU (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	72	Fineline Ⅱ EZ PU (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	73	Fineline Ⅱ Sterox (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	74	Fineline Ⅱ Sterox EZ (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 185 days	Dec. 17, 2010 Foreign clinical study results	75	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A long, flexible, steerable catheter is used as an adjunctive device in the endocardial treatment of paroxysmal atrial fibrillation. This product is to be used in conjunction with “Arctic Front Advance Cardiac Cryoablation Catheter” (simultaneously submitted). It is used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites, or creation of an ablation line between the inferior vena cava and the tricuspid valve. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 166 days	Dec. 10, 2010 Foreign clinical study results	76	Medtronic CryoConsole (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical unit to be used for the treatment of arrhythmia. The device is for the exclusive use of Medtronic cryoablation catheters. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 204 days	Apr. 12, 2012 Foreign clinical study results	77	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon catheter used for cardiac cryoablation to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]
4	Feb. 28, 2014 Total review time: 851 days Regulatory review time: 685 days	- Domestic clinical study results	78	Coopdech i-Cool (Daiken Medical Co., Ltd.)	Approval	Instrument & apparatus 12 Temperature management system	A system used to lower the brain temperature by bringing a cuff in which temperature-controlled physiological saline circulates into contact with parts of pharyngeal and esophagus of the patients who require therapeutic hypothermia following cardiac arrest. A domestic clinical study was conducted to confirm that brain temperature becomes lower early in therapeutic hypothermia by cooling pharyngeal with this device, that it does not worsen outcomes in the patients significantly, and that the risks are acceptable.
4	Feb. 28, 2014 Total review time: 77 days Regulatory review time: 15 days	Jan. 17, 2014 (Approval of application corresponding to the present partial change) No clinical study results	79	Thermogard System (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheterballoon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. An application for a partial change to change the manufacturing site. (A partial change during the reexamination period)
4	Mar. 26, 2014 Total review time: 272 days Regulatory review time: 183 days	Feb. 1, 2001 Clinical evaluation report	80	Nykanen RF Wire (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A wire used for puncture of atrial septum or membranous atresia of pulmonary artery in patients with severe congenital heart diseases by delivering radiofrequency energy. A clinical evaluation report based on published literatures in foreign countries was submitted without conducting a domestic or foreign clinical study. [Priority review]
4	Mar. 26, 2014 Total review time: 91 days Regulatory review time: 71 days	Jan. 15, 2013 No clinical study results	81	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change the conditions of usable MRI devices. (A partial change during the reexamination period)
4	Mar. 26, 2014 Total review time: 90 days Regulatory review time: 68 days	- Clinical evaluation report	82	Protego Pro S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable electrode lead with a screw-shaped tip having a quadrupolar connector (DF4-Standard). It is used for the treatment of ventricular tachycardia, with being connected to ICD or CRT-D. This lead, having one defibrillation electrode, was developed based on the main body of “Protego Pro SD (Approval No. 22500BZX00295A01).” The patients with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
5	Apr. 12, 2013 Total review time: 197 days Regulatory review time: 97 days	−(No application for this indication) Clinical evaluation report	83	Histoacryl (B. Braun Aesculap Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels	An n-butyl-2-cyanoacrylate is injected for endoscopic vascular embolization for gastric varices. This product has been already used in and out of Japan as material for endoscopic vascular embolization. Based on the current situation, a clinical evaluation report was submitted to evaluate the efficacy and safety of this product. [Priority review]
5	Jun. 21, 2013 Total review time: 396 days Regulatory review time: 192 days	− Domestic clinical study results	84	Magnetic Stimulator TMU-1100 (Nihon Kohden Corporation)	Approval	Instrument & apparatus 12 Magnetic stimulation device for treatment of urinary incontinence	A magnetic stimulation device to improve symptoms of overactive bladder with urinary incontinence. This product is used for adult female patients with overactive bladder who are not responsive to or cannot use therapeutic agents for urinary incontinence. Pulse current flowing in a stimulation coil under the sealing surface of a chair-shaped stimulation unit generates magnetic energy through the upper portion of the sealing surface. The variable magnetic fields induce eddy currents in the body of the patient who is seated on the stimulation unit. The eddy currents primarily stimulate the nerves in the pelvic floor area of the patient. A clinical study was conducted to evaluate the efficacy and safety of this product in female patients with overactive bladder with urinary incontinence.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
5	Jul. 5, 2013 Total review time: 43 days Regulatory review time: 12 days	- No clinical study results	85	CryoSeal CS-1 (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Apparatus for blood component separation	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. An application for a partial change to change the manufacturing sites. (A partial change during the reexamination period)
5	Sep. 20, 2013 Total review time: 386 days Regulatory review time: 126 days	Mar. 14, 2011 Domestic and foreign clinical study results	86	InterStim II Neurostimulator for Sacral Neuromodulation (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for bladder and bowel control	An implantable nerve stimulation system to improve fecal incontinence by electrical stimulation to sacral nerves for the patients with fecal incontinence who have not responded or cannot apply to conservative treatment. Clinical studies were conducted to evaluate therapeutic effect of this device for fecal incontinence and the safety during a test stimulation period and an implantation period.
5	Feb. 19, 2014 Total review time: 72 days Regulatory review time: 19 days	- No clinical study results	87	Cryoseal Disposable Kit (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Blood component separation kit	Blood component separation kit to be used to isolate/collect blood components in a sterile state when preparing a biological tissue adhesive from autologous plasma. Patients are to undergo preoperative autologous blood donation. An application for a partial change of approval application for medical device to change manufacturing sites. (A partial change during the reexamination period)
6-1	Sep. 20, 2013 Total review time: 756 days Regulatory review time: 371 days	May 14, 2004 (stem, etc.) Mar. 16, 2005 (baseplate, etc.) Jul. 20, 2006 (baseplate long post, etc.) Clinical evaluation report	88	Aequalis Reversed Shoulder Prosthesis (Tornier S.A.S.)	Approval	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system in a reversed form of the conventional, anatomically-structured shoulder prosthesis with a spherical glenoid component and a humeral head component that is a concave hemispherical shell. Since there was no similar device in Japan, a clinical evaluation report was submitted to confirm the efficacy and safety of this device equivalent to similar devices based on overseas usage history and publications of this device and the similar devices by taking into account that the indication and operative procedure had already been established by its long-term usage history overseas.
6-1	Oct. 30, 2013 Total review time: 1038 days Regulatory review time: 666 days	Dec. 19, 2005 Clinical evaluation report	89	Trabecular Metal Reverse Shoulder System (Zimmer K.K.)	Approval	Medical products 4 Total shoulder prosthesis	A total shoulder prosthesis having the concept of a reversed shoulder prosthesis system in which the anatomical structure is reversed. It is used for cases of having difficulty in elevetion of a shoulder with an unreconstructible rotator cuff function such as a massive rotator cuff tear. When it can not be used in reversed combination for the reason that a base plate can not be applied during surgery, it can be emergently combined in an anatomical shape. Trabecular metal is applied to portions contacting bone on a humeral stem and a reversed base plate. A clinical evaluation report was submitted to confirm the efficacy and safety of this device is equivalent to the existing approved devices based on overseas usage histories and publications of this device and similar devices. (The original product is in a reexamination period)
6-2	Oct. 11, 2013 Total review time: 416 days Regulatory review time: 112 days	Feb. 20, 2013 Foreign clinical study results	90	Natrelle 410 Breast Implant (Allergan Japan K. K.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled artificial breast for restoring or forming the shape of a breast after the insertion into the application site. It is used for breast reconstruction surgery or augmentation mammaplasty. It is improved compared with the approved "Natrelle Breast Implant (Approval No. 22400BZX00354000)".The improvements are that it is designed with an anatomical shape that mirrors a woman's real breast and the gel with increased degree of crosslinking makes the breast harder. A clinical study was conducted to evaluate the performance as an artificial breast and adverse events in breast reconstruction surgery or augmentation mammaplasty. (The original product is in a reexamination period)
Cellular and tissue-based products	Jul. 30, 2013 Total review time: 75 days Regulatory review time: 40 days	- No clinical study results	91	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This is an autologous-cultured epidermis processed from epidermal cells and multiple animal origin-materials for severe burn injury. This application for partial changes to add a new supplier of bovine serum used in the processes of this product and to change the preparation method of culture medium.
Cellular and tissue-based products	Mar. 17, 2014 Total review time: 109 days Regulatory review time: 39 days	- No clinical study results	92	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This is an autologous-cultured epidermis processed from epidermal cells and multiple animal origin-materials for severe burn injury. An application for partial changes to change and add raw materials of this product, and to change storage period of the intermediates.

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Specified partial change	Jan. 16, 2014 Total review time: 83 days Regulatory review time: 37 days	Feb. 13, 2014 No clinical study results	93	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system used in percutaneous coronary stent placement. The stent is coated with everolimus with immunosuppression. An application for a partial change of approval application for medical device to add everolimus with a different manufacturing number. (A partial change during the reexamination period)
Specified partial change	Mar. 11, 2014 Total review time: 62 days Regulatory review time: 29 days	- No clinical study results	94	Cryoseal Disposable Kit (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Blood component separation kit	Blood component separation kit to be used to isolate/collect blood components in a sterile state when preparing a biological tissue adhesive from autologous plasma. Patients are to undergo preoperative autologous blood donation. An application for a partial change of approval application for medical device to add new raw materials of the components for stabilizing supply of the materials. (A partial change during the reexamination period)

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Products Approved in FY2013: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 8, 2013 Total review time: 299 days Regulatory review time: 141 days	Jun. 5, 2012 Foreign clinical study results	1	Biotrue Oneday (B.L.J. Company, Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lens for correcting visual acuity	A single use soft contact lens with 78% water content and oxygen permeability (Dk) of 42 composed of nesofilcon A. It is integrally colored light blue and contains an ultraviolet absorber. Because the product has novel raw materials, but not a novel design, a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Aug. 27, 2013 Total review time: 382 days Regulatory review time: 207 days	Apr. 15, 2013 Foreign clinical study results	2	Tecnis Toric 1-Piece (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A one-piece monofocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery accompanied with corneal astigmatism. The same raw materials as those of “Tecnis one-piece (Approval No. 22000BZX01610000)” are used. A cylindrical frequency was newly added to the front of the lens to correct corneal astigmatism, which is difference from the existing approved product. A clinical study was conducted to evaluate the clinical efficacy and safety of this product with the newly added correcting function of corneal astigmatism.
1	Jan. 14, 2014 Total review time: 491 days Regulatory review time: 141 days	- Domestic clinical study results	3	HOYA iSert Micro Toric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	A posterior chamber lens with an injector in which a monofocal posterior chamber lens is preloaded to insert it into an aphakic eye with corneal astigmatism after cataract surgery. The raw materials of the lens are the same as those of “HOYA iSert Micro (Approval No. 22200BZX00615000).” A cylindrical power is newly added to one side of the lens to correct corneal astigmatism, which is the difference from the existing approved product. A domestic clinical study was conducted to evaluate the clinical efficacy and safety of this lens with the newly added correcting function of corneal astigmatism.
1	Jan. 15, 2014 Total review time: 292 days Regulatory review time: 227 days	- Domestic clinical study results	4	Alcon Acrysof IQ Restor Toric Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal toric intraocular lens to be inserted into an aphakic eye with corneal astigmatism. This product has an aspheric, diffractive, and multifocal structure on the anterior optical surface and a toric structure on the posterior surface. The each optical design is identical to that of the company’s approved product. In addition, the raw material and basic structure of the lens are also identical to those of the company’s approved product. A domestic clinical study was conducted to evaluate that this device corrects corneal astigmatism and provides adequate multifocal function, compared to clinical study results of the approved single-function lenses of multifocal or toric.
1	Mar. 3, 2014 Total review time: 213 days Regulatory review time: 150 days	- Clinical evaluation report	5	ICL KS-AquaPORT (STAAR Japan Inc.)	Approval	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	A one-piece intraocular lens to correct refractive errors. It is designed to be implanted in the posterior chamber of a phakic eye (in front of the human crystalline lens). A through-hole is added to the center of the optical zone of the company’s approved product “ICL (Approval No. 22200BZY00001000),” which makes laser iridotomy, required as a preoperative procedure in the original product, unnecessary. A clinical evaluation report was submitted to evaluate the effects on the change on visual function and corneal endothelial cells, and the presence or absence of increased ocular pressure associated with the absence of laser iridotomy.
2	Jan. 23, 2014 Total review time: 391 days Regulatory review time: 188 days	Jun. 30, 2004 Domestic and foreign clinical study results	6	Straumann Implant (SLActive) TL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	The first dental implant in Japan that enables earlier loading than conventional loading. This device is sealed into vial filled with normal saline to keep hydrophilic nature of titanium until just before use, which accelerates osteointegration. A domestic clinical study on an implant of 4.1mm in diameter was conducted to evaluate its efficacy and safety in early loading compared to in conventional loading. In addition, results of foreign clinical studies on a thinner implant of 3.3mm in diameter were submitted.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	Jul. 10, 2013 Total review time: 349 days Regulatory review time: 233 days	Dec. 21, 2012 Foreign clinical study results	7	XIENCE Xpedition Drug Eluting Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent composed of a drug-eluting stent used for treatment of patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 32mm or less) with a reference vessel diameter of 2.50-3.75mm and a delivery catheter used to implant a stent to the coronary stenosis site. The device has a different stent delivery system from the company's approved product “XIENCE PRIME Drug Eluting Stent (Approval No. 22400BZX00145000).” A new stent diameter of 3.25mm is added. Results from clinical studies on “XIENCE PRIME Drug Eluting Stent” were submitted to confirm the efficacy and safety of this product.
3-1	Sep. 26, 2013 Total review time: 300 days Regulatory review time: 205 days	Oct. 15, 2009 Clinical evaluation report	8	Hyperform/Hyperglide Occlusion Balloon Catheter (Covidien Japan, Inc.)	Change	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for cerebral aneurysm. An application for a partial change to change the intended use and the operation procedures to enable this product to be used in coil embolization for wide-neck cerebral aneurysm as an assisting balloon, in addition to an indication as an occlusion balloon. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Dec. 9, 2013 Total review time: 404 days Regulatory review time: 265 days	Feb. 22, 2013 Foreign clinical study results	9	Resolute Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. Application for a partial change to add a product with a stent length of 34mm and 38mm to the existing products for extending the target lesion length from 27mm to 35mm and change the specification of drug content uniformity. A clinical study was conducted to evaluate the efficacy and safety of the product for patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 35mm or less).
3-1	Jan. 30, 2014 Total review time: 265 days Regulatory review time: 192 days	- Clinical evaluation report	10	Kaneka Assistant Balloon Catheter NE-N3 (Kaneka Corporation)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	A intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for cerebral aneurysm. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Feb. 4, 2014 Total review time: 221 days Regulatory review time: 112 days	Feb. 22, 2012 Foreign clinical study results	11	AbsolutePro Vascular Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A self-expanding stent and stent delivery system inserted and placed at the site of new lesions or restenotic lesions of symptomatic atherosclerosis in the iliac artery (common iliac artery and external iliac artery) to secure intravascular lumen. A clinical study was conducted to evaluate that the efficacy and safety of the product are not inferior compared to the results from past clinical studies.
3-1	Feb. 28, 2014 Total review time: 182 days Regulatory review time: 76 days	Jul. 31, 2012 Foreign clinical study results	12	Omnilink Elite Vascular Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A balloon-expanding stent and stent delivery system inserted and placed at the site of new lesions or restenotic lesions of symptomatic atherosclerosis in the iliac artery (common iliac artery and external iliac artery) to secure intravascular lumen. A clinical study was conducted to evaluate that the efficacy and safety of the product are not inferior compared to the results from past clinical studies.
3-1	Mar. 26, 2014 Total review time: 363 days Regulatory review time: 129 days	Mar. 19, 2013 Clinical evaluation report	13	Guidezilla Extension Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter to enhance access to the stenotic site of the coronary artery and facilitate placement of interventional devices including a guidewire. A clinical evaluation report was submitted to evaluate that the device has equal efficacy and safety to those of the approved devices.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	Mar. 28, 2014 Total review time: 361 days Regulatory review time: 147 days	- Clinical evaluation report	14	Nipro Guiding Catheter B (Nipro Corporation)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter providing back-up support for insertion of a therapeutic device. It is inserted into the coronary artery when it is difficult for a guidewire or an intravascular therapeutic device to reach a target lesion or pass a lesion in percutaneous transluminal coronary angioplasty. A clinical evaluation report was submitted to evaluate that the device has equal efficacy and safety to those of the approved devices.
3-2	Jul. 19, 2013 Total review time: 618 days Regulatory review time: 389 days	Nov. 9, 2006 Foreign clinical study results	15	Gore Propaten Vascular Graft (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel using heparin	An artificial blood vessel used in vascular replacement, bypass grafting, hemodialysis or other vascular techniques for patients with occlusive diseases or aneurysms or trauma patients who require vascular replacement. It has a basic structure of a stretched polytetrafluoroethylene (PTFE) tube. Heparin bonded covalently to the luminal surface of the graft is expected to produce a local and long-term antithrombotic effect and improve the 1-year patency rate and limb salvage rate after peripheral vascular bypass surgery for patients with peripheral artery occlusive disease. A clinical study was conducted to evaluate its efficacy and safety in above-knee femoropopliteal artery bypass surgery for vascular occlusive diseases.
3-2	Sep. 27, 2013 Total review time: 434 days Regulatory review time: 254 days	Aug. 23, 2011 Foreign clinical study results	16	GORE CTAG Thoracic Endoprosthesis (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for endovascular treatment of thoracic aortic aneurysm. The product consists of a stent graft and delivery catheter. The main differences from the approved product “GORE TAG Thoracic Endoprosthesis (Approval No. 22000BZX00185000)” include a shape change of the stent graft (removal of flare parts at both ends of a stent graft), an increase in the stent wire diameter, a change of the apex number of the stent, an addition of a new stent graft size, and a position change of adhesive tape, etc. These changes enhanced compression resistance of the stent graft and followability to an implanted vessel so that the product is applicable to more diversified blood vessel diameters. A clinical study was conducted to evaluate its efficacy and safety in cases with thoracic aortic aneurysm.
3-2	Oct. 11, 2013 Total review time: 178 days Regulatory review time: 148 days	Apr. 16, 2013 Foreign clinical study results	17	ENDURANT II Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for endovascular treatment of infrarenal abdominal aortic aneurysm. The product consists of a stent graft and delivery system. An application for a partial change to add AUI (aorta uni-iliac) configuration. Results from a clinical study using the first generation product were submitted to evaluate the efficacy and safety of the AUI configuration for infrarenal abdominal aortic aneurysm.
3-2	Dec. 6, 2013 Total review time: 595 days Regulatory review time: 380 days	Dec. 1, 2011 Clinical evaluation report	18	GuideLiner Catheter (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter providing back-up support for insertion of the therapeutic device. It is inserted into the coronary artery when it is difficult for a guidewire or an intravascular therapeutic device to reach a target lesion or pass a lesion in percutaneous transluminal coronary angioplasty. A clinical evaluation report was submitted to confirm the efficacy and safety when this device is used as a slave catheter.
3-2	Jan. 30, 2014 Total review time: 456 days Regulatory review time: 419 days	- Domestic clinical study results	19	J Graft Open Stent Graft (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic open stent graft used for the treatment of diseases which require aorta replacement from the distal aortic arch to the proximal descending aorta. This product is capable of being fixed securely on the central side in a similar suturing way with a conventional synthetic graft, and is fixed on the peripheral side by the spring force of the stent graft without suture which provide one-stage, low invasive treatment for a widespread lesion. A clinical study was conducted to confirm the efficacy and safety of this device for diseases requiring aorta replacement.

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3-2	Feb. 6, 2014 Total review time: 132 days Regulatory review time: 99 days	- Clinical evaluation report	20	BA Soft Balloon Catheter (Fuji Systems Corporation)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for a cerebral aneurysm to prevent a coil body from protruding or being disengaged toward the parent artery. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-2	Feb. 24, 2014 Total review time: 594 days Regulatory review time: 366 days	OTW System (Jan. 31, 2007) DV System (Sep. 19, 2007) Clinical evaluation report	21	AERO Hybrid Stent for Airway Stenosis (Sugan Co., Ltd.)	Approval	Instrument & apparatus 7 Tracheal stent	A tracheal stent used to secure an airway for tracheal or bronchial stenosis caused by malignant tumors. Since this stent made of nitinol is fully covered with polyurethane film, it has the advantage of both metal stent which can be inserted by rigid or flexible endoscope and silicon stent which has low complication rates in granulation, tumor infiltration and so on. A clinical study report was submitted to confirm the efficacy and safety of this device for tracheal and bronchial stenosis caused by malignant tumors.
3-2	Feb. 28, 2014 Total review time: 1428 days Regulatory review time: 167 days	Aug. 30, 2008 Foreign clinical study results	22	ATS 3f Aortic Bioprosthesis (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Equine pericardial valve	The ATS 3f Aortic Bioprosthesis is used for replacement as an alternative to dysfunctional aortic valve. Its leaflets are made of equine pericardium. This aortic bioprosthetic valve is designed as a tubular structure without a stent, which allows the valve to open and close like a native valve. A clinical study was conducted to confirm the efficacy and safety of this device when it was implanted in patients with aortic stenosis.
3-2	Feb. 28, 2014 Total review time: 730 days Regulatory review time: 270 days	Jan. 7, 2010 Foreign clinical study results	23	Floseal (Baxter Limited)	Approval	Medical products 4 Gelatin-based local absorbable hemostatic material with human thrombin	A local absorbable hemostatic material used in surgical procedures (other than in ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. A clinical study was conducted to evaluate its performance and safety for a bleeding area in cardiac, vascular and spine/spinal surgery.
3-2	Mar. 28, 2014 Total review time: 302 days Regulatory review time: 153 days	Sep. 11, 2008 Foreign clinical study results	24	NAV 6 Filter (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device is used to prevent distal emboli by capture and removal of obstructing materials such as thrombi during carotid artery stent procedure. It is percutenously and temporarily placed in the distal sites from stenotic region in the cervical part of carotid artery. A clinical study was conducted to confirm the effectiveness and safety when this device is used during CAS.
4	Jul. 18, 2013 Total review time: 335 days Regulatory review time: 193 days	Jan. 29, 2013 Global clinical trials	25	Viva CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. The device is newly equipped with AdaptivCRT technology developed to automatically control CRT parameters (AV and VV delays) based on patients' conduction and CardioSync Optimization supporting CRT parameter control by measuring patients' electric conduction property at follow-up visits, with which the approved product “Protecta XT CRT-D (Approval No. 22200BZX00913000)” was equipped. There are six models of the products having different shapes of connectors of lead connection parts and different mounting functions. A clinical study was conducted to evaluate the efficacy and safety of the AdaptivCRT function.
4	Aug. 9, 2013 Total review time: 696 days Regulatory review time: 280 days	Aug. 14, 2008 Foreign clinical study results	26	Watch PAT (Philips Respironics GK)	Approval	Instrument & apparatus 21 Sleep evaluation device	A medical device used as an adjunct in evaluation and diagnosis of sleep-disordered breathing events and sleep stages in patients suspected of sleep-disordered breathing. The wrist-worn device records PAT (Peripheral Artery Tonometry) signal (finger plethysmogram), $Sp0_2$, snoring, and body position and motion during sleep. Results from clinical studies on the precedent device equipped with the same software as this device were submitted to examine whether the software of this device can evaluate sleep disorder.

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4	Sep. 12, 2013 Total review time: 265 days Regulatory review time: 172 days	- Global clinical trials	27	Viva Quad CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. One of the IS-1 connector ports of the original product “Viva CRT-D Series (Approval No. 22500BZX00320000)” is changed to a IS4 connector port capable of being adopted to a left ventricle (LV) lead that has four independent pacing electrodes. There are three models of the products having different mounting functions. It also has VectorExpress, a support function to be used for selecting a pacing vector, which provides automatic measurement of the capture threshold based on impedance and pulse width of 16 types of LV vector and relative battery life. A clinical study was conducted to evaluate the efficacy and safety of AdaptivCRT technology.
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 382 days	- Foreign clinical study results	28	DBS 4 contacts lead (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrode lead placed on the deep brain in deep brain stimulation therapy. It transmits electric stimulus generated from an implanted stimulation device. The product consists of an electrode lead and its accessories. It is used in conjunction with “Libra Single 8 Neurostimulator (Approval No. 22500BZX00450000)” and “Brio Dual 8 Neurostimulator (Approval No. 22500BZX00451000).” A clinical study was conducted to evaluate the efficacy and safety of product in Parkinson’s disease and dystonia.
4	Jan. 28, 2014 Total review time: 1033 days Regulatory review time: 401 days	Sep. 24, 2003 Domestic clinical study results	29	AB5000 Ventricle (Medix Japan, Inc.)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	An pneumatic ventricular support system that is placed external to the patient. A domestic clinical trial was conducted to evaluate its adaptability to domestic medical circumstances. Results of a post-marketing surveillance submitted to the US FDA were reviewed as reference data.
4	Jan. 28, 2014 Total review time: 944 days Regulatory review time: 314 days	Aug. 1, 2006 Foreign clinical study results	30	Endovenous Closure System (Covidien Japan Inc.)	Approval	Instrument & apparatus 29 Therapeutic electrosurgical device	An electrosurgical device used for the treatment of primary varicose veins of lower extremities. It generates a laser in the veins to obstruct saphenous veins. It thermally coagulates the main saphenous vein to cause vascular obstruction. This device is composed of a generator which generates high-frequency current and a catheter which is connected to the generator. The catheter, to the tip of which a heating coil is attached, is inserted via the skin and lumina to an objective lesion region (the main saphenous vein). The heating coil obstructs a vascular vessel. A clinical study in which it is compared to the domestically approved product “ELVeS Laser (Approval No. 22200BZX00660000)” was conducted to evaluate its clinical efficacy and safety.
4	Feb. 28, 2014 Total review time: 375 days Regulatory review time: 252 days	Apr. 4, 2012 Foreign clinical study results	31	Protecta XT CRT-D (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. An application for a partial change to add NYHA class II (mild) cardiac function to the current indications of class III or IV (moderate or severe) for extending its indication. A clinical study was conducted to confirm the validity of the new indication. In addition, results from evaluations of multiple clinical studies were submitted as a clinical evaluation report.
4	Mar. 7, 2014 Total review time: 345 days Regulatory review time: 167 days	Nov. 17, 2011 Foreign clinical study results	32	INCEPTA Plus CRT-D (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. An application to add NYHA class II (mild) cardiac function to the current indications of class III (moderate) or IV (severe). A clinical study was conducted to evaluate the validity of the new indication.
4	Mar. 7, 2014 Total review time: 245 days Regulatory review time: 172 days	- Domestic clinical study results	33	ELVeS Laser 1470 (Integral Corporation)	Approval	Instrument & apparatus 31 Diode laser	A laser treatment device used for varicose veins of lower extremities. It generates a laser in the veins to obstruct saphenous veins. A domestic clinical study was conducted to confirm that this device provides a similar degree of interruption of blood flow to the original product “ELVeS Laser” and that it is less associated with postoperative pains than the original.

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4	Mar. 11, 2014 Total review time: 326 days Regulatory review time: 160 days	Jun. 11, 2001 Clinical evaluation report	34	Subcutaneous Implantable Lead System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A subcutaneously implanted lead with a defibrillation coil electrode for ICD and CRT-D. This product is used for patients with a high defibrillation threshold in whom it is difficult for a normal transvenous defibrillation lead to work effectively. A clinical evaluation report summarizing results of foreign clinical studies was submitted to confirm the efficacy and safety of this device.
5	Apr. 17, 2013 Total review time: 279 days Regulatory review time: 240 days	- (About these changes) Clinical evaluation report	35	Dornier Delta II (Dornier Medtech Japan Co., Ltd.)	Change	Instrument & apparatus 12 Extracorporeal lithotripter	An electromagnetic lithotripter used in bloodless treatment by radiating a shock wave from outside the body to a calculus to crush it into small fragments. The product consists of a shock wave generating device, a X-ray device, an ultrasonic device, ECG device, and a treatment table. An application for a partial change to add an indication for pancreatolithiasis to the conventional indication for calculus of the upper urinary tract and biliary calculus with no change of the product itself. A clinical evaluation report summarizing literature cited in three domestic guidelines on treatment of pancreatolithiasis and literature on clinical use of this product.
5	May 21, 2013 Total review time: 294 days Regulatory review time: 142days	- Clinical evaluation report	36	Niti-S Colorectal Stent (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Colonic stent	A biliary stent used to relieve obstructive symptoms before surgery for stricture of the large intestine caused by malignant tumors or for palliation in patients with unresectable malignant tumors or who are not expected to respond to other treatments. A clinical study report, which summarizes literature information using technical success of stent placement, improvement of obstructive symptoms after the placement, and the incidence of adverse events as evaluation items, was submitted to confirm the efficacy and safety of this device when it is used for relief of obstructive symptoms before surgery or palliation.
5	Jun. 5, 2013 Total review time: 125 days Regulatory review time: 114 days	- Domestic clinical study results	37	PEPA Hemodiafilter GDF (Nikkiso Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has been markedly reduced due to chronic or acute renal failure, etc. Because equivalence to the approved haemodiafiltration device was not demonstrated with regard to the semipermeable membrane material, a clinical study was conducted to confirm the efficacy and safety.
5	Jul. 3, 2013 Total review time: 400 days Regulatory review time: 115 days	- Clinical evaluation report	38	Niti-S Comvi Pyloric/Duodenal stent (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Gastroduodenal stent	A gastroduodenal stent for patients with unresectable malignant gastroduodenal stenosis who cannot be managed by palliative surgical therapy and are not expected to achieve improvement with other treatments. The main difference from the approved product “Niti-S Gastroduodenal Stent (Approval No. 22300BZX00428000)” is that this product has a cover made of PTFE. A clinical study report was submitted summarizing results of literature research on clinical data to evaluate the efficacy and safety of this device compared to an uncovered stent.
5	Jul. 11, 2013 Total review time: 296 days Regulatory review time: 172 days	- Domestic clinical study results	39	PillCam COLON 2 Capsule Endoscopy System (Given Imaging K.K.)	Approval	Instrument & apparatus 25 Capsule electronic endoscope system	A capsule electronic endoscope system to take images of colorectal mucosa and provide the images when colonoscopy is required for diagnosis of colonic diseases but it is difficult to be performed. The main difference from the approved product “Given Capsule Endoscopy (Approval No. 22100BZX00363000)” is that this product is used for diagnosis of colonic diseases. A clinical study was conducted to evaluate the sensitivity of this device in subjects who were detected by colonoscopy to have diseases which require endoscopic or surgical therapy.

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5	Sep. 12, 2013 Total review time: 295 days Regulatory review time: 164 days	- Domestic clinical study results	40	Prismaflex ST (Gambro K.K.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter to improve clinical conditions by performing continuous hemodiafiltration. It is used in patients with severe sepsis or septic shock, patients with acute renal failure accompanying diseases or conditions including sepsis, multi organ failure, acute hepatic failure, acute respiratory failure, acute cardiovascular failure, acute pancreatitis, burn injury, traumatic injury, postoperative diseases or patients with chronic renal failure who have unstable circulation dynamics associated with these diseases or conditions. This product is a filter used for slow continuous hemofiltation that is connected to a blood circuit. The main difference from the approved product “Hemofeel SH (Approval No. 21200BZZ00274000)” is that the product is indicated for patients with severe sepsis or septic shock. A clinical study was conducted to evaluate the efficacy and safety of this device in patients with severe sepsis or septic shock.
5	Sep. 12, 2013 Total review time: 295 days Regulatory review time: 164 days	- Domestic clinical study results	41	SepXiris (Gambro K.K.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter to improve clinical conditions by performing continuous hemodiafiltration. It is used in patients with severe sepsis or septic shock, patients with acute renal failure accompanying diseases or conditions including sepsis, multi organ failure, acute hepatic failure, acute respiratory failure, acute cardiovascular failure, acute pancreatitis, burn injury, traumatic injury, postoperative diseases or patients with chronic renal failure who have unstable circulation dynamics associated with the diseases or conditions. The main difference from the approved product “Hemofeel SH (Approval No. 21200BZZ00274000)” is that the product is indicated for patients with severe sepsis or septic shock. A clinical study was conducted to evaluate the efficacy and safety of this device in patients with severe sepsis or septic shock.
5	Jan. 14, 2014 Total review time: 264 days Regulatory review time: 162 days	- Domestic clinical study results	42	Fineflux (Nipro Corporation)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has been markedly reduced due to chronic or acute renal failure, etc. Cellulose triacetate, which has been conventionally used as a hollow fiber membrane raw material of a hemodialyzer, is adopted as a hollow fiber membrane raw material of the hemodiafilter. A clinical study was conducted to evaluate the efficacy and safety because the raw material of its semipermeable membrane was proved to be not equivalent to that of the approved product.
5	Jan. 28, 2014 Total review time: 152 days Regulatory review time: 113 days	- Clinical evaluation report	43	MucoUp (Seikagaku Corporation)	Change	Medical products 4 Submucosal filling material for endoscope	A submucosal filling material for an endoscope containing the active ingredient sodium hyaluronate. It is injected submucosally during endoscopic mucosal resection or endoscopic submucosal dissection to form a mucosal protrusion and maintain it. This application for a partial change for medical devices is to add an indication for the site of esophageal tumors. A clinical evaluation report summarizing literature information was submitted to evaluate the efficacy and safety when it is used in endoscopic mucosal resection/endoscopic submucosal dissection.
6-1	Jun. 12, 2013 Total review time: 957 days Regulatory review time: 260 days	- Clinical evaluation report	44	Biomet Biolox Delta Ceramic Liner (At the time of approval, Biomet Japan, Inc.; currently, Biomet Japan, LLC)	Approval	Medical products 4 Artificial hip joint, acetabular component	A liner made of zirconia-toughened alumina ceramic composites used in combination with the company’s approved product “Biomet Biolox Delta Ceramic Head (Approval No. 22400BZX00141000).” Because the combination of the company’s liner material and head material was an unprecedented combination, a clinical evaluation report summarizing its efficacy and safety based on foreign use results and published literature was submitted.
6-1	Sep. 6, 2013 Total review time: 134 days Regulatory review time: 107 days	- Clinical evaluation report	45	Adler BIOLOX delta Ceramic System (Robert Reid Inc.)	Approval	Medical products 4 Total hip prosthesis	A femoral stem-head and an acetabulum-forming liner made of alumina-zirconia ceramics composite used in hip replacement used in combination with the approved products “Alder prosthetic hip joint system (Approval No. 22500BZX00017000),” “HYDRA Femoral Component (Approval No. 22500BZX00018000),” and “BIOLOX delta Ceramic Head (Approval No. 22500BZX00019000).” Because combination of the company’s head and liner made of the raw material was unprecedented, a clinical evaluation report evaluating the incidence of repeat replacements and the incidence of defects based on foreign use results and published literature was submitted.

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6-1	Jan. 28, 2014 Total review time: 144 days Regulatory review time: 62 days	- Clinical evaluation report	46	R3 Delta Ceramic Liner (Smith & Nephew Orthopaedics KK)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for total hip replacement. It is made of zirconia-toughened alumina (BIOLOX delta) for improvement of its brittleness and abrasion property. It was developed to obtain a hip joint bearing with excellent abrasion characteristics and fracture strength by delta on delta in combination with a delta ceramic head made of the same material. A clinical evaluation report was submitted to confirm the performance of the bearing surface with the new material.
6-1	Feb. 13, 2014 Total review time: 539 days Regulatory review time: 159 days	- Domestic clinical study results	47	Zimmer Delta Ceramic Liner (Zimmer K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for total hip replacement. It is made of zirconia-toughened alumina (BIOLOX delta) for improvement of its brittleness and abrasion property. It was developed to obtain a hip joint bearing with excellent abrasion characteristics and fracture strength by delta on delta in combination with the company's artificial caput made of the same material. Domestic clinical study results were submitted to demonstrate that this device with the newly adopted material is not inferior to the approved prosthetic hip joint in the efficacy and safety.
6-2	Aug. 9, 2013 Total review time: 591 days Regulatory review time: 220 days	Mar. 31, 2004 Domestic clinical study results	48	CranioFix Absorbable (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Absorbable cranial fixation clamp	An implantable cranial fixation device composed of two absorbable discs, of which are made of polyester [Poly (L-lactide-co-D, L-lactide) 70:30], and a non-absorbable suture to fix them. It is used to fix a free bone flap during closing of the cranium in a craniotomy. This device has the following points as differences from the approved devices: (1) The device offers a more simple operation of cranial fixation in a shorter time because operation to heat and shape a plate and exclusive tools became unnecessary; (2) It also has no artifact in postoperative MRI or CT images; (3) The absorbable material causes no problems of impeding growth of bones in children or its moving and it is not necessary to be removed at the time of repeat surgery. Clinical studies were conducted to confirm the efficacy and safety of this product with the newly adopted absorbable material.
6-2	Sep. 6, 2013 Total review time: 220 days Regulatory review time: 138 days	Mar. 11, 2009 Domestic clinical study results	49	GRYPHON BR Anchor (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	A suture anchor used to fix soft tissues such as ligaments in a shoulder, foot/ankle, elbow, hip to a bone. The product consists of an absorbable anchor, partially absorbable sutures, and an inserter. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate which is unprecedented in Japan, is adopted as a raw material of the anchor. A clinical study was conducted to confirm the efficacy and safety of this product with the newly adopted absorbable material.
6-2	Sep. 6, 2013 Total review time: 220 days Regulatory review time: 140 days	Feb. 29, 2012 Domestic clinical study results	50	HEALIX ADVANCE BR Anchor (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	A suture anchor to fix a rotator cuff to a bone. The product consists of an absorbable anchor, partially absorbable sutures, and an inserter. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate of which a remaining period is shorter than that of a poly-L-lactic acid anchor, is adopted as a raw material. Clinical study results using anchors of the same raw material as that of this product were submitted to confirm that failure caused by the material does not occur.
6-2	Sep. 6, 2013 Total review time: 190 days Regulatory review time: 103 days	Mar. 31, 2004 Domestic clinical study results	51	MILAGRO Interference Screw (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	An interference screw used to fix soft tissue to a bone. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate of which a remaining period is shorter than that of a poly-L-lactic acid anchor, is adopted as a raw material. Clinical study results using anchors of the same raw material as that of this product were submitted to confirm that failure caused by the material does not occur.
6-2	Sep. 17, 2013 Total review time: 1040 days Regulatory review time: 529 days	Apr. 3, 2009 Foreign clinical study results	52	Hydrosite Gentle Ag (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	An antibacterial wound dressing and protecting material containing sulfadiazine silver as an antibacterial ingredient added to the absorption pad layer of the approved product "Hydrosite AD Gentle (Approval No. 22100BZX00942000)." It is used for wounds with exudate fluid which have a high possibility of infection. Foreign clinical study results on a similar product which has a different adhesive agent on a wound contact layer were submitted to confirm if the antibacterial ingredient causes no problems such as protracted wound healing.

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6-2	Sep. 17, 2013 Total review time: 1040 days Regulatory review time: 529 days	Apr. 3, 2009 Foreign clinical study results	53	Hydrosite Ag (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	An antibacterial wound dressing and protecting material containing sulfadiazine silver as an antibacterial ingredient added to the absorption pad layer of the approved product “Hydrosite Plus (Approval No. 22100BZX01097000).” In addition, soft gel is applied to the wound contact surface of the approved product to improve the operability. It is used for wounds with exudate fluid which have a high possibility of infection. Foreign clinical study results on a similar product which has a different adhesive agent on a wound contact layer were submitted to confirm if the antibacterial ingredient causes no problems such as protracted wound healing.
6-2	Sep. 24, 2013 Total review time: 501 days Regulatory review time: 197 days	Aug. 1, 2011 Domestic clinical study results	54	Versajet II (Smith & Nephew Wound Management KK)	Approval	Instrument & apparatus 12 Hydraulic knife	A device to be used for wound debridement (acute wounds, chronic wounds and burn wounds), soft tissue debridement and operative wound cleaning with waterjet. Improvement in connectivity between the hand piece and the console and water resistance of the console was provided to enhance the operability of the approved product “Versajet S (Approval No. 22400BZX00233000)”. A non-clinical study demonstrated the performance equality between both products. A clinical study was conducted to confirm the efficacy and safety of debridement.
6-2	Sep. 27, 2013 Total review time: 1646 days Regulatory review time: 346 days	Jan. 25, 2007 Clinical evaluation report	55	Mepilex Ag (Mölnlycke Health Care K.K.)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	A wound dressing and protecting material used to "protect wound" reaching subcutaneous adipose tissue (except for third degree burns), "maintain a moist environment," "promote healing," and "relieve pain." It is used for wounds with exudate fluid which have a high possibility of infection. The product consists of a silicone gel-coated hydrophilic polyurethane foam containing silver and a vapor-permeable polyurethane film. A clinical evaluation report based on foreign use-results and published literature of this product and similar products was submitted to confirm if silver contained in the product causes no problem such as protracted wound healing.
6-2	Dec. 12, 2013 Total review time: 1081 days Regulatory review time: 256 days	- Clinical evaluation report	56	Laminoplasty Basket Plate Set (Ammtec Inc.)	Approval	Medical products 4 Internal fixation plate	An internal fixation plate used for fixing severed bone parts after spinal decompression for spinal cord compression. It is fixed to the space of vertebral lamina removed in laminoplasty by a screw. In addition, an implanted bone is able to be filled into the basket portion. A clinical evaluation report based on literature research on usual laminoplasty and use results of the approved product used in the surgery was submitted to demonstrate that the fixation performance and safety of this product are equivalent to the approved product.
6-2	Dec. 25, 2013 Total review time: 288 days Regulatory review time: 75 days	- Clinical evaluation report	57	SonicWeld Rx System (Nippon Martin K.K.)	Approval	Medical products 4 Absorbable plate for internal fixation	A device consisting of a plate and a pin used in a bone junction or reconstruction of cranio-maxillo-facial bone or bone fragment fixation in bone transplantation to cranio-maxillo-facial bone, and an ultrasonic fixator to fix them. The pin and the plate are made of polylactic acid which is absorbed into the body. This product has a characteristic that its ultrasonic fixator generates vibrating energy, which melts and hardens the pin in the bone hole to fix the plate. A clinical evaluation report was submitted to evaluate that the fixation performance and safety with this absorbable material are equivalent to those of similar products.
6-2	Jan. 28, 2014 Total review time: 1065 days Regulatory review time: 123 days	May 6, 2003 Clinical evaluation report	58	Simplex P with Tobramycin (Stryker Japan K.K.)	Approval	Medical products 4 Orthopedic bone cement	The acrylic orthopedic bone cement used to fix a substitution material (artificial bone head, hip joint or knee joint) to an in vivo bone. One gram of tobramycin is sterilely added to the approved product “Surgical Simplex.” It is used in the second stage of a two-stage revision prosthetic joint replacement associated with postoperative infection in a prosthetic joint replacement. A clinical evaluation report was submitted to demonstrate that the added antibacterial agent does not affect the efficacy and safety of the orthopedic bone cement.

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6-2	Feb. 28, 2014 Total review time: 273 days Regulatory review time: 94 days	Aug. 3, 2005 Clinical evaluation report	59	Cobalt G-HV Bone Cement (At the time of approval, Biomet Japan, Inc.; currently, Biomet Japan, LLC)	Approval	Medical products 4 Orthopedic bone cement	A device that gentamicin sulfate is added to the company's approved orthopedic bone cement "Cobalt HV Bone Cement" as an antibacterial agent. It is used in the second stage of a two-stage revision prosthetic joint replacement associated with postoperative infection in a prosthetic joint replacement. A clinical evaluation report was submitted to demonstrate that the added antibacterial agent does not affect the efficacy and safety of the orthopedic bone cement.
6-2	Mar. 19, 2014 Total review time: 2211 days Regulatory review time: 484 days	Jun. 2, 2006 Foreign clinical study results	60	Juvederm Vista Ultra (Allergan Japan KK)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft-tissue using hyaluronic acid. It is injected into the dermis to correct facial wrinkles and folds. Crosslinked and non-crosslinked hyaluronic acid, non-animal derived, obtained by fermentation of bacteria are mixed and filled into a syringe. Compared to the conventional injectable material using animal-derived collagen, the risk of allergy and infection was reduced. This product has different degrees of gel crosslinking from "Juvederm Vista Ultra Plus," an application of which was submitted at the same time. This product is a softer injectable material. Foreign clinical study results were submitted to demonstrate its non-inferiority and safety compared to a control injectable material using collagen and safety.
6-2	Mar. 19, 2014 Total review time: 2211 days Regulatory review time: 484 days	Jun. 2, 2006 Foreign clinical study results	61	Juvederm Vista Ultra Plus (Allergan Japan KK)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material into soft tissue using hyaluronic acid. It is injected into the dermis to correct facial wrinkles and folds. Crosslinked and non-crosslinked hyaluronic acid, non-animal derived, obtained by fermentation of bacteria are mixed and filled into a syringe. Compared to the conventional injectable material using animal-derived collagen, the risk of allergy and infection was reduced. This product has different degrees of gel crosslinking from "Juvederm Vista Ultra," an application of which was submitted at the same time. This product is a harder injectable material. Foreign clinical study results were submitted to demonstrate its non-inferiority and safety compared to a control injectable material using collagen and safety.
8	Dec. 6, 2013 Total review time: 525 days Regulatory review time: 118 days	- Domestic clinical study results	62	Visceral Fat Meter EW-FA90 (Panasonic Corporation)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A body component analyzer consisting of an apparatus body, a measuring belt for abdomen, and pads. The cross section area of visceral fat estimated by a unique calculating formula based on abdominal impedance and the measured value of abdominal circumference is displayed on the apparatus body. A clinical study was conducted to evaluate the correlation between the cross section area of visceral fat by CT tomogram of the abdomen and an estimated value by this product and its screening performance (sensitivity and specificity).
8	Jan. 16, 2014 Total review time: 294 days Regulatory review time: 100 days	- Clinical evaluation report	63	Elmammo, Dedicated PET Scanner for Breast Imaging (Shimadzu Corporation)	Approval	Instrument & apparatus 10 Positron emission tomography device for nuclear medicine diagnosis	A dedicated PET scanner for breast imaging to provide image information of distribution of a positron radioactive drug administered to patients within breasts by detecting exogenously with a gamma radiation detector. A clinical evaluation report was submitted to evaluate the effectiveness of images provided by this product in comparison to those by whole-body PET, contract-enhanced MRI and mammography.

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Products Approved in FY 2012: New Medical Devices

Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-1	Apr. 6, 2012 Total review time: 282 days Regulatory review time: 244 days	Nov. 1, 2011 Foreign clinical study results	1	XIENCE PRIME Drug-eluting Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. The improvements from the company's predicate device are the different strut and the new stent lengths, 33 mm and 38 mm. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with symptomatic ischemic heart disease. (The original product is in a reexamination period)
3-1	Jul. 9, 2012 Total review time: 69 days Regulatory review time: 45 days	– No clinical study results	2	Nobori (Terumo Corporation)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent used for treatment of patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 30 mm or less) with a reference vessel diameter of 2.5-3.5 mm. An application for a partial change to alter the test specifications for the drug (biolimus). (A partial change during the reexamination period)
3-1	Jul. 27, 2012 Total review time: 854 days Regulatory review time: 327 days	Oct. 15, 2009 Foreign clinical study results	3	MOMA Ultra (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting with dilatation of 2 balloons to occlude the common carotid artery and external carotid artery. Clinical studies were conducted by using the pre-improvement product to confirm the efficacy and safety of this product for patients at a high surgical risk of complications of carotid artery endarterectomy.
3-1	Sep. 6, 2012 Total review time: 385 days Regulatory review time: 291 days	Jun. 1, 2012 Global clinical trial and domestic clinical study results	4	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. The stent with a diameter of 2.25 mm included in this product is the first coronary stent in Japan which is used for elective cases in patients with symptomatic ischemic heart diseases due to de novo lesions in native coronary arteries with a reference vessel diameter of 2.25-2.50 mm. Clinical studies were conducted to confirm the efficacy and safety of this product for small vascular lesions.
3-1	Nov. 29, 2012 Total review time: 49 days Regulatory review time: 47 days	- No clinical study results	5	MOMA Ultra (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting with dilatation of 2 balloons to occlude the common carotid artery and external carotid artery. An application for a partial change to change the specifications, etc. of endotoxin test. (A partial change during the reexamination period)
3-1	Dec. 5, 2012 Total review time: 433 days Regulatory review time: 195 days	- Domestic clinical study results	6	Misago (Terumo Corporation)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in percutaneous angioplasty) and a delivery system to deliver the stent to the site of the lesion, for the treatment of symptomatic arterial diseases in the superficial femoral artery region. A clinical study was conducted to evaluate the efficacy and safety in bail-out treatment for stenosis or occlusion of the superficial femoral artery. (The original product is in a reexamination period)
3-1	Mar. 7, 2013 Total review time: 463 days Regulatory review time: 390 days	Nov. 1, 2011 Domestic clinical study results	7	XIENCE PRIME SV Drug-eluting Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. This product is used for elective cases in patients with symptomatic ischemic heart diseases due to *de novo* lesions in native coronary arteries with a reference vessel diameter of 2.25-2.50 mm. Clinical studies were conducted to evaluate the efficacy and safety of this product for small vascular lesions. (The original product is in a reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
3-2	Sep. 28, 2012 Total review time: 470 days Regulatory review time: 109 days	May. 27, 2010 Domestic clinical study results	8	Neuroform Stent (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	An intracranial artery stent (for treatment of cerebral aneurysm) used to prevent coil migration in coil embolization for wide-necked cerebral aneurysm. "Codman Enterprise VRD (Approval No. 22200BZX00078000)", an already-approved similar medical device, has a stent with a closed cell structure, but this product is characterized by a stent with an open cell structure. Clinical studies were conducted to evaluate the efficacy and safety of this product for patients with wide-necked cerebral aneurysm. (The original product is in a reexamination period)
3-2	Sep. 28, 2012 Total review time: 458 days Regulatory review time: 317 days	Sep. 9, 2003 Domestic clinical study results	9	AMPLATZER Vascular Plug (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material to promote vascular embolization which is used to occlude blood vessels and reduce, block, or alter blood flow by inserting and placing it transdermally in arteries/veins, except blood vessels in the heart and the skull. Clinical studies were conducted to confirm the efficacy and safety of this product for occlusion of vascular lesions, alteration of blood flow, and hemostasis for hemorrhagic lesions.
3-2	Nov. 21, 2012 Total review time: 100 days Regulatory review time: 38 days	- No clinical study results	10	Penumbra System (Medico's Hirata Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A catheter for removal of emboli in the central circulation system to be used to restore the blood flow by aspirating thrombi in patients in acute phase of cerebral infarction who fail intravenous infusion of a tissue plasminogen activator (t-PA). An application for a partial change to prolong the expiration period. (A partial change during the reexamination period)
3-2	Dec. 27, 2012 Total review time: 505 days Regulatory review time: 348 days	- Domestic clinical study results	11	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of thoracic aortic aneurysm. For the product, 64 kinds of stent skeletons are set up as basic shapes by making differences in stent length, curvature, and torsion angle in order for it to fit the site and shape of the aorta where the product is placed. A straight-type or a tapered-type graft is sutured and fixed in accordance with the diastolic diameter of this stent skeleton, and fenestration is present or absent in a graft; and therefore there are 952 patterns of stent grafts depending on the combination. A clinical study was conducted to evaluate the efficacy and safety in the treatment of thoracic aortic aneurysm.
3-2	Mar. 22, 2013 Total review time: 493 days Regulatory review time: 199 days	- Clinical evaluation report	12	Serescue (Astellas Pharma Inc.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A porous gelatin sponge plate was developed as a vascular embolization material. Users cut this plate to an appropriate size using the sterilized medical knife, medical scissors, etc. with consideration of the vascular diameter of the site to be applied, suspend it with an appropriate amount of a contrast medium, and deliver it to the site in the blood vessel via a catheter to block the blood flow or to support forming an embolus. In this way, the hemostatic effect is expected for bleeding to which direct pressure cannot be applied from the body surface. A clinical evaluation report summarizing the results of literature searches on the efficacy and safety of transcatheter hemostasis using a gelatin sponge equivalent to this product was submitted.
3-2	Mar. 29, 2013 Total review time: 499 days Regulatory review time: 194 days	Jun. 18, 2007 Domestic clinical study results	13	AMPLATZER Vascular Plug II (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels consisted of a self-expandable plug with a nitinol mesh wire of a cylindrical form, a push wire to send the plug to a target site, and a loader that stores the plug in the expanded state. It blocks a blood vessel by being percutaneously inserted and placed in the arteries and veins except blood vessels in the heart and the skull, and reduces, blocks or alters the blood flow. A major difference from the approved "AMPLATZER Vascular Plug" (Approval No. 22400BZX00361000) is a change in the plug shape from a simple cylindrical shape to a shape composed of three cylindrical blocks. The change intends to shorten the time for vascular occlusion by creating many barriers against the blood flow and adding size variations. Results from Japanese clinical studies using the approved product were submitted to evaluate the efficacy and safety of this product in patients with occlusion of vascular lesions, patients indicated for alternation of blood flow, and patients indicated for hemostasis of hemorrhagic lesions. (The original product is in a reexamination period)

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3-2	Jan. 28, 2013 Total review time: 374 days Regulatory review time: 247 days	- Domestic clinical study results	14	Bronchial Blocker EWS (Harada Corporation)	Approval	Instrument & apparatus 7 Bronchial blocker	A silicone resin bronchial blocker that is used to fill the bronchi and close fistula in patients who have refractory and inoperable, secondary pneumothorax, prolonged airleak following pneumectomy or other fistula. Clinical studies were conducted to evaluate the efficacy and safety of this product for the target diseases. [Orphan device]
4	May. 31, 2012 Total review time: 168 days Regulatory review time: 85 days	Dec. 19, 2008 (Approval of application corresponding to the present partial change) No clinical study results	15	Vagus Nerve Stimulation Device VNS System (Nihon Kohden Corporation)	Change	Instrument & apparatus 12 Vagus nerve stimulation device with anti-seizure effects	An electrical stimulation device to stimulate vagus nerve as an adjuvant therapy to reduce the frequency of seizures for patients with drug-resistant epilepsy who have refractory epileptic seizures. An application for a partial change to add a lead which is intended to improve fatigue durability. (A partial change during the reexamination period)
4	Jun. 25, 2012 Total review time: 1666 days Regulatory review time: 446 days	Aug.1, 2003 Foreign clinical study results	16	Thermogard System (ZOLL Circulation, Inc.)	Approval	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheter balloon in which a perfusion fluid (physiological saline) circulates in patients who need body temperature management. The product consists of a main device to deliver the perfusion fluid whose temperature is adjusted in the thermostatic chamber of the product and a central venous catheter with a perfusion-type balloon. Clinical studies were conducted to evaluate the performance and adverse events of this product when used in the human body.
4	Sep. 7, 2012 Total review time: 263 days Regulatory review time: 161 days	- No clinical study results	17	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. This application for a partial change was filed to alter the alarm and to add a small, light controller, etc. (A partial change during the reexamination period) [Orphan device]
4	Nov. 7, 2012 Total review time: 57 days Regulatory review time: 40 days	- No clinical study results	18	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which heart transplant is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as the use of an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. An application for a partial change in order that the power connector will not easily come off, in accordance with the Instruction 1 given at the time of approval: "Continuously examine measures for reducing power disruption risk, and consider revising the specifications of the product." (A partial change during the reexamination period) [Orphan device]
4	Nov. 29, 2012 Total review time: 513 days Regulatory review time: 131 days	Apr. 21, 2008 Domestic and foreign clinical study results	19	Implantable ventricular assist device HeartMate II (Thoratec Corporation)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	The first axial-flow implantable ventricular assist device system in Japan to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which heart transplant is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as the use of an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. A clinical study was conducted in the US to evaluate the efficacy and safety of this product, and a domestic clinical study was conducted to evaluate the efficacy and safety in Japan where healthcare environments are different from those in the US.
4	Nov. 29, 2012 Total review time: 139 days Regulatory review time: 91 days	- Foreign clinical study results	20	CapSure Sense MRI Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead used by connecting them to an implantable cardiac pacemaker. The patients implanted the device can conditionally undergo an MRI scan. Efficacy and safety evaluations of this product were performed based on the results of overseas clinical studies of the original product "CapSure FIX MRI Lead (approval No.: 22400BZX00132000)." (The original product is in a reexamination period)
4	Nov. 29, 2012 Total review time: 139 days Regulatory review time: 99 days	- No clinical study results	21	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. An application for a partial change to add the pacemaker lead "CapSure Sense MRI Lead," which is newly available for connection, as a compatible medical device. (A partial change during the reexamination period)

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4	Dec. 26, 2012 Total review time: 159 days Regulatory review time: 49 days	Aug. 23, 2007 No clinical study results	22	Thermogard System (ZOLL Circulation, Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheter balloon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. An application for partial changes including modification of the compressor in the main device and partial deletion of options for flow rate settings. (A partial change during the reexamination period)
4	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 295 days	Jan. 4, 2008 Domestic clinical study results	23	NaviStar RMT ThermoCool (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter for the radiofrequency catheter ablation and for the electrophysiological study; it is used to treat symptomatic drug refractory paroxysmal and persistent atrial fibrillation, atrial flutter and ventricular tachycardia which is not treated effectively by other ways. This device is manipulated with "Magnetic Navigation System Niobe" (Approval No. 22500BZX00103000). It also has an irrigation system that flows with saline from an irrigation hole at the tip electrode. The clinical study was conducted to evaluate the efficacy and safety of manipulating it by the Magnetic Navigation System Niobe.
4	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 295 days	Jan. 26, 2006 Domestic clinical study results	24	NaviStar RMT (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter for the radiofrequency catheter ablation and for the electrophysiological study; it is used to treat supraventricular tachycardia. This device is manipulated with "Magnetic Navigation System Niobe" (Approval No. 22500BZX00103000). The clinical study was conducted to evaluate the efficacy and safety of manipulating it by the Magnetic Navigation System Niobe.
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	25	Evia T Series Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as an implantable cardiac pacemaker which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	26	Evia Series Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as an implantable cardiac pacemaker which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	27	Solia S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as a pacemaker lead which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	28	Solia T (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as a pacemaker lead which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 29, 2013 Total review time: 210 days Regulatory review time: 60 days	Aug. 23, 2007 No clinical study results	29	Thermogard System (ZOLL Circulation Inc.)	Change	Instrument & apparatus 12 Central venous placement temperature management system	A temperature management device to regulate the body temperature by heat exchange with the blood within a blood vessel through a central venous catheter balloon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. An application for partial change to add a catheter introducer kit to components. (A partial change during the reexamination period)

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6-2	Jun. 25, 2012 Total review time: 278 days Regulatory review time: 216 days	- (No application filed for pustular psoriasis in US) Domestic clinical study results	30	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Purifier for blood cell removal	A extracorporeal column for improving pathological conditions by adsorption/apheresis of white blood cells, mainly granulocytes in the peripheral blood, and suppressing inflammatory reactions. An application for a partial change to add the improvement of clinical symptoms of pustular psoriasis to the indications. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with moderate or severe pustular psoriasis. [Orphan medical device]
6-2	Jul. 31, 2012 Total review time: 319 days Regulatory review time: 230 days	Feb. 25, 2009 Domestic clinical study results	31	RENASYS Wound Therapy System (Smith & Nephew Wound Management K.K.)	Approval	Medical products 4 Negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by maintaining a local negative-pressure environment, protecting wounds, and removing exudative fluid, infectious material, etc. for patients with refractory wounds who have not responded to existing treatments or are considered to not be responding. Clinical studies were conducted to evaluate the efficacy and safety of this product for acute, subacute, and chronic refractory wounds. (The original product is in a reexamination period)
6-2	Sep. 12, 2012 Total review time: 104 days Regulatory review time: 95 days	- No clinical study results	32	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. An application for a partial change to add a new size of a component of the single-use vertebral body restoration device and manufacturing sites. (A partial change during the reexamination period)
6-2	Sep. 28, 2012 Total review time: 2080 days Regulatory review time: 436 days	Nov. 17, 2006 Foreign clinical study results	33	Natrelle Breast Implant (Allergan Japan K. K.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled breast in which silicone gel is filled in a shell made of silicone elastomer which repairs or forms the shape of a breast after insertion into the application site. It is used for breast reconstruction surgery or augmentation mammaplasty. Clinical studies were conducted to evaluate the efficacy and safety of this product when used for breast reconstruction surgery, augmentation mammaplasty, and revision surgery.
6-2	Sep. 28, 2012 Total review time: 309 days Regulatory review time: 147 days	- No clinical study results	34	V.A.C.ATS Therapy System (KCI K.K.)	Change	Medical products 4 Negative pressure wound therapy system	A negative-pressure wound therapy system to promote wound healing by maintaining the local negative-pressure environment, protect wounds, and remove exudative fluid, infectious material, etc. for patients with refractory wounds who have not responded to existing treatments or are considered to not be responding. An application for partial changes for addition of manufacturing sites and updating of approved matters regarding sizes, raw materials, etc. (A partial change during the reexamination period)
6-2	Oct. 22, 2012 Total review time: 39 days Regulatory review time: 28 days	- No clinical study results	35	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. Addition of a manufacturing site. (A partial change during the reexamination period)
6-2	Nov. 12, 2012 Total review time: 60 days Regulatory review time: 28 days	- No clinical study results	36	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	A therapeutic spinal bone cement used in percutaneous kyphosis correction in acute spinal compression fracture performed for restoration of the height of fractured vertebrae, fixation of the vertebral body, and pain relief. This product is used with KYPHON BKP System. Addition of a manufacturing site. (A partial change during the reexamination period)
6-2	Dec. 18, 2012 Total review time: 280 days Regulatory review time: 102 days	Dec. 7, 2007 No clinical study results	37	VertaPlex Bone Cement (Stryker Japan K.K.)	Change	Medical products 4 Orthopedic bone cement	The product is used in percutaneous vertebroplasty to mitigate pain in patients with malignant spinal tumor such as painful metastatic bone tumor and myeloma who have not responded to conventional therapy. An application for a partial change to change the setting time (hardening time). (A partial change during the reexamination period)

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6-2	Mar. 22, 2013 Total review time: 387 days Regulatory review time: 143 days	- Domestic clinical study results	38	Nerve Regeneration Guidance Conduit Nerbridge (Toyobo Co., Ltd.)	Approval	Medical products 4 Collagen-containing absorbable nerve regeneration inducing material	A polyglycolic acid conduit filled with sponge-like collagen which is inserted into defects of the peripheral nerves that have been ruptured or broken because of injuries, etc. in order to induce regeneration of the nerve and reconstruct the function by bridging both ends of nerve. A prospective clinical study was conducted to evaluate the efficacy and safety of this product in patients with peripheral nerve defect on the distal wrist.
8	Oct. 18, 2012 Total review time: 385 days Regulatory review time: 235 days	Feb. 18, 2009 Foreign clinical study results	39	da Vinci Si Surgical System (Intuitive Surgical Inc.)	Approval	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist the surgeon's manipulation of endoscopic surgical devices when endoscopic surgery is performed in areas of general digestive surgery, thoracic surgery (except cardiac surgery), urology, and gynecology. Improvement from the original product "da Vinci Surgical System (approval No.: 22100BZX01049000)" includes downsizing of the surgeon consoles and enabling setting of the position of movement according to the needs of the surgeon. In addition, as a secondary function, two surgeons can manipulate the device, when two surgeon consoles are connected. Results of clinical studies using the original product were submitted to explain the extrapolability to efficacy and safety evaluation of this product. (The original product is in a reexamination period)
8	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 327 days	Jan. 15, 2003 Domestic clinical study results	40	Magnetic Navigation System Niobe (Siemens Japan K.K.)	Approval	Instrument & apparatus 51 Cardiac Mapping System Workstation	A guiding system that navigates "NaviStar RMT ThermoCool" (Approval No. 22500BZX00104000) or "NaviStar RMT" (Approval No. 22500BZX00107000), both of which are exclusive catheters to this system, to a target region in intervention procedures. Clinical studies were conducted to evaluate the efficacy and safety of manipulating these exclusive catheters with this device.
Biologics -2	Jul. 27, 2012 Total review time: 1068 days Regulatory review time: 200 days	- Domestic clinical study results	41	Jacc (Japan Tissue Engineering Co., Ltd.)	Approval	Instrument & apparatus 7 Human autologous cells and tissue	An autologous cultured cartilage to alleviate clinical symptoms by implanting it in the affected site of traumatic cartilage deficiency and osteochondritis dissecans (excluding knee osteoarthritis) in knee joints with a cartilage defective area of 4 cm2 or more for which there are no other treatment options. Chondrocytes isolated from the non-load-bearing site of a knee joint of patients by taking a small amount of cartilage tissue are three-dimensionally cultured in atelocollagen gel to obtain this product. Clinical studies were conducted to evaluate the efficacy and safety of this product for patients with traumatic cartilage deficiency, osteochondritis dissecans, and knee osteoarthritis.
Biologics -2	Sep. 28, 2012 Total review time: 1652 days Regulatory review time: 357 days	Nov. 21, 2003 Foreign clinical study results	42	Contegra Pulmonary Valved Conduit (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel with a bovine-derived valve	A conduit with a pulmonary valve made of bovine jugular veins which is used to repair/reconstruct the right ventricular outflow tract leading to the pulmonary arteries from the heart. A clinical study was conducted to evaluate the efficacy and safety of this product in children (aged under 18 years) with abnormality of the right ventricular outflow tract or functional failure of an already-implanted homograft, etc.
Cellular and tissue-based products	Dec. 27, 2012 Total review time: 59 days Regulatory review time: 37 days	- No clinical study results	43	Jacc (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This autologous cultured cartilage uses atelocollagen as a scaffolding material for culture. It is necessary to perform an allergy test for atelocollagen before applying this product. An application for partial changes, including addition of a syringe for intradermal tests of the atelocollagen as a component of this product, and change in biological ingredients in the raw materials. (A partial change during the reexamination period)
Cellular and tissue-based products	Mar. 29, 2013 Total review time: 205 days Regulatory review time: 102 days	- No clinical study results	44	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	An autologous-cultured epidermis manufactured with epidermal cells derived from patients with severe burn injury and multiple biological materials. An application for partial changes, including change in the biological raw materials and addition of component(s). (A partial change during the reexamination period)
Specified Partial Change	Apr. 19, 2012 Total review time: 56 days Regulatory review time: 34 days	- No clinical study results	45	Zilver PTX Drug-eluting Peripheral Stent (Cook Japan Inc.)	Change	Instrument & apparatus 7 Drug-eluting femoral artery stent	A nitinol self-expanding stent to be inserted and placed at the site of a lesion to maintain the lumen of a femoropopliteal stenotic site and a delivery system used to deliver the stent to the site of the lesion. An application for a partial change to change the specification of paclitaxel, etc. (A partial change during the reexamination period)

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Review Category	Approval Date	Approval Date in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval /Partial Change	Classification Generic Name	Notes
Specified Partial Change	Sep. 28, 2012 Total review time: 73 days Regulatory review time: 51 days	- No clinical study results	46	CryoSeal Disposable Kit (Asahi Kasei Medical Co., Ltd.)	Change	Instrument & apparatus 7 Blood component separation kit	Blood component separation kit to be used to isolate/collect blood components in a sterile state when preparing a biological tissue adhesive from autologous plasma. Patients are to undergo preoperative autologous blood donation. The raw material of spike needles was changed. (A partial change during the reexamination period)

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Products Approved in FY 2012: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	May 15, 2012 Total review time: 407 days Regulatory review time: 115 days	- Foreign clinical study results	1	Tecnis 1-Piece VB (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A monofocal posterior chamber lens to be implanted in the posterior chamber of the eye as a substitute for the crystalline lens to correct the vision of the aphakic eye. As the raw materials, an ultraviolet absorbing agent and a violet light absorbing agent, both of which are new covalent materials, were added to acrylic-methacrylic cross-linked copolymer, a base material of the approved "Tecnis 1-Piece". A clinical study was conducted to evaluate the optical efficacy and safety of the new raw materials.
1	Oct. 30, 2012 Total review time: 246 days Regulatory review time: 140 days	Mar. 30, 2012 Domestic clinical study results	2	Dailies Total 1 (Ciba Vision Corporation)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Single-use tinted contact lenses for correcting visual acuity. The silicone hydrogel lens is indicated for daily wear. The product has high oxygen transmissibility and uses a new material called Delefilcon A to improve the quality. The raw material has novelty, and a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Dec. 26, 2012 Total review time: 512 days Regulatory review time: 118 days	- Domestic clinical study results	3	Four Seasons (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored contact lenses for correcting visual acuity. The lens is indicated for daily wear and replaced in three-month intervals. A silicon-containing material which has oxygen transmissibility equivalent to or greater than the approved "Menicon Tinu" (Approval No. 21800BZZ10125000) is used for this product. The combination of major component monomers in the raw material has novelty, and a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Dec. 26, 2012 Total review time: 348 days Regulatory review time: 236 days	- Domestic clinical study results	4	HOYA Vivinex iSert (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	A posterior chamber lens with an injector, for which single focus posterior chamber lens that is inserted into the aphakic eye after cataract surgery is preloaded in an injector. With the haptics and the optics made of the same raw material, it has a casting one-piece structure. A major difference from the approved "HOYA iSert Micro (Approval No. 22200BZX00615000) is a change in the raw material of the posterior chamber lens to reduce the risk of capsule opacification. The raw material has novelty, and a clinical study was conducted to evaluate the optical efficacy and safety of this product in clinical use.
2	Feb. 14, 2013 Total review time: 637 days Regulatory review time: 116 days	Jun. 11, 1997 (Initial approval) Nov. 15, 2004 (Addition of GTR method) Aug. 9, 2005 (Change in manufacturing process) Domestic clinical study results	5	Geistlich Bio-Gide (Geistlich Pharma AG)	Approval	Medical products 4 Absorbent periodontal tissue regeneration material	An absorbent material using collagen derived from porcine membrane (originated in Switzerland) as a raw material. It is used in combination with autologous bone or bone substitute in guided (periodontal) tissue regeneration (GTR) for a defective part of the alveolar bone as a protective membrane against epithelial migration to new bone. A clinical study was conducted to evaluate the efficacy and safety of the combined use of this product with a dental bone substitute.
3-1	May 18, 2012 Total review time: 1569 days Regulatory review time: 374 days	Feb. 16, 2006 Foreign clinical study results	6	Spider Protection Device (At the time of approval, ev3 K.K.; currently (post-approval transfer of approval), Covidien Japan Inc.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting. It is transdermally inserted into blood vessels and temporarily placed in the distal side of a lesion. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with angiostenosis in the carotid artery with the rate of stenosis of at least 70% (for asymptomatic patients) and at least 50% (for symptomatic patients).

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	May 18, 2012 Total review time: 1449 days Regulatory review time: 356 days	Jan. 24, 2007 Foreign clinical study results	7	PROTEGE Carotid Stent Set (At the time of approval, ev3 K.K.; currently [post-approval transfer of approval], Covidien Japan Inc.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	A stent which is used to expand the carotid artery (common carotid artery, internal carotid artery) or maintain the lumen in patients who are at high risk for adverse events by surgical treatment (carotid endarterectomy), and a delivery catheter that transdermally delivers the stent to the site of stenosis in the carotid artery. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with angiostenosis in the carotid artery with the rate of stenosis of at least 70% (for asymptomatic patients) and at least 50% (for symptomatic patients).
3-1	May 18, 2012 Total review time: 364 days Regulatory review time: 242 days	Feb. 17, 2012 Domestic and foreign clinical study results	8	Resolute Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with zotarolimus to inhibit the neointimal proliferation and a delivery catheter. The improvemjent from the approved "Endeavor Coronary Stent System" is the prolonged drug-eluting duration as a result of modification of the drug coating base material. A clinical study was conducted to evaluate the efficacy and safety of this product including such improvement in patients with symptomatic ischemic heart disease.
3-1	Jun. 25, 2012 Total review time: 620 days Regulatory review time: 280 days	- Clinical evaluation report	9	Expansor Balloon Catheter (Fuji Systems Corporation)	Approval	Instrument & apparatus 51 Balloon catheter for neuroendoscopy	A balloon catheter which is inserted through a working channel of the endoscopy to expand a puncture hole created by an endoscopic clamp, etc. during surgery for hydrocephalus using neuroendoscopy (ventriculostomy, laparoscopic fenestration of cyst, etc.). Because there is no balloon catheter indicated for this treatment, a clinical evaluation report summarizing the results of literature searches on the efficacy and safety of this treatment using the balloon catheter was submitted.
3-1	Sep. 28, 2012 Total review time: 277 days Regulatory review time: 235 days	- Foreign clinical study results	10	Kaname (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A cobalt-chromium alloy coronary stent which is used for the treatment of patients with symptomatic ischemic disease (including the treatment of acute or threatened coronary artery closure as a result of unsuccessful intervention) whose reference vessel diameter is in the range of 3.0 mm to 4.0 mm and who have new or restenosis coronary lesion (length of lesion up to 25 mm). Clinical studies were conducted to confirm the efficacy and safety of this product for the treatment of symptomatic ischemic disease.
3-1	Dec. 27, 2012 Total review time: 302 days Regulatory review time: 77 days	Apr. 13, 2012 Foreign clinical study results	11	Epic Vascular Stent (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for iliac artery	This product consists of a self-expandable stent made of nickel-titanium alloy and its delivery system. The stent is transdermally inserted and placed in a blood vessel to maintain or expand the vascular lumen for the treatment of symptomatic vascular disease in the iliac artery such as stenotic lesion. The stent has a tandem structure, including closed cells at both ends and an open cell at the center in order to reduce a position gap when it is expanded. Clinical studies were conducted to confirm the efficacy and safety of this product for the treatment of symptomatic vascular disease in the iliac artery.
3-2	Jun. 27, 2012 Total review time: 565 days Regulatory review time: 139 days	Mar. 23, 2010 (Approval of application corresponding to the present partial change) Foreign clinical study results	12	Gore TAG Thoracic Endoprosthesis (W.L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of thoracic aortic aneurysm. Application for a partial change to add a 45 mm-diameter stent graft, etc. A clinical study was conducted to evaluate the equivalence of the efficacy and safety between the existing stent graft and the added 45 mm-diameter stent graft.
3-2	Sep. 28, 2012 Total review time: 826 days Regulatory review time: 127 days	Mar. 5, 2009 Foreign clinical study results	13	Gore Excluder AAA Endoprosthesis (W.L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of abdominal aortic aneurysm. Application for a partial change to add a 31 mm-diameter Trunk-Ipsilateral Leg, 32 mm-diameter Aortic Extender, etc. A clinical study was conducted to evaluate the equivalence of the efficacy and safety between the existing stent graft and the stent graft with the added diameter.

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3-2	Nov. 27, 2012 Total review time: 1246 days Regulatory review time: 269 days	Oct. 23, 2007 Foreign clinical study results	14	Mitroflow (Sorin Biomedica Cardio S.r.l.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve used to replace the aortic valve which has become dysfunctional due to disease, etc. Unlike the existing product, this product has a valve leaflet outside the stent frame. A clinical study was conducted to confirm that the efficacy and safety of this product in target patients are within the assumed range.
3-2	Mar. 29, 2013 Total review time: 407 days Regulatory review time: 237 days	Sep. 21, 2012 Foreign clinical study results	15	Relay Plus Thoracic Stent Graft System (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of descending thoracic aortic aneurysm. The two covered stent rings at the proximal end of the stent graft are free from a spiral support wire, which allows independent bending at the proximal end. The placement position of the stent graft can be adjusted by keeping a bare stent on the proximal end with a holder at the tip in the delivery system. A clinical study was conducted to evaluate the efficacy and safety of this product for the treatment of descending thoracic aortic aneurysm in comparison with a control group treated with surgical procedures.
4	Apr. 24, 2012 Total review time: 407 days Regulatory review time: 237 days	- Foreign clinical study results	16	Thermocool Smarttouch (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation system used for radiofrequency catheter ablation and electrophysiological study. The contact force-sensing function is loaded at the tip of electrode; it is used to calculate and to display the degree of contact between the tip and the tissue. A clinical study was conducted to evaluate the behavior of contact force level in clinical use.
4	Jul. 26, 2012 Total review time: 848 days Regulatory review time: 314 days	- Clinical evaluation report	17	Linox Smart S DX (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A screw-type electrode lead that is used to conduct atrial sensing, ventricular sensing/pacing, anti-trancycardia pacing treatment and defibrillation with one lead. It consists of 1 defibrillation electrode, 3 ring electrodes and 1 screw electrode. A clinical evaluation report was submitted to evaluate that defibrillation is properly achieved when this product is used in clinical practice.
4	Aug. 24, 2012 Total review time: 534 days Regulatory review time: 344 days	Feb. 7, 2007 Clinical evaluation report	18	Servo Ventilator Series (Fukuda Denshi Co., Ltd.)	Change	Instrument & apparatus 6 Versatile artificial respirator	A versatile artificial ventilator that sends the mixed gas of oxygen and air to the lung through the oral or nasal cavity under the mechanical adjustment. In the application for a partial change, the assisted ventilation mode is added; the mode detects a patient's electrical activity of the diaphragm and drives a pressure support in line with respiratory timing. Furthermore, components needed for the mode are added. A clinical evaluation report of this device was submitted to evaluate that the support in line with respiratory timing is achieved in clinical use.
4	Oct. 30, 2012 Total review time: 193 days Regulatory review time: 141 days	May 28, 2008 Clinical evaluation report	19	NRG RF Transseptal Needle (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 47 Transseptal needle	A transseptal needle with an electrode to be used to create a puncture in interatrial septum in order to insert a catheter, etc. from the right atrium to the left atrium. The atrial septum is punctured by the tissue causarization with high-frequency energy generated from a dedicated high-frequency generator. In contrast to conventional transseptal needles, this device can puncture using high-frequency energy. A clinical evaluation report summarizing the clinical data of literature was submitted to evaluate the efficacy and safety of this product in comparison with conventional transseptal needles.
4	Oct. 30, 2012 Total review time: 181 days Regulatory review time: 99 days	Nov. 21, 2007 Clinical evaluation report	20	Medtronic Reveal XT (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 Implantable data recorder for electrocardiogram	An implantable electrocardiogram recorder, subcutaneously implanted to continuously monitor the electrocardiogram. This device detects, records and stores wave patterns of atrial fibrillation, and sends the information recorded in this product to a server through the approved "Medtronic CareLink Monitor" (Approval No. 21900BZX00664000); the functions are the major improvements from the approved device "Medtronic Reveal DX" (Approval No. 22000BZX01025000). A clinical evaluation report was submitted to evaluate that this product can detect atrial fibrillation.

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4	Mar. 28, 2013 Total review time: 1554 days Regulatory review time: 577 days	Mar. 3, 2008 Foreign clinical study results	21	Niox Mino (Chest M.I., Inc.)	Approval	Instrument & apparatus 21 Nitric oxide analysis instrument	A measuring instrument used to measure the level of nitric oxide, used as a biomarker of eosinophic inflammation, in the expired air. In a clinical study, the measuring performance for the concentration of nitric oxide is evaluated on equivalence to predicate devices outside Japan, and the changes in the concentration of nitric oxide was compared before and after the treatment of inflammation.
4	Feb. 22, 2013 Total review time: 231 days Regulatory review time: 149 days	- Clinical evaluation report	22	FastView (Terumo Corporation)	Approval	Instrument & apparatus 51 Intravascular optical tomographic catheter	An intravascular optical coherence tomographic (OCT) catheter to conduct OCT of the coronary artery; it is connected to "Lunawave" (Approval No. 22500BZX00058000), an OCT image diagnosis equipment for exclusive use with this catheter. The broadband near-infrared light guided from the exclusive equipment is irradiated toward the circumferential direction from near the tip of the catheter. Then, the reflected from the vessel interferes with the reference light, and the interference signal is generated. This equipment obtains the cross-sectional images of blood vessels by Fourier-transforming the interference signal. A clinical evaluation report was submitted to evaluate the efficacy and safety of this equipment in clinical use.
5	May 25, 2012 Total review time: 1123 days Regulatory review time: 397 days	Nov. 19, 2002 Foreign clinical study results	23	Monarc Transobturator System (American Medical Systems, Inc.)	Approval	Instrument & apparatus 30 Urinary incontinence treatment tape	This product consists of a mesh to be placed suburethrally and its introducer, both of which are intended to improve stress urinary incontinence in women caused by urethral hypermobility or intrinsic sphincter deficiency of the urethra. While the approved product is placed retropubically, this product is placed in the obturator foramen. A clinical study was conducted to evaluate the objective efficacy (pad weight test, cough stress test, etc.), subjective efficacy (QOL improvement), and safety of this product for stress urinary incontinence.
5	May 31, 2012 Total review time: 330 days Regulatory review time: 86 days	- Domestic clinical study results	24	Nipro Polyether Sulfone Dialyzer (Nipro Corporation)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow-fiber dialyzer intended to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has markedly reduced due to chronic or acute renal failure, etc. Although this product uses the same membrane material as the approved products, because equivalence to the approved products was not demonstrated with regard to the performance profile, a clinical study was conducted to evaluate its performance profile.
5	Jul. 27, 2012 Total review time: 872 days Regulatory review time: 332 days	- Domestic clinical study results	25	Bipolar RFA System CelonPOWER (Olympus Medical Systems Corporation)	Approval	Instrument & apparatus 29 Radiofrequency ablation system	A device to be used to coagulate a malignant tumor of the liver with radiofrequency current. While the approved product is a monopolar system, this product is a bipolar system with two electrodes for one applicator. It also has a mode to energize up to 6 electrodes (15 pairs) sequentially by simultaneous puncture of up to 3 applicators. A clinical study was conducted to evaluate the necrogenic effect and safety of this product for hepatic malignancy.
5	Sep. 7, 2012 Total review time: 1036 days Regulatory review time: 427 days	Apr. 17, 2002 Clinical evaluation report	26	Cook Postpartum Balloon (Cook Japan Inc.)	Approval	Instrument & apparatus 51 Uterine balloon	A balloon used to relieve or stop uterine bleeding after delivery. There is no product that specializes in such intended use in Japan. Considering the fact that pressure hemostasis using a balloon such as this product is common in and out of Japan, a clinical evaluation report was submitted to evaluate the efficacy and safety of this product.
5	Feb. 19, 2013 Total review time: 358 days Regulatory review time: 80 days	- Domestic clinical study results	27	Double-balloon Endoscopy System (Fujifilm Corporation)	Approval	Instrument & apparatus 25 Balloon-guided small-intestine endoscopy system	A system that inserts an endoscope deep inside of the small intestine by using the technique to fold the intestinal tract with the combination of the endoscope, an over-tube with a balloon, a balloon to be attached to the endoscope and a balloon controller. A clinical study was conducted to verify the capability of this system to reach deep inside of the small intestine with the technique to fold the small intestine and to ensure the safety of the system.

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6-1	Jul. 10, 2012 Total review time: 1489 days Regulatory review time: 444 days	Apr. 29, 2009 Clinical evaluation report	28	Biolox Option Head (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Hemi hip prosthesis	A stem head made of a zirconia-toughened high-purity aluminum matrix composite (BIOLOX® Delta) and used in combination with the company's approved system and "Ceramic Hip System Delta". The raw material of this system is innovative as an artificial hip prosthesis in Japan. The equivalence of the shape between the approved products and this product was explained, and a clinical evaluation report was submitted to provide clinical evaluation of differences in the raw materials.
6-1	Jul. 10, 2012 Total review time: 1404 days Regulatory review time: 565 days	Nov. 20, 2008 (Delta head) Clinical evaluation report	29	Ceramic Hip System Delta (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Total hip prosthesis	This product consists of a stem head made of a zirconia-toughened high-purity aluminum matrix composite (BIOLOX® Delta) and a liner for shelf operation. It is used in combination with the company's approved system. Although the raw material of this system is innovative as an artificial hip prosthesis in Japan, a clinical evaluation report was submitted to explain the equivalence of the shape between the approved products and this product and the clinical evaluation of differences in the raw materials.
6-1	Sep. 28, 2012 Total review time: 161 days Regulatory review time: 96 days	Oct. 18, 2007 Clinical evaluation report	30	Restoration ADM (Stryker Japan K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	This product consists of an acetabular cup and an acetabular insert used for hip replacement. The inner side of the acetabular insert is located on the femoral stem head, while the external side forms a bearing surface with the acetabular cup. This product was developed to increase the range of motion for the artificial hip prosthesis by the two bearing surfaces (dual-mobility) of the acetabular insert and to enhance the stability of the prosthesis because dislocation of the hip requires severer displacement of the femoral head in the vertical direction. A clinical evaluation report was submitted to evaluate the treatment outcome of the artificial hip prosthesis with the dual-mobility structure.
6-1	Nov. 21, 2012 Total review time: 601 days Regulatory review time: 400 days	Jan. 14, 2011 Clinical evaluation report	31	Active Articulation E1 (Biomet Japan, Inc.)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for hip replacement. It is used in combination with an acetabular cup and a femoral stem head. It is a dual-mobility system that has bearing surfaces both inside and outside the product. This double-mobility system enables increase of the range of motion and enhances the implant stability. It is made of ultra high molecular weight polyethylene which was given cross-linking treatment to enhance the resistance to abrasion, and was immersed in vitamin E to enhance the resistance to oxygen. A clinical evaluation report was submitted to evaluate the efficacy and safety of the dual-mobility structure.
6-1	Jan. 28, 2013 Total review time: 581 days Regulatory review time: 73 days	- Clinical evaluation report	32	Adler Hip Prosthesis System (Robert Reid Inc.)	Approval	Medical products 4 Total hip prosthesis	This product consists of a press-fit fixed stem, modular neck and head which are used on the femoral side and a cup and liner which are used on the acetabular side to replace the hip function in total hip replacement. Aluminum oxide (alumina) is adopted for the liner and head to improve the resistance to abrasion and toughness of the bearing surface, while the acetabular cup surface has a porous structure by layering technique to improve the synostosis. Since there have been concerns about a risk of breakage caused by a new raw material of alumina, a clinical evaluation report that evaluated the incidence of repeat replacement when this product was used for total hip replacement was submitted.
6-1	Jan. 28, 2013 Total review time: 356 days Regulatory review time: 109 days	- Clinical evaluation report	33	BIOLOX Delta Ceramic Head (Robert Reid Inc.)	Approval	Medical products 4 Hemi hip prosthesis	An artificial head prosthesis used to replace the hip function on the femoral side in total hip replacement. The raw material, shape and structure of this product are equivalent to those of the approved product "BIOLOX Delta Ceramic Femoral Head" (Approval No. 22300BZX00018000). A major difference is the acetabular liner, which is used in combination with this product, made of aluminum oxide (alumina). A clinical evaluation report that evaluated the incidence of repeat replacement, incidence of defects, etc. when this product and the alumina-made acetabular liner were used together was submitted.

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6-1	Mar. 29, 2013 Total review time: 273 days Regulatory review time: 131 days	Dec. 23, 2010 (inner diameter 28 mm) Apr. 2, 2013 (inner diameter 36 mm) (inner diameter 32 mm: has not been applied in the US) Foreign clinical study results	34	Pinnacle Ceramic Liner (CERAMAX) (Johnson & Johnson K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	A liner that costitutes an acetabular component used in total hip replacement. The major improvement is its raw material, an Alumina-Zirconia ceramic matrix composites (BIOLOX delta) that has better intensity than the conventional ceramic material. Used in combination with the company's artificial femoral head made by the same raw material, this product composes a ceramic-on-ceramic system. A clinical study was conducted to evaluate the usability and safety of this product in clinical use.
6-1	Mar. 29, 2013 Total review time: 273 days Regulatory review time: 154 days	Jul. 1, 2003 (excluding some sizes) Apr. 8, 2004 (some sizes) Nov. 30, 2006 (same as above) (36 mm 9/10 taper has not been applied in the US) Foreign clinical study results	35	BIOLOX Delta Ceramic Head (CERAMAX) (Johnson & Johnson K.K.)	Change	Medical products 4 Hemi hip prosthesis	An application for partial change to add "Pinnacle Ceramic Liner (CERAMAX)" (Approval No. 22500BZX00165000) as a liner to be combined with this product and add a head component with the bearing surface of 36 mm in diameter. A clinical study was conducted to evaluate the usability and safety of this product in combination with the aforementioned liner.
6-2	Jun. 26, 2012 Total review time: 358 days Regulatory review time: 167 days	- Domestic clinical study results	36	Refit (Hoya Corporation)	Approval	Medical products 4 Artificial bone using collagen	An artificial bone implant made of sponge-like low-crystalline calcium phosphate and swine collagen. It is intended to enhance the porosity and improve the elasticity and bioabsorption. Since this product is a new raw material, a clinical study was conducted to confirm the effect of this product to promote bone regeneration for bone defects is equivalent to or greater than the existing products.
6-2	Jul. 3, 2012 Total review time: 627 days Regulatory review time: 242 days	Mar. 31, 2000 Domestic clinical study results	37	Versajet S (Smith & Nephew Wound Management K.K.)	Approval	Instrument & apparatus 12 Hydraulic knife	A device to be used for wound debridement (acute wound, chronic wound and thermal burn), soft tissue debridement and cleaning of surgical wound site. With the high-pressure water flow and its Venturi effect, it enables debridement and cleaning of surgical wound site. While it has the same mechanism of tissue ablation as the approved product, a major difference is that this product was developed as a device for debridement. A clinical study was conducted to evaluate the efficacy and safety of this product in wound debridement.
6-2	Sep. 19, 2012 Total review time: 1267 days Regulatory review time: 775 days	- Clinical evaluation report	38	Nerve Regeneration Guidance Conduit Nerbridge (Toyobo Co., Ltd.)	Approval	Medical products 4 Collagen-containing absorbable nerve regeneration inducing material	A femoral component of artificial hip prosthesis used for reconstruction of joint function in patients with femur head necrosis and coxarthrosis. While the shape and structure of this product are the same as those of the approved product, this product uses different raw materials for the compression bolt and cortical crew. A clinical evaluation report was submitted to confirm the efficacy and safety of hip replacement and bipolar hip arthroplasty using this product.
6-2	Sep. 28, 2012 Total review time: 1642 days Regulatory review time: 87 days	Jul. 23, 1986 Clinical evaluation report	39	Natrelle 133 Tissue Expander (Allergan Japan K.K.)	Approval	Medical products 4 Skin tissue expander	A device to be temporary implanted under the breast subcutaneous tissue or the pectoralis major muscle to facilitate placement of artificial breast in which purpose is to expand/extend the skin and tissues surrounding the breast prior to breast reconstruction surgery. A clinical evaluation report was submitted to confirm that the insertion of a round-type breast implant is possible after skin/tissue expansion using this product in breast reconstruction surgery.
6-2	Dec. 5, 2012 Total review time: 344 days Regulatory review time: 138 days	Aug. 7, 2009 Foreign clinical study results	40	SNaP Negative Pressure Wound Therapy System (Century Medical, Inc.)	Approval	Medical products 4 Single-use negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by adding the controlled negative-pressure, protecting wounds, promoting granulation of the wound, and removing exudative fluid and infectious waste materials for patients with refractory wounds who have not responded to existing treatments or are considered not to be responding. This product is a portable device for single use and can be used for outpatients. Thus, a clinical study was conducted to evaluate the efficacy and safety of this product in outpatients.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
6-2	Dec. 20, 2012 Total review time: 869 days Regulatory review time: 307 days	Jun. 6, 2005 Clinical evaluation report	41	CENTERPIECE OD Plate System (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Fixation device placed in the spine	A fixation device placed in the spine. This product is used for laminectomy to maintain the location of the vertebral arch which is dilated from the lower cervical spine to the upper thoracic spine (C3 to Th3). It is used for the treatment of cervical spine diseases such as spondylitic myelopathy and ossification of posterior longitudinal ligament, spinal cord tumor, etc. It consists of a cervical spine plate and a cervical spine screw. While one-side open laminectomy is performed for the existing therapy using a titanium plate in the same way with this product, the form structure has been improved for this product to optimize the surgical technique. Since there is no other product with the similar form and structure, a clinical evaluation report was submitted to confirm the efficacy and safety of the surgical technique with this product.
6-2	Dec. 21, 2012 Total review time: 360 days Regulatory review time: 282days	Nov. 3, 2008 Domestic clinical study results	42	Osteoraptor HA Anchor (Smith & Nephew Endoscopy K.K.)	Approval	Medical products 4 Absorbable ligament anchor	This product consists of absorbable anchors made of poly-L-lactic acid and hydroxyapatite, suture and inserter. Multiple anchors are implanted in the bone to secure them to the bone by surgically suturing damaged, ruptured or exfoliated soft tissues such as tendons, ligaments or muscles. The point of improvement is that hydroxyapatite was mixed to poly-L-lactic acid, which is an absorbable material of the existing product. A clinical study was conducted to confirm the efficacy and safety of the aforementioned purpose and usage of this new absorbable material.
8	Jul. 24, 2012 Total review time: 589 days Regulatory review time: 346 days	Mar. 31, 2009 Clinical evaluation report	43	PEM Flex Solo II PET Scanner (Sceti K.K.)	Approval	Instrument & apparatus 10 Positron emission tomography device for nuclear medicine diagnosis	A positron CT device for nuclear medicine diagnosis; it images distribution of the pre-dosed radioactive agent that releases positive electrons in the breast. The breast is sandwiched by a tray with built-in gamma-ray scanner and the distribution of a radioactive agent is imaged. A clinical evaluation report was submitted to evaluate the images obtained when this product was applied to the breast.
8	Mar. 22, 2013 Total review time: 276 days Regulatory review time: 229 days	Sep. 22, 2009 Clinical evaluation report	44	Leksell Gamma Knife Perfexion (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	A radioactive nuclide system for stereotactic radiotherapy; it is used for non-incisional surgery by gamma ray irradiation for the treatment of cerebral vascular disorder and brain tumor. In an application for partial change, a component that fixes and positions the patient head in a non-invasive manner is added. A clinical evaluation report was submitted to evaluate the positioning and re-positioning accuracy of the mouth piece which is prepared with respect to each patient.

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Products Approved in FY 2011: New Medical Devices

Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	Aug. 31, 2011 Total review time: 518 days Regulatory review time: 209 days	Feb. 11, 1991 Clinical evaluation report	1	Baerveldt Glaucoma Implant (AMO Japan K.K..)	New	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the anterior or posterior chamber to the episclera to decrease intraocular pressure. It consists of a silicone plate and a tube and has holes for suturing the device to the sclera. It is available in straight tube type and pars plana insertion type. A clinical evaluation report summarizing the results of literature search on overseas clinical studies and experiences of this product was submitted to evaluate its safety and efficacy in decreasing intraocular pressure. [Priority review]
1	Nov. 24, 2011 Total review time: 594 days Regulatory review time: 191 days	– Foreign clinical study results	2	ICL (STAAR Japan Inc.)	Change	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	A phakic posterior chamber intraocular lens. The existing product is a myopia correction model which is intended for vision correction of myopia. Application for a partial change to add "vision correction for eyes with refractive error (myopic astigmatism)" as an intended use by addition of the astigmatism correction model. In the astigmatism correction model, the placement position of the lens and the postoperative rotation of the lens affect the efficacy, and therefore a clinical study was conducted to evaluate the efficacy and safety by using the astigmatism correction model. (A partial change in the reexamination period)
1	Dec. 20, 2011 Total review time: 418 days Regulatory review time: 238 days	Mar. 13, 2003 Clinical evaluation report	3	Alcon Ex-PRESS Glaucoma Filtration Device (Alcon Japan Ltd.)	New	Medical products 4 Intraocular drain	A stainless-steel glaucoma filtration device intended to create an aqueous humor outflow pathway between the anterior chamber and extraocular segment and to lower the intraocular pressure by puncture and placement from the limbus into the anterior chamber under the scleral flap. A clinical evaluation report summarizing the results of literature search on the foreign clinical studies for subconjunctival placement and the survey results of literature regarding the experience of this product was submitted to evaluate the safety and efficacy for intraocular pressure lowering.
1	Mar. 19, 2012 Total review time: 537 days Regulatory review time: 270 days	– Domestic clinical study results	4	Breath-O Correct (Universal View Co., Ltd.)	New	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens with a special shape added to the inner lens surface that is intended to reshape the corneal surface by wearing it during sleep and to correct and maintain the unaided vision during daytime after removal of the lens. A clinical study was conducted to evaluate the efficacy of the correction precision, etc. and the safety for corneal disorder, etc. (The original product is in a reexamination period)
1	Mar. 29, 2012 Total review time: 66 days Regulatory review time: 30 days	– No clinical study results	5	ICL (STAAR Japan Inc.)	Change	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	An intraocular lens to be implanted in the posterior chamber of the phakic eye (in front of the human crystalline lens) to correct refractive errors in the eye (myopia or myopic astigmatism). Addition of a manufacturing site. (A partial change in the reexamination period)
3-1	Jun. 3, 2011 Total review time: 49 days Regulatory review time: 14 days	Jul. 2, 2008 No clinical study results	6	PROMUS Drug-Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. Changes of manufacturing site. (A partial change in the reexamination period)
3-1	Jun. 3, 2011 Total review time: 49 days Regulatory review time: 14 days	Jul. 2, 2008 No clinical study results	7	XIENCE V Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. Changes of manufacturing site. (A partial change in the reexamination period)
3-1	Jan. 24, 2012 Total review time: 543 days Regulatory review time: 133 days	– Global clinical trial results	8	Zilver PTX Drug-Eluting Peripheral Stent (Cook Japan Inc.)	New	Instrument & apparatus 7 Drug-eluting stent for femoral artery	A stent system consisting of a self-expanding nitinol stent to be inserted and placed at the site of a lesion to maintain the inner cavity of a stenosis site of the femoropopliteal artery and a delivery system to deliver the stent to the site of the lesion. The outer surface of the stent tube is coated directly with paclitaxel to prevent restenosis of the treated site due to neointimal proliferation. A clinical study was conducted to evaluate the efficacy and safety of this product in the treatment of symptomatic vascular diseases in the above-knee femoropopliteal artery.

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Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-1	Jan. 24, 2012 Total review time: 375 days Regulatory review time: 129 days	– Global clinical trial results	9	Zilver Flex Vascular Stent for SFA (Cook Japan Inc.)	New	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nitinol stent to be inserted and placed at the site of a lesion to maintain the inner cavity of a stenosis site of the femoropopliteal artery and a delivery system to deliver the stent to the site of the lesion. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out use at the time of failure in intervention therapy for the treatment of symptomatic vascular diseases in the above-knee femoropopliteal artery.
3-1	Feb. 8, 2012 Total review time: 103 days Regulatory review time: 88 days	Sep. 30, 2011 No clinical study results	10	Endeavor Sprint Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with zotarolimus coating used for dilating and maintaining the stenotic site of the coronary artery in symptomatic ischemic heart diseases. An application for a partial change to alter specifications of zotarolimus drug substance, shelf life, etc. (A partial change in the reexamination period)
3-1	Feb. 8, 2012 Total review time: 330 days Regulatory review time: 252 days	Nov. 22, 2011 Global clinical trial results	11	Promus Element Stent System (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Coronary stent	A product consisting of a drug-eluting stent coated with everolimus used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Platinum chromium alloy is used as a raw material for the stent, and the stent strut design was changed from the original product. A clinical study was conducted to confirm the efficacy and safety for the treatment of coronary stenotic sites when using this product. (The original product is in a reexamination period)
3-2	May. 19, 2011 Total review time: 286 days Regulatory review time: 142 days	Aug. 11, 2004 No clinical study results	12	Merci Retriever (Century Medical, Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A wire device with helical loops at the distal end used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for treatment. Application for a partial change to add V2.0 Soft and V3.0 Soft of Merci Retriever and an insertion tool for V2.0 Soft. (A partial change in the reexamination period)
3-2	Jun. 9, 2011 Total review time: 479 days Regulatory review time: 150 days	Dec. 28, 2007 (Types 1 - 3) Sep. 21, 2009 (Type 4) Foreign clinical study results	13	Penumbra System (Medico's Hirata Inc.)	New	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A device used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for treatment. It is a product to aspirate the thrombus by connecting a reperfusion catheter and an aspiration pump (Penumbra aspiration pump) via an aspiration tubing. A clinical study was conducted to evaluate its efficacy and safety in thrombectomy for cerebral infarction.
3-2	Jun. 13, 2011 Total review time: 138 days Regulatory review time: 92 days	Jul. 21, 2005 No clinical study results	14	ONYX Liquid Embolic System LD (Ev3 K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthesis for embolization in vessels of the central circulation system to be used as an embolic material in cases where preoperative embolization is necessary in surgical resection of cerebral arteriovenous malformation that cannot be managed by treatment with other means than surgery. This product consists of a vial containing Onyx solution, a vial containing dimethyl sulfoxide (DMSO), and syringes. Application for a partial change to modify descriptions concerning the stopper thickness of vials containing Onyx solution and DMSO. (A partial change in the reexamination period)
3-2	Dec. 20, 2011 Total review time: 554 days Regulatory review time: 338 days	- Domestic clinical study results	15	Matsudaito (Sanyo Chemical Industries, Ltd.)	New	Medical products 4 Non-absorbable local hemostatic material for central circulation system	A non-absorbable local hemostatic material consisting of a viscous liquid made of polyether-based fluorine-containing urethane prepolymer filled in syringe and accessory sheets and spatula. It is used for auxiliary hemostasis at the site of artificial anastomosis associated with thoracic aorta replacement or branching artery arch replacement in which hemostasis cannot be achieved by usual surgical procedures including ligation. Clinical studies were conducted to evaluate the efficacy and safety of the hemostatic effect of this product at sites of vascular anastomosis in thoracic aorta replacement.

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Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
3-2	Mar. 29, 2012 Total review time: 262 days Regulatory review time: 196 days	Aug. 11, 2004 No clinical study results	16	Merci Retriever (Century Medical, Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A wire device with helical loops at the distal end used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for this treatment. An application for a partial change to add an insertion tool improved for easily pushing out the main body of this device from the insertion tool. (A partial change in the reexamination period)
4	Nov. 24, 2011 Total review time: 79 days Regulatory review time: 40 days	- No clinical study results	17	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for a partial change to alter the shape of the battery connector part. (A partial change in the reexamination period)
4	Feb. 8, 2012 Total review time: 65 days Regulatory review time: 25 days	– No clinical study results	18	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. Change of manufacturing site. (A partial change in the reexamination period)
4	Feb. 14, 2012 Total review time: 54 days Regulatory review time: 39 days	– No clinical study results	19	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for a partial change to add an emergency controller which can cancel the alarm during a magnetic levitation error due to cable disconnection or another cause. (A partial change in the reexamination period)
4	Feb. 29, 2012 Total review time: 176 days Regulatory review time: 136 days	– No clinical study results	20	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for a partial change to add a type in which the inside of the artificial blood vessel of the outflow graft is coated with the same material as the inflow cannula for reducing the amount of fluid drained from the thoracic cavity drain. (A partial change in the reexamination period)
4	Mar. 29, 2012 Total review time: 538 days Regulatory review time: 341 days	– Foreign clinical study results	21	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker used to treat bradycardia. The design concept allows MRI examination to patients implanted with the device; it is the first MRI-compatible pacemaker in Japan. The device has the identical pacing function with the approved product "Medtronic Advisa DR." It is used in combination with "CapSure FIX MRI leads" as implantable pacemaker leads. A clinical study using the previous product was conducted to confirm the safety of MRI examination to patients implanted with the device.
4	Mar. 29, 2012 Total review time: 538 days Regulatory review time: 341 days	Feb. 8, 2011 Foreign clinical study results	22	CapSureFix MRI Lead (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Endocardial implantable pacemaker leads	Implantable pacemaker leads used by connecting them to an implantable cardiac pacemaker. The design concept allows MRI examination to patients implanted with the device when used in combination with "Medtronic Advisa MRI." A clinical study was conducted to confirm the safety of MRI examinations to patients implanted with the device.
5	Aug. 31, 2011 Total review time: 257 days Regulatory review time: 154 days	Jul. 26, 2007 Domestic and foreign clinical study results	23	CryoSeal Disposable kit (Asahi Kasei Kuraray Medical Co., Ltd.)	New	Instrument & Blood component separation kit	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. This product is to be used with "CryoSeal CS-1." Biological tissue adhesives prepared with this product are used in the adhesion and closure of tissues (in the case of leakage of blood, body fluid, or internal gas from sutured or bonded tissues). Clinical studies were conducted to evaluate efficacy and safety concerning the adhesion and closure of tissues by biological tissue adhesives prepared using this product.

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Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
5	Aug. 31, 2011 Total review time: 257 days Regulatory review time: 154 days	Jul. 26, 2007 Domestic and foreign clinical study results	24	CryoSeal CS-1 (Asahi Kasei Kuraray Medical Co., Ltd.)	New	Instrument & apparatus 7 Apparatus for blood component separation	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. This product is to be used with "CryoSeal Disposable Kit." Biological tissue adhesives prepared with this product are used in the adhesion and closure of tissues (in the case of leakage of blood, body fluid, or internal gas from sutured or bonded tissues). Clinical studies were conducted to evaluate efficacy and safety concerning the adhesion and closure of tissues by biological tissue adhesives prepared using this product.
5	Dec. 20, 2011 Total review time: 390 days Regulatory review time: 164 days	- Clinical evaluation report	25	Fetal Shunt (Hakko Co., Ltd.)	New	Instrument & apparatus 51 Shunt for fetal pleural effusion	A shunt tube to be placed in the fetal pleural cavity under ultrasonic guidance and a delivery system for the purpose of continuously draining fetal pleural effusion into the maternal amniotic cavity. A clinical evaluation report summarizing the results of literature research on the efficacy and safety of fetal thoraco-amniotic shunt and results of clinical research in Japan was submitted. [Orphan device]
6-2	May. 19, 2011 Total review time: 90 days Regulatory review time: 65 days	Oct. 10, 2003 No clinical study results	26	V.A.C.ATS Therapy System (KCI K.K.)	Change	Medical products 4 Negative pressure wound therapy system	A therapy system used for protection of wounds, maintaining a healing environment, and promoting and shortening the time of wound healing in patients with intractable traumatic wounds or dehisced wounds, post-operative open wounds or skin defective wounds, and post-operative wounds after dismemberment of extremities due to diabetes, etc. Application for a partial change to add manufacturing and sterilization facilities. (A partial change in the reexamination period)
6-2	Jun. 3, 2011 Total review time: 308 days Regulatory review time: 190 days	Jul. 7, 2004 Foreign clinical study results	27	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	A therapeutic spinal bone cement used in percutaneous kyphosis correction in spinal compression fracture performed for restoration of the height of fractured vertebrae, fixation of the vertebral body, and pain relief. This product is used with KYPHON BKP System. This application for a partial change is to add an indication for painful spinal compression fracture of up to three levels due to multiple myeloma or metastatic bone tumor to an already approved indication for acute compression fracture of one vertebral body due to primary osteoporosis. A clinical study was conducted to evaluate the efficacy and safety of this product for the additional indication. (A partial change in the reexamination period)
6-2	Jun. 3, 2011 Total review time: 308 days Regulatory review time: 190 days	Jul. 9, 2004 Foreign clinical study	28	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in spinal compression fracture performed for restoration of the height of fractured vertebrae, fixation of the vertebral body, and pain relief. This product is used with KYPHON BKP Bone Cement HV-R. This application for a partial change is to add an indication for painful spinal compression fracture of up to three levels due to multiple myeloma or metastatic bone tumor to an already approved indication for acute compression fracture of one vertebral body due to primary osteoporosis. A clinical study was conducted to evaluate the efficacy and safety of this product for the additional indication. (A partial change in the reexamination period)
6-2	Jul. 21, 2011 Total review time: 659 days Regulatory review time: 309 days	Dec. 7, 2007 Clinical evaluation report	29	VertaPlex Bone Cement (Stryker Japan K.K.)	New	Medical products 4 Orthopedic bone cement	An orthopedic bone cement to mitigate pain that is used in percutaneous vertebroplasty in patients with malignant spinal tumor such as painful metastatic bone tumor and myeloma who have not responded to conventional therapy. This product was developed with the aim of attaining a working time longer than that of the original product "Stryker Bone Cement for Exclusive Use in the Spine" (22100BZX01112000) by containing a homopolymer component without the styrene group and decreasing a catalyst. A clinical evaluation report summarizing a literature search on the results of domestic general clinical studies including previous products and the clinical results of bone cement that is used in percutaneous vertebroplasty in Japan and overseas was submitted to evaluate its efficacy and safety.

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Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
6-2	Jul. 21, 2011 Total review time: 13 days Regulatory review time: 13 days	Aug. 8, 2006 No clinical study results	30	X-STOP PEEK Implant (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Single-use interspinous implant device	An implant to be placed between target spinous processes in order to hold the lumbar spine in flexion and prevent it from going into extension for relief of lower back pain and leg pain in patients with lumbar spinal stenosis. Application for a partial change to correct the column for operation methods. (A partial change during the reexamination period)
8	Aug. 26, 2011 Total review time: 169 days Regulatory review time: 141 days	Apr. 29, 2005 No clinical study results	31	da Vinci Surgical System (Johnson & Johnson K.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist a surgeon in controlling endoscopic instruments attached to three arms of the patient cart with master-slave control in order to cut, coagulate and suture the tissue by manipulating the master controller on the surgeon console. Addition of a manufacturing site. (A partial change during the reexamination period)
8	Dec. 27, 2011 Total review time: 292 days Regulatory review time: 208 days	Apr. 29, 2005 No clinical study results	32	EndoWrist Instrument (Johnson & Johnson K.K.)	Change	Instrument & apparatus 25 Reusable active endotherapy device	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping, suturing, ligation etc. under endoscopic visualization. Addition of a manufacturing site. (A partial change in the reexamination period)
8	Dec. 27, 2011 Total review time: 111 days Regulatory review time: 86 days	Apr. 29, 2005 No clinical study results	33	EndoWrist Bipolar Instrument (Johnson & Johnson K.K.)	Change	Instrument & apparatus 25 Reusable active endotherapy device using radio frequency	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping, suturing etc. and to cut and coagulate the tissue by using radiofrequency electrosurgery current under endoscopic visualization. Addition of a manufacturing site. (A partial change in the reexamination period)

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Products Approved in FY 2011: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval / Partial Change	Classification Generic Name	Notes
1	Jul. 13, 2011 Total review time: 351 days Regulatory review time: 134 days	May 3, 2011 Foreign clinical study results	1	Alcon AcrySof IQ Toric Single-Piece (Alcon Japan Ltd.)	Change	Instrument & apparatus 72 Posterior chamber lens	A posterior chamber lens to be inserted into an aphakic eye after cataract surgery, with corneal astigmatism-correcting function. This product is the only approved posterior chamber lens for astigmatism correction. The existing product is models with cylinder power of 1.50D, 2.25D, and 3.00D. This application is an application for a partial change to add the models with cylinder power of 3.75D, 4.50D, 5.25D, and 6.00D to deal with severe astigmatic eyes. A clinical study was conducted to confirm the efficacy and safety for correction of severe astigmatism.
1	Aug. 26, 2011 Total review time: 227 days Regulatory review time: 140 days	Jan. 4, 2008 Domestic clinical study results	2	Avaira (CooperVision Japan, Inc.)	New	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored contact lenses for correcting visual acuity. The silicone hydrogel lens is indicated for daily wear and replaced in two-week intervals. There is no novelty in the lens design, but the use of cross-linking agent and ultraviolet absorbing agent and the blend ratio of monomer among raw materials have novelty, and therefore a clinical study was conducted to confirm the efficacy and safety for wearing the lens for vision correction.
1	Nov. 14, 2011 Total review time: 1102 days Regulatory review time: 176 days	– Domestic clinical study results	3	HOYA iSii (HOYA Corporation)	New	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery, with multifocal function consisting of three zones for distant, near, and distant visions in a concentric pattern on the optic surface. A clinical study was conducted to evaluate the efficacy and safety of the intraocular lens, focusing on the efficacy of the multifocal mechanism.
1	Nov. 14, 2011 Total review time: 1095 days Regulatory review time: 169 days	– Domestic clinical study results	4	AF-1 iSii (HOYA Corporation)	New	Instrument & apparatus 72 Posterior chamber lens with an injector	A posterior chamber lens with an injector, for which "HOYA iSii" is preloaded in an injector. A clinical study was conducted to evaluate the efficacy and safety of the intraocular lens, focusing on the efficacy of the multifocal mechanism.
1	Nov. 18, 2011 Total review time: 326 days Regulatory review time: 207 days	Mar. 19, 2003 Clinical evaluation report	5	O_2 Optix (Ciba Vision Corporation)	Change	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A silicon hydrogel contact lens that can be worn continuously for up to 1 month. An application for a partial change to add the intended use "for treatment accompanied with vision correction capability for eyes with corneal diseases" to the conventional use "for visual acuity." A clinical evaluation report summarizing the results of a literature research on use-results of this product and other contact lenses used for treatment in Japan and overseas was submitted to evaluate the efficacy and safety in therapeutic use.
1	Feb. 23, 2012 Total review time: 1704 days Regulatory review time: 383 days	Oct. 12, 2000 Domestic clinical study results	6	Mechanical Microkeratome M2 (Moria Japan K.K.)	New	Instrument & apparatus 34 Mechanical keratome	A medical blade (mechanical keratome) for lamellar resection of the cornea in LASIK (laser in situ keratomileusis). A flap is made by putting negative pressure around the sclera to stabilize the cornea and resecting the corneal surface layer with the self-propelled blade. A clinical study was conducted to evaluate the efficacy in terms of the precision, quality, etc. of the flap, and the safety for the cornea, etc.
1	Feb. 28, 2012 Total review time: 1169 days Regulatory review time: 497 days	Apr. 11, 2006 (hardware) Aug. 17, 2006 (software) Foreign clinical study results	7	HiRes Auria Sound Processor (Nihon Bionics Co., Ltd.)	Change	Medical products 4 Cochlear implant	A cochlear implant for recovering sound perception by electrical stimulation in patients with bilateral severe hearing loss who have not responded sufficiently to wearing hearing aids. This application is an application for a partial change to add a sound processor and the HiRes 120 sound processing strategy. A clinical study was conducted to evaluate the efficacy and safety of HiRes 120.
1	Mar. 19, 2012 Total review time: 493 days Regulatory review time: 220 days	– Domestic clinical study results	8	Avansee 1P (Kowa Company, Ltd.)	New	Instrument & apparatus 72 Posterior chamber lens	A monofocal posterior chamber lens to be implanted in the posterior chamber of the eye as a substitute for the crystalline lens to correct the vision of the aphakic eye. A one-piece lens for which the optic and haptic are made from the same material. As the raw material has novelty, a clinical study was conducted to evaluate the efficacy for vision correction and the safety for the eye.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval / Partial Change	Classification Generic Name	Notes
2	Dec. 6, 2011 Total review time: 832 days Regulatory review time: 222 days	Jan. 15, 2004 Domestic clinical study results	9	Geistlich Bio-Oss (Geistlich Pharma AG)	New	Medical products 4 Nonabsorbable material for bone regeneration	A nonabsorbable bone substitute that uses bovine bones originating from Australia as raw material and is prepared in the form of granules by heating and drying. It is used with a membrane for filling up bone defects when Guided Tissue Regeneration (GTR) is performed for vertical bone defects and defects in bones with class II root bifurcation lesions that are destroyed by periodontal disease. A clinical study was conducted to evaluate the efficacy and safety with the objective of bone improvement by conducting combination therapy of this product which is a bone substitute for bone regeneration and a dental collagen membrane for vertical bone defects and root bifurcation lesions caused by periodontitis.
2	Jan. 13, 2012 Total review time: 840 days Regulatory review time: 341 days	Jul. 22, 2005 Clinical evaluation report	10	Cerasorb M (Hakuho Corporation)	New	Medical products 4 Absorbable dental bone reconstruction implant material	An absorbable dental bone reconstruction implant material made from beta tricalcium phosphate (β-TCP) with a phase purity of higher than 99% in compliance with ASTM F 1088 and a granular product to be used as a substitute for bone for alveolar bone defects as a dental bone substitute (excluding indications on the assumption of placement of an implant). A clinical evaluation report was submitted to evaluate the clinical efficacy and safety of the product as a dental bone substitute.
3-1	May 23, 2011 Total review time: 879 days Regulatory review time: 457 days	May 5, 2005 (change of the time limit for removal） Nov. 18, 2007 (addition of a type) Foreign clinical study results	11	Inferior Vena Cava Filter Set (Cook Japan Inc.)	Change	Instrument & apparatus 51 Inferior vena cava filter	A permanent thrombus-capturing filter to be placed in the inferior vena cava to capture thrombi occurring in veins in the lower limb or pelvis for the prevention of pulmonary artery embolism or the prevention of its recurrence. If removal of this product is required for some reason, the product can be removed by using the dedicated loop system for removal. An application for a partial change was filed to add a type of delivery system and change the time limit for removal from within 10 days to an indefinite period. A clinical study was conducted to confirm the feasibility of removal after long-term placement.
3-1	Jul. 7, 2011 Total review time: 251 days Regulatory review time: 216 days	– Clinical evaluation report	12	Kaneka PTCA Catheter CO-R5 (Kaneka Corporation)	New	Instrument & apparatus 51 Balloon-dilating coronary perfusion catheter for angioplasty	A balloon catheter to be used for dilating stenotic sites in percutaneous transluminal coronary angioplasty (PTCA) or temporary sealing of blood vessel perforations caused during PTCA. With multiple holes made on the proximal and distal sides of the balloon, it enables perfusion from the proximal to distal side during expansion of the balloon. A clinical evaluation report was submitted to confirm the efficacy and safety of the use of the catheter for sealing of blood vessel perforations.
3-1	Aug. 2, 2011 Total review time: 368 days Regulatory review time: 209 days	Sep. 14, 2010 Clinical evaluation report	13	Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Coronary stent	A stent set for percutaneous coronary stent placement to be inserted and placed at the site of a lesion to maintain the vascular lumen. The approved product is formed by lining up the rings with crowns, whereas this product is formed by wrapping a wire that has crowns. A clinical evaluation report was submitted to confirm that this product can be used similarly to the approved product.

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3-1	Sep. 5, 2011 Total review time: 418 days Regulatory review time: 243 days	Apr. 22, 2011 Foreign clinical study results	14	Taxus Element Stent System (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Coronary stent	A product consisting of a drug-eluting stent coated with paclitaxel and a delivery catheter to inhibit neointimal proliferation. The stent strut design of this product is changed and platinum chromium is used as a raw material for the stent to enhance the deliverability. The use of semisynthetic paclitaxel was also added. A clinical study was conducted to confirm the efficacy and safety for the treatment of coronary stenotic sites by using this product.
3-1	Feb. 21, 2012 Total review time: 424 days Regulatory review time: 118 days	May 19, 2011 Foreign clinical study results	15	ExoSeal (Johnson & Johnson K.K.)	New	Medical products 4 Absorbable topical hemostatic material	An absorbable topical hemostatic material to be used for hemostasis at the femoral artery puncture site in patients who have undergone percutaneous catheterization. The product consists of a polyglycolic acid plug which is a bioabsorbable material and a delivery system to place the plug. This product is intended for hemostasis by placement of the plug on the side of the vascular wall tissue. A clinical study was conducted to confirm the efficacy and safety of this product for hemostasis at the femoral artery puncture site.
3-2	Sep. 16, 2011 Total review time: 421 days Regulatory review time: 215 days	Dec. 16, 2010 Foreign clinical study results	16	ENDURANT Stent Graft System (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Aortic stent graft	The product consists of a stent graft and a delivery system used for endovascular treatment of lower abdominal aortic aneurysm of the renal artery. Compared to the approved product "TALENT Abdominal Stent Graft System," a tip-capture system was introduced and also the low profile delivery system was adapted in order to enhance the control capability for positioning the stent graft. A clinical study was conducted to confirm the efficacy and safety of this product for the treatment of aortic aneurysm.
3-2	Mar. 29, 2012 Total review time: 359 days Regulatory review time: 117 days	Apr. 1, 2011 Foreign clinical study results	17	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of descending thoracic aortic aneurysm. Compared to the approved product "TALENT Thoracic Stent Graft System" (Approval No. 22100BZX00355000), improvements such as improvement of the stent graft design and introduction of a tip-capture system to the distal side of the delivery system (enhancement of the control capability for positioning the stent graft) were performed. A clinical study was conducted to evaluate the efficacy and safety of this product in the treatment of descending thoracic aortic aneurysm.
4	Apr. 13, 2011 Total review time: 285 days Regulatory review time: 164 days	– Foreign clinical study results	18	Fortify ST Pre (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator with the function of bradycardia pacing. The four variations of conectors are as follows: single-chamber types (VR) (IS-1/DF-1 or DF4 connector) and dual-chamber types (DR) (IS-1/DF-1 or IS-1/DF4 connector). Improvements compared with approved defibrillators are as follows: (1) downsizing, (2) addition of thoracic impedance measurement function, (3) addition of ATP treatment in the VF zone, (4) addition of pacing rate alert, (5) addition of low-frequency attenuation filter and (6) setting of the maximum defibrillation energy to be 40J. The device automatically adjusts pulse amplitude, when the patient's ventricular and atrial thresholds change. The efficacy and safety of the function was evaluated by the results of clinical studies for the different defibrillator, because another device with the identical function was under review at the time to compile this application.

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4	Apr. 13, 2011 Total review time: 285 days Regulatory review time: 164 days	– Foreign clinical study results	19	Unify (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function. The two variations of connector are as follows: IS-1/DF4 connectors. Improvements from approved defibrillators are as follows: (1) downsizing, (2) addition of thoracic impedance measurement function, (3) addition of ATP treatment in the VF zone, (4) addition of pacing rate alert, (5) addition of low-frequency attenuation filter, and (6) setting of the maximum defibrillation energy to be 40J. The device automatically adjusts pulse amplitude, when the patient's ventricular and atrial thresholds change. The efficacy and safety of the function was evaluated by the results of clinical studies for the different defibrillator, because another device with the identical function was under review at the time to compile this application.
4	Jul. 5, 2011 Total review time: 333 days Regulatory review time: 137 days	May 3, 2010 Foreign clinical study results	20	SJM FD-OCT Imaging System (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 12 OCT diagnostic imaging instrument	The OCT diagnostic imaging instrument is intended for intravascular tomographic imaging. The device is for exclusive use with the catheter "SJM OCT Imaging Catheter". A clinical study was conducted to evaluate the observation capability and the intrinsic safety for target patients.
4	Jul. 5, 2011 Total review time: 333 days Regulatory review time: 137 days	May 3, 2010 Foreign clinical study results	21	SJM OCT Imaging Catheter (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 51 Intravascular optical tomographic catheter	The catheter is intended for intravascular tomographic imaging. The device is for exclusive use with "SJM FD-OCT Imaging System." A clinical study was conducted to evaluate the observation capability and the intrinsic safety for target patients.
4	Aug. 19, 2011 Total review time: 479 days Regulatory review time: 187 days	Nov. 26, 2010 Foreign clinical study results	22	Evia DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. In the application for a partial change, the following functions are added: a capture control function for the right atrium, a ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and ventricular pacing suppression function.
4	Aug. 19, 2011 Total review time: 280 days Regulatory review time: 204 days	Nov. 26, 2010 Foreign clinical study results	23	Evia DR (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker. In the application for a partial change, the following functions are added: a capture control function for the right atrium, a ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and the ventricular pacing suppression function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	24	Evia DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	25	Evia SR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A single-chamber implantable cardiac pacemaker with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.

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4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	26	Lumax 540 HF-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	A CRT-D with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device are provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	27	Lumax 540 DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	A dual-chamber pacing ICD with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via the component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to verify the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	28	Lumax 540 VR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	A single-chamber pacing ICD with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device are provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	Apr. 16, 2009 Foreign clinical study results	29	Cardio Messenger (Biotronik Japan, Inc.)	Change	Instrument & apparatus 21 Telemetry data transmitter	A device to receive information of patients from implanted pacemaker, ICD, etc, with the remote monitoring function and to transmit them to healthcare professionals by wireless communication. In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 22, 2011 Total review time: 328 days Regulatory review time: 94 days	Nov. 26, 2010 Foreign clinical study results	30	Entovis DR-T (Nihon Kohden Corporation)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. In the application for a partial change, the following functions are added: a capture control function for the right atrium, ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and the ventricular pacing suppression function.
4	Oct. 5, 2011 Total review time: 559 days Regulatory review time: 224 days	Aug. 11, 2006 Foreign clinical study results	31	NaviStar ThermoCool (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation function used for radiofrequency catheter ablation and electrophysiological study. In the application for a partial change, the use for atrial fibrillation and ventricular tachycardia were added to the indication. Clinical studies were conducted to evaluate the efficacy and safety of the use for atrial fibrillation and ventricular tachycardia.

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4	Oct. 20, 2011 Total review time: 360 days Regulatory review time: 209 days	Mar. 27, 2009 Clinical evaluation report	32	Activa RC (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrical stimulation device to reduce tremors associated with Parkinson's disease, essential tremor, etc. that do not sufficiently respond to drug therapy. The device stimulates the deep brain unilaterally or bilaterally. It is designed based on the intrinsic concept of the approved product "Itrel II (Approval No. 21100BZY00563000)" with changing to a dual-channel type, adding an electrical charge function, multi-program function, and constant current mode stimulation function, increasing the maximum pulse rate, etc. The clinical efficacy and safety of the multi-program function, the increased maximum pulse rate and constant current mode are evaluated with a clinical evaluation report.
4	Oct. 20, 2011 Total review time: 360 days Regulatory review time: 212 days	Jan. 26, 2011 Clinical evaluation report	33	Activa SC (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrical stimulation device to reduce tremors associated with Parkinson's disease, essential tremor, etc. that do not sufficiently respond to drug therapy. The device stimulates the deep brain unilaterally or bilaterally. It is designed based on the intrinsic concept of the approved product "Itrel II (Approval No. 21100BZY00563000)" with adding a multi-program function and constant current mode stimulation function, increasing the maximum pulse rate, etc. The clinical efficacy and safety of the multi-program function, the increased maximum pulse rate and constant current mode are evaluated with a clinical evaluation report.
4	Dec. 12, 2011 Total review time: 605 days Regulatory review time: 204 days	Dec. 21, 2011 Foreign clinical study results	34	NaviStar ThermoCool SF (Johnson & Johnson K.K.)	New	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation function used for radiofrequency catheter ablation and electrophysiological study. The device was developed based on the approved product "NaviStar ThermoCool (Approval No. 22000BZX01645000)", and the catheter tip electrode design and the irrigation flow rate were changed. Clinical studies were conducted to evaluate the efficacy and safety of the use for atrial fibrillation and ventricular tachycardia.
4	Jan. 17, 2012 Total review time: 823 days Regulatory review time: 365 days	Aug. 3, 2005 Foreign clinical study results	35	Select Secure Lead (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Endocardial implantable pacemaker leads	A screw-in bipolar transvenous lead. The diameter of device is made smaller than usual leads by modifications such as removal of the lumen for stylet insertion; it aims to combine with "Medtronic Deflectable Catheter" that can be bent at the distal part of the catheter and to be located in cardiac chamber. A clinical study was conducted to evaluate the efficacy and the safety to place the device with "Medtronic Deflectable Catheter" through the comparison with lead placement using the conventional stylet.
4	Jan. 17, 2012 Total review time: 823 days Regulatory review time: 365 days	Oct. 25, 2006 Foreign clinical study results	36	Medtronic Deflectable Catheter (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 51 Cardiac catheter introducer kit	A guiding catheter and accessories to be used to pass leads for implantable cardiac pacemakers through the atrium or ventricle. It is used together with "Select Secure Lead." A clinical study was conducted to evaluate the efficacy and the safety to place "Select Secure Lead" with the device through the comparison with lead placement using the conventional stylet.
4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 192 days	– Foreign clinical study results	37	Promote Quadra (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device conducts cardiac resynchronization therapy that synchronizes the ventricular contraction. The design concept is similar to that of the approved product "Promote Accel RF (Approval No.: 22200BZX00962000)", but the connector is changed from IS-1 (2 poles) to IS4 (4 poles) and the left ventricular pacing polarity is added. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead) .

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4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 192 days	– Foreign clinical study results	38	Unify Quadra (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device conducts cardiac resynchronization therapy that synchronizes the ventricular contraction. The design concept is similar to that of the approved product "Unify (Approval No. 22300BZX00210000)", but the connector is changed from IS-1 (2 poles) to IS4 (4 poles) and the left ventricular pacing polarity is added. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead).
4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 182 days	Nov. 29, 2011 Foreign clinical study results	39	Quartet (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	A left ventricular lead and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device is connected with a biventricular pacing pulse generator with defibrillator function when performing cardiac resynchronization therapy. The device has 4 poles and allows to select the more options for pacing polarity than the approved left ventricular leads, which have 2 poles. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead).
4	Feb. 13, 2012 Total review time: 770 days Regulatory review time: 310 days	– Domestic clinical study results	40	Intracardiac Defibrillation Multi-catheter (Japan Lifeline Co., Ltd.)	New	Instrument & apparatus 51 Cardiac catheter-type electrode	A cardiac catheter electrode used for cardiac electrophysiological examination. Moreover, the device is connected with "Intracardiac Defibrillator" and used for defibrillation when atrial fibrillation, atrial flutter, or atrial tachycardia occurs during percutaneous catheter ablation or cardiac electrophysiological examination. A clinical study was conducted to evaluate the efficacy and safety of the defibrillation using the device.
4	Feb. 13, 2012 Total review time: 770 days Regulatory review time: 276 days	– Domestic clinical study results	41	Intracardiac Defibrillator (Japan Lifeline Co., Ltd.)	New	Instrument & apparatus 12 Manual defibrillator	This is a generator for electric defibrillation connected with "Intracardiac Defibrillation Multi-catheter" when atrial fibrillation, atrial flutter, or atrial tachycardia occurs during percutaneous catheter ablation or cardiac electrophysiological examination. A clinical study was conducted to evaluate the efficacy and safety of the defibrillation using the device.
4	Feb. 23, 2012 Total review time: 423 days Regulatory review time: 234 days	Oct. 2, 2009 Foreign clinical study results	42	Blazer Prime XP Ablation Catheter (Boston Scientific Japan K.K.)	New	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter to apply radiofrequency current to the target site of arrhythmia identified electrophysiologically, in order to treat persistent or recurrent type I atrial flutter. The shaft part was improved in order to enhance the delivery capability. A clinical study was conducted to evaluate the efficacy and safety to use the device for persistent or recurrent type I atrial flutter.
5	Apr. 18, 2011 Total review time: 755 days Regulatory review time: 404 days	Dec. 1, 2006 Foreign clinical study results	43	AMS GreenLight HPS Console (American Medical Systems, Inc.)	New	Instrument & apparatus 31 Double-frequency neodymium-YAG laser	A surgical device for resection of the prostate gland with 532 nm double-frequency neodymium-YAG laser under cystoscopy for the treatment of benign prostate hypertrophy/hyperplasia. Improvements from the approved product are the use of the oscillation wavelength of 532 nm and change of the maximum output power to 120 W. A clinical study was conducted to confirm the efficacy and safety of this product for benign prostate hypertrophy/hyperplasia.

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5	Apr. 18, 2011 Total review time: 755 days Regulatory review time: 404 days	Dec. 1, 2006 Foreign clinical study results	44	AMS GreenLight HPS Fiber (American Medical Systems, Inc.)	New	Instrument & apparatus 31 Single-use probe for laser guidance	A side-firing fiber to be used in combination with the surgical device "AMS GreenLight HPS Console" to resect the prostate gland with 532 nm double-frequency neodymium-YAG laser under cystoscopy for the treatment of benign prostate hypertrophy/hyperplasia. A clinical study was conducted to confirm the efficacy and safety of this product for benign prostate hypertrophy/hyperplasia.
5	Jul. 7, 2011 Total review time: 645 days Regulatory review time: 225 days	Sep. 30, 2004 Clinical evaluation report	45	WallFlex Colonic Stent (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Colonic stent	A colonic stent to be used for colonic strictures produced by malignant neoplasm to relieve large bowel obstruction prior to operation, also to be used for the palliative treatment for patients who cannot be managed by palliative surgical treatment or are not expected to achieve improvement with other treatments. A clinical evaluation report was submitted to evaluate the efficacy and safety for the use of this product for preoperative relief of bowel obstruction or as palliative treatment.
5	Nov. 14, 2011 Total review time: 693 days Regulatory review time: 363 days	– Clinical evaluation report	46	Niti-S Gastroduodenal Stent (Century Medical, Inc.)	New	Instrument & apparatus 7 Gastroduodenal stent	A gastroduodenal stent to be used to maintain patency at stenotic sites in patients with unresectable malignant gastroduodenal stenosis who are not expected to achieve improvement with surgical treatment or other treatment methods. A clinical evaluation report summarizing the results of literature research on clinical data on gastroduodenal stent placement was submitted to evaluate the efficacy and safety.
5	Mar. 26, 2012 Total review time: 536 days Regulatory review time: 331 days	May 8, 2006 Clinical evaluation report	47	Given Patency Capsule Endoscope (Given Imaging K.K.)	New	Instrument & apparatus 25 Capsule electronic endoscope system	A product to take and provide images of the small-intestinal mucosa for diagnosis of small-intestinal diseases. The approved product "Given Capsule Endoscope (Approval No. 22100BZX00363000) has been improved with the addition of Agile J Patency Capsule (AJP), which is used to assess appropriateness of the patency of the digestive tract prior to the use of a capsule endoscope in patients who have or are suspected of having stenosis or narrowing of the digestive tract. A clinical evaluation report summarizing literature information, etc. on occurrence of retention of capsule endoscopes after assessment of patency by AJP was submitted to evaluate the accuracy of assessment of patency with AJP.
6-1	Apr. 28, 2011 Total review time: 388 days Regulatory review time: 195 days	– Domestic clinical study results	48	Aquala Liner (Japan Medical Materials Corporation)	New	Medical products 4 Artificial hip joint, acetabular component	An ultra-high-molecular-weight polyethylene liner for an artificial hip joint. This product is photoinduced graft-polymerized with 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer on the bearing surface in addition to cross-link processing, in order to improve the wear resistance of the bearing surface while inheriting the design of the approved products. A clinical study was conducted to confirm the efficacy and safety of the liner for which the bearing surface was modified with the novel raw material.
6-2	Jun. 14, 2011 Total review time: 1174 days Regulatory review time: 788 days	– Domestic clinical study results	49	Osmix (Kuraray Medical Inc.)	New	Medical products 4 Artificial bone implant	An artificial bone implant in paste form for which silane-coating hydroxyapatite particles and polymerizable monomers are mixed. This product is designed to start polymerization when discharged from the dedicated injector. It is injected into the affected site in paste form to compensate for bone defects after reconstruction of bone fracture of non-loaded region and for bone defects after removals of bone tumor/necrosis bone. A clinical study was conducted to confirm the efficacy and safety of the use of the novel raw material.

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6-2	Jun. 14, 2011 Total review time: 287 days Regulatory review time: 172 days	Jun. 27, 2001 Aug. 8, 2003 Domestic clinical study results	50	TwinFix AB Anchor (Smith & Nephew Endoscopy KK)	New	Medical products 4 Absorbable ligament anchor	An absorbable suture anchor to be used to repair the binding of soft tissues such as ruptured tendons, ligament, and muscles to bones. The product is only indicated for repair of rotator cuff tear in the shoulder. The improvement from the approved nonabsorbable product is the use of absorbable poly-L-lactic acid as raw material for the anchor. A clinical study was conducted to evaluate the efficacy and safety of this product which is an absorbable screw-type anchor.
6-2	Dec. 1, 2011 Total review time: 975 days Regulatory review time: 674 days	Nov. 20, 2001 Clinical evaluation report	51	Lacto Screw Suture Anchor (Biomet Japan, Inc.)	New	Medical products 4 Absorbable ligament anchor	A resorbable screw-type suture anchor made of polylactic/polyglycolic acid copolymer used to attach ligaments or tendons to bones with a suture. The device is to be used in patients who require repair due to damage of soft tissues in regions adjacent to the shoulder joint such as the articular labrum, and soft tissues of the elbow and hand joints. A clinical evaluation report summarizing literatures on clinical data using this device and other screw-type anchor made from the same raw material, was submitted to evaluate the efficacy and safety.
6-2	Dec. 1, 2011 Total review time: 945 days Regulatory review time: 868 days	Jul. 19, 2006 Clinical evaluation report	52	AllThread Screw L15 (Biomet Japan, Inc.)	New	Medical products 4 Absorbable ligament anchor	A resorbable screw-type suture anchor made of polylactic/polyglycolic acid copolymer used to attach ligaments or tendons to bones with a suture. The device is to be used in patients who require repair due to damage of soft tissues in regions adjacent to the shoulder joint, and soft tissues of the elbow and hand joints. A clinical evaluation report summarizing literatures on clinical data using other screw-type anchor made from the same raw material as this device, was submitted to evaluate the efficacy and safety.
6-2	Feb. 17, 2012 Total review time: 1803 days Regulatory review time: 805 days	May 1, 2000 Domestic clinical study results	53	Arthrex Bio-FASTak Suture Anchor (Kobayashi Medical Co., Ltd.)	New	Medical products 4 Absorbable screw for internal fixation	An absorbable screw-type suture anchor made of poly DL-lactic acid to be used to fix soft tissues to bones in shoulder joints. A clinical study was conducted to evaluate the efficacy and safety for the treatment of shoulder joint instability in order to evaluate whether tissues such as ligaments in shoulder joints can be repaired.
Biologics	Apr. 8, 2011 Total review time: 952 days Regulatory review time: 315 days	Nov. 15, 2007 Foreign clinical study results	54	SJM Epic Stented Tissue Valve (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Porcine cardiac valve	A biological prosthetic cardiac valve with stent derived from pig aortic valve that is intended to substitute for the function of aortic valves or mitral valves with a disease, damage, or dysfunction. This product is treated for anticalcification and uses bovine pericardial membrane at the stent part for the protection of the valve leaflet. A clinical study was conducted to confirm the efficacy and safety of this product.
Biologics	Mar. 8, 2012 Total review time: 416 days Regulatory review time: 122 days	Apr. 20, 2011 Foreign clinical study results	55	SJM Trifecta Valve (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve to be used to substitute for the function of aortic valves with a disease, damage, or dysfunction. This product is to be implanted into the supra annular position. It is treated for anticalcification. Pig pericardial membrane is used at the outflow of the stent for the protection of the valve leaflet. A clinical study was conducted to confirm the clinical safety and efficacy of this product.

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Products Approved in FY 2010: New Medical Devices

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Aug. 23, 2010 Total review time: 1055 days Regulatory review time: 385 days	Aug. 2, 2004 Domestic clinical study results	1	Bausch&Lomb Ortho-k (B.L.J. Company, Ltd.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct the unaided vision after removal of the lens. A clinical study was conducted to confirm the efficacy and safety of this product. (The original product is in a reexamination period)
1	Sep. 1, 2010 Total review time: 908 days Regulatory review time: 517 days	Jun. 7, 2004 Domestic clinical study results	2	My Emerald (Technopia Co., Ltd.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct the unaided vision after removal of the lens. A clinical study was conducted to confirm the efficacy and safety of this product. (The original product is in a reexamination period)
1	Sep. 1, 2010 Total review time: 908 days Regulatory review time: 170 days	Jun. 7, 2004 No clinical study results	3	Visual Emerald (Technopia Co., Ltd.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct the unaided vision after removal of the lens. Application for multiple brand name of "My Emerald". (The original product is in a reexamination period)
1	Mar. 9, 2011 Total review time: 538 days Regulatory review time: 182 days	Aug. 9, 1996 Domestic clinical study results	4	Cochlear Baha System (Cochlear Ltd.)	Approval	Instrument & apparatus 73 Bone-anchored hearing aid	A bone-anchored hearing aid that transmits sound vibrations to the bone to improve the ability to hear environmental sounds and speech sounds. A clinical study was conducted to evaluate the efficacy and safety of this product in patients who are not expected to achieve improvement with existing treatments.
3-1	Apr. 2, 2010 Total review time: 119 days Regulatory review time: 104 days	Sep. 22, 2006 No clinical study results	5	Angioguard (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli by capturing and removing embolic substances including thrombi while a stent is placed in the carotid artery. Application for a partial change to add Rapid Exchange (RX) type to the delivery system. (A partial change in the reexamination period)
3-1	Apr. 30, 2010 Total review time: 458 days Regulatory review time: 223 days	Aug. 11, 2004 Foreign clinical study results	6	Merci Retriever (Century Medical,Inc.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A wire device with helical loops at the distal end used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for treatment. A clinical study was conducted to evaluate its efficacy and safety in thrombectomy for cerebral infarction. [Priority review]
3-1	Jul. 6, 2010 Total review time: 617 days Regulatory review time: 162 days	Oct. 31, 2007 Foreign clinical study results	7	GuardWire Protection System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A balloon-type device to prevent distal emboli by capturing and removing embolic substances including thrombi released while a stent is placed in the carotid artery. The efficacy (the effect of preventing distal emboli) and safety of this product were evaluated based on a clinical study for a carotid artery stent used in combination with this product. (The original product is in a reexamination period)
3-1	Mar. 9, 2011 Total review time: 439 days Regulatory review time: 202 days	- Domestic and foreign clinical study results	8	Nobori (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The stent is coated with biolimus A9 with cytostatic effect to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. Clinical studies were conducted to evaluate the efficacy and safety of this product with high-novelty coating.
3-2	Jun. 14, 2010 Total review time: 620 days Regulatory review time: 238 days	Nov. 6, 2007 Foreign clinical study results	9	Bard Agento I.C. (Medicon,Inc.)	Approval	Instrument & apparatus 51 Antimicrobial endotracheal tube	An endotracheal tube inserted into the trachea for airway management. The device has a hydrophilic silver coating with antimicrobial activity to reduce the incidence and delay the onset of ventilator-associated pneumonia (VAP). A clinical study was conducted to verify its effects on reducing the incidence and delaying the onset of VAP.
3-2	Aug. 23, 2010 Total review time: 320 days Regulatory review time: 213 days	Jun. 27, 2008 No clinical study results	10	TALENT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysm used to prevent blood flow into the thoracic aortic aneurysm and its rupture. Application for a partial change to alter the delivery system and the method of sterilization. (A partial change in the reexamination period)

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Apr. 30, 2010 Total review time: 497 days Regulatory review time: 251 days	Dec. 7, 2007 Foreign clinical study results	11	The Crosser System (USCI Japan, Ltd.)	Approval	Instrument & apparatus 51 Oscillating peripheral artery recanalization catheter system	A medical device used to facilitate guidewire recanalization with mechanical vibration for a stenotic lesion in the peripheral vessel that a conventional guidewire for angioplasty cannot cross in percutaneous transluminal angioplasty. A clinical study was conducted to confirm its efficacy and safety in the treatment of a stenotic lesion that a conventional guidewire for angioplasty cannot cross.
4	Jun. 14, 2010 Total review time: 766 days Regulatory review time: 476 days	Aug. 13, 2002 Domestic clinical study results	12	ELVeS Laser (Integral Corporation)	Approval	Instrument & apparatus 31 Diode laser	A system intended for endovenous laser treatment of varicose veins of lower extremities. Endovenous laser irradiation obstructs a target vessel and blocks blood flow in the saphenous vein that causes varicose veins of lower extremities. A clinical study was conducted to confirm its efficacy and safety using stripping, a standard treatment, as a control.
4	Dec. 8, 2010 Total review time: 447 days Regulatory review time: 127 days	− Domestic and foreign clinical study results	13	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Approval	Instrument &apparatus 7 Implantable ventricular assist device	An implantable left ventricular assist device intended for use to improve the blood circulation in patients with end-stage heart failure who require cardiac transplantation. In addition to clinical studies conducted in Europe, where it was used earlier than in Japan, clinical studies were also conducted to investigate the efficacy and safety of this product to the target patients and to confirm the conformity to the medical environment in Japan. [Orphan device]
4	Dec. 8, 2010 Total review time: 688 days Regulatory review time: 160 days	− Domestic clinical study results	14	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Approval	Instrument &apparatus 7 Implantable ventricular assist device	An implantable left ventricular assist device intended for use to improve the blood circulation in patients with end-stage heart failure who require cardiac transplantation. Clinical studies were conducted to investigate the efficacy and safety of this product to the target patients and to confirm the conformity to the medical environment in Japan. [Orphan device]
6	Jun. 11, 2010 Total review time: 49 days Regulatory review time: 18 days	Jul. 2, 1998 No clinical study results	15	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. Addition of a manufacturing site. (A partial change in the reexamination period)
6	Jun. 14, 2010 Total review time: 500 days Regulatory review time: 373 days	Aug. 8, 2006 Foreign clinical study results	16	X-STOP PEEK Implant (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Single-use interspinous implant device	An implant to be implanted between target spinous processes in order to hold the lumbar spine in flexion and prevent it from going into extension for relief of lower back pain and leg pain in patients with lumbar spinal stenosis. A clinical study was conducted to verify its efficacy and safety with regard to the mechanism to physically broaden the gap between the upper and lower spinous processes.
Specified Partial Change	Jan. 27, 2011 Total review time: 90 days Regulatory review time: 75 days	2003/5/14 No clinical study results	17	PDA Occlusion Set (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthesis for embolization in vessels of the central circulation system that transdermally places an occluder at the site of patent ductus arteriosus using a delivery system for occlusion of the arterial canal. Addition of an outside manufacturer of the raw material for an occluder end screw and a delivery cable screw. (A partial change in the reexamination period)
Biologics	Mar. 18, 2011 Total review time: 310 days Regulatory review time: 240 days	- No clinical study results	18	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autogenous transplant	An autologous-cultured epidermis in the shape of a sheet, which is manufactured by culturing keratinocytes isolated from patients' skin tissue, using Green’s technique. It is applied to the wound surface of severe burn patients for wound closure through epithelialization. Application for a partial change to alter the method of mycoplasma testing and the subculture process for keratinocytes, etc in the manufacturing process. (A partial change in the reexamination period)

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Products Approved in FY 2010: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Jun. 2, 2010 Total review time: 789 days Regulatory review time: 426 days	Aug. 16, 2006 Clinical evaluation report	1	Intralase FS Laser (AMO Japan K.K.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	A Nd:Glass laser (wave length 1053 nm) surgical instrument used for creation of a corneal flap in LASIK (laser in-situ keratomileusis) and for cut/resection in keratoplasty. Creation of a corneal flap, lamellar and penetrating cut/incision can be performed with this product, instead of using a keratome or scalpel, in LASIK and keratoplasty. A clinical evaluation report summarizing the results of post-marketing clinical studies conducted by the manufacturer in the USA and literature searches were submitted to evaluate its efficacy and safety.
1	Jul. 21, 2010 Total review time: 411 days Regulatory review time: 186 days	Dec. 6, 2005 Domestic clinical study results	2	Aime Aquafinity (Asahi Kasei Aime Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A soft contact lens using silicone hydrogel for correcting visual acuity in myopia, hyperopia and astigmatism. The lens is made from a novel material that aims to improve the comfort in wearing while maintaining high oxygen permeability.
1	Nov. 22, 2010 Total review time: 423 days Regulatory review time: 243 days	Jan. 30, 2007 Domestic clinical study results	3	Alcon Acrysof IQ Restor Single-Piece (Alcon Japan Ltd.)	Change	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery for correcting near and distance visual acuity. A model with an additional power of 3.0D (focal distance: approximately 40 cm) was added in this application, while the additional power of the existing model is 4.0D (focal distance: approximately 30 cm). A clinical study was conducted to evaluate the efficacy and safety of the additional model.
1	Feb. 2, 2011 Total review time: 92 days Regulatory review time: 13 days	- Domestic clinical study results	4	Fall in Eyez (Destiny International Co., Ltd.)	Approval	Instrument & apparatus 72-2 Reusable colored contact lenses not for correcting visual acuity	A reusable colored contact lens that is not for correcting visual acuity that is indicated for daily wear and replaced monthly. Since equivalence to the approved product was not demonstrated with regard to the compounding ratio of the raw material monomer and cross-linker, a clinical study was conducted to evaluate its efficacy and safety.
2	Jun. 2, 2010 Total review time: 1098 days Regulatory review time: 610 days	- Clinical evaluation report	5	Oral Moisture Checking Device Mucus (Life Co., Ltd.)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A device used as a diagnostic aid that quantifies dryness of oral mucosa by converting an impedance level at the dorsum of the tongue measured by bioelectrical impedance analysis (BIA) technique to an amount of water. Quantification using this product is different from conventional gum test and Saxon test in that the measurement time is as short as approximately 2 seconds and measurement is possible regardless of the presence or absence of patient's consciousness. A clinical evaluation report summarizing the results of literature searches was submitted with regard to the appropriateness of a cut-off level for the degree of dryness and a correlation with the existing methods.
2	Aug. 31, 2010 Total review time: 1516 days Regulatory review time: 768 days	The main body is not subject to regulatory control as a medical device. January 5, 2005 (only resin part for gingival protection) Domestic clinical study results	6	Tion In Office (GC Corporation)	Approval	Dental 2 Dental bleaching material	A dental bleaching agent exclusively designated for office bleaching containing hydrogen peroxide solution and urea hydrogen peroxide as major ingredients. This product was improved to achieve efficient bleaching using a reactor containing visible light-titanium oxide. A clinical study was conducted to evaluate the bleaching performance and safety of this product in discolored human teeth.
3-1	Dec. 2, 2010 Total review time: 308 days Regulatory review time: 258 days	Oct. 10, 2008 Jul. 13, 2009 (38 mm added) Foreign clinical study results	7	Taxus Liberté Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a stent and delivery catheter. The stent is coated with antineoplastic agent paclitaxel to topically inhibit neointimal proliferation. Application for a partial change to add a product with a stent length of 38 mm to the existing products for extending the target lesion length from 28 mm to 34 mm. A clinical study was conducted to evaluate the efficacy and safety of a 38-mm-long stent.
3-1	Dec. 14, 2010 Total review time: 595 days Regulatory review time: 345 days	Dec. 11, 2008 Foreign clinical study results	8	Express SD Renal Artery Dilatation Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A balloon dilating stent system developed for maintaining vascular patency of an atherosclerotic lesion occurring at the opening of the renal artery. A clinical study was conducted to evaluate the efficacy and safety of this product in maintaining vascular dilatation when it was placed at an atherosclerotic lesion occurring at the entrance of the renal artery.
3-1	Feb. 23, 2011 Total review time: 1052 days Regulatory review time: 600 days	Jun. 26, 2006 Foreign clinical study results	9	COOK Vascular Stent (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Stent for iliac artery	This product consists of a stent and delivery system used for treatment of symptomatic vascular diseases such as a stenotic lesion with a reference vessel diameter of 5-9 mm in the iliac artery. A clinical study was conducted to evaluate the efficacy and safety of this product in maintaining vascular patency when it was placed at a stenotic lesion in the iliac artery.

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Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-2	Apr. 28, 2010 Total review time: 1083 days Regulatory review time: 829 days	Sep. 21, 2006 Foreign clinical study results	10	ASD Occlusion System (Japan Lifeline Co., Ltd.)	Change	Medical products 4 Prosthetic material for artificial cardiac membrane	A device used for occlusion of ostium secundum atrial septal defect by transdermally placing an occluder (septal occluder) made from a nickel-titanium alloy wire in an atrial septal defect (ASD). This is a partial change approval application to add a septal occluder MF type with a smaller waist diameter to enable placement of the device at multiple atrial septal defects. A clinical study was conducted to evaluate the occlusion performance of this product in multiple defects of the atrial septum.
3-2	Jun. 14, 2010 Total review time: 377 days Regulatory review time: 152 days	Apr. 5, 2007 Foreign clinical study results	11	Tegaderm CHG Dressing (3M Health Care Limited)	Approval	Medical products 4 Antibacterial catheter dressing and protecting material	A catheter dressing and protecting material that covers and protects an insertion site of a vascular catheter. A gel pad included in this device contains an antibacterial agent chlorhexidine gluconate that inhibits regrowth of skin bacterial flora at the insertion site. A clinical study was conducted to evaluate whether use of this product inhibited regrowth of skin bacterial flora on normal skin and the performance of fixation of a catheter with this product in patients inserted with a catheter.
3-2	Sep. 29, 2010 Total review time: 2009 days Regulatory review time: 676 days	Apr. 23, 1998 (IDE Approval) Domestic clinical study results	12	Bioglue Surgical Adhesive (Century Medical, Inc.)	Approval	Medical products 4 Surgical adhesive	A surgical adhesive containing bovine serum albumin and glutaraldehyde as major ingredients. This product is used for adhesion and hemostasis at an artificial blood vessel suture site associated with closure of aortic dissection and aortic dissection lumen (including dissecting aneurysm of the aorta). A clinical study was conducted to evaluate the degree of adhesion (efficacy) and safety of this product in such surgeries.
3-2	Dec. 17, 2010 Total review time: 521 days Regulatory review time: 216 days	Apr. 15, 2008 Jul. 15, 2008 (change to the current product) Foreign clinical study results	13	TALENT Abdominal Stent Graft System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm used to prevent blood flow into abdominal aortic aneurysm and prevent rupture of aortic aneurysm. A clinical study was conducted to evaluate the efficacy and safety of stent graft treatment for abdominal aortic aneurysm.
3-2	Mar. 16, 2011 Total review time: 866 days Regulatory review time: 215 days	May. 21, 2008 Foreign clinical study results	14	COOK Zenith TX2 TAA Endovascular Graft (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of descending thoracic aortic aneurysm. It consists of a self-expanding stainless-steel stent and polyester graft. A clinical study was conducted to evaluate the efficacy and safety of stent graft treatment for thoracic aortic aneurysm.
4	Jun. 23, 2010 Total review time: 545 days Regulatory review time: 289 days	May. 16, 2008 Foreign clinical study results	15	Acuity Spiral (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A spirally-molded lead to be placed in the coronary vein for CRT. A clinical study was conducted to demonstrate that the safety and efficacy of this product were within an acceptable range compared to the existing products.
4	Jul. 5, 2010 Total review time: 1036 days Regulatory review time: 528 days	May. 21, 2004 Foreign clinical study results	16	ZOLL AED Plus Automated External Defibrillator (Zoll Medical Corporation)	Approval	Instrument & apparatus 12 Automatic defibrillator for non-healthcare professionals	A semi-automatic external defibrillator using biphasic defibrillation waveform dedicated for use by non-healthcare professionals, equipped with a pad with an acceleration sensor to enable the display of the rate and depth of chest compression during cardiopulmonary resuscitation. A clinical study was conducted to confirm the efficacy and safety of defibrillator function using biphasic waveform.
4	Aug. 23, 2010 Total review time: 482 days Regulatory review time: 302 days	Oct. 1, 2004 Foreign clinical study results	17	Precision Plus SCS System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief to be applied to patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. It can be charged non-invasively from outside the body. A clinical study was conducted to evaluate the safety and efficacy of this product for relief of chronic pain.
4	Sep. 3, 2010 Total review time: 1326 days Regulatory review time: 229 days	Jun. 20, 2005 Foreign clinical study results	18	Revolution 2 (Volcano Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system intravascular ultrasound catheter	A catheter for intravascular ultrasound diagnostic imaging with a built-in ultrasound transducer for imaging intravascular lumen and vascular wall using ultrasound. The ultrasonic frequency of this product is 45 MHz. A clinical study was conducted to primarily evaluate system-related adverse events.
4	Oct. 8, 2010 Total review time: 259 days Regulatory review time: 157 days	- Foreign clinical study results	19	Attain Ability Straight Leads (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A tined lead to be placed in a coronary vein for CRT. A clinical study was conducted to demonstrate that the safety and efficacy of this product were within an acceptable range compared to the existing products.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	20	Accent DR ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.

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4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	21	Accent RF DR ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	22	Anthem ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	23	Anthem RF ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 9, 2010 Total review time: 324 days Regulatory review time: 168 days	Jan. 29, 2010 Foreign clinical study results	24	Nuance DR RF (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 9, 2010 Total review time: 324 days Regulatory review time: 168 days	Jan. 29, 2010 Foreign clinical study results	25	Nuance DR (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 14, 2010 Total review time: 897 days Regulatory review time: 377 days	May. 15, 2008 Foreign clinical study results	26	Ovatio CRT-D (Sorin CRM)	Approval	Instrument & Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. A clinical study was conducted to evaluate the efficacy and safety of this product as a CRT-D system.
4	Dec. 14, 2010 Total review time: 482 days Regulatory review time: 226 days	Oct. 27, 2009 Foreign clinical study results	27	Paradym CRT-D (Sorin CRM)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. A clinical study was conducted to evaluate the efficacy and safety of this product as a CRT-D system.
4	Dec. 17, 2010 Total review time: 366 days Regulatory review time: 168 days	- Foreign clinical study results	28	AnalyST Accel RF VR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	Automatic implantable defibrillator with the function of single-chamber bradycardia pacing. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular threshold were submitted to evaluate the efficacy and safety of this function.
4	Dec. 17, 2010 Total review time: 365 days Regulatory review time: 167 days	- Foreign clinical study results	29	AnalyST Accel RF DR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	Automatic implantable defibrillator with the function of dual-chamber bradycardia pacing. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 17, 2010 Total review time: 365 days Regulatory review time: 167 days	Jan. 29, 2010 Foreign clinical study results	30	Promote Accel RF (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT. A clinical study was conducted to evaluate the efficacy and safety of a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds.
4	Mar. 29, 2011 Total review time: 456 days Regulatory review time: 161 days	- Foreign clinical study results	31	Situs 2 OTW Lead (Sorin CRM)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A bipolar left ventricular pacing lead for coronary veins and its accessory connected to CRT-P and CRT-D and used during cardiac resynchronization treatment. The first left ventricular pacing lead of the company. Results from clinical studies were submitted to evaluate its efficacy and safety.
5	Apr. 30, 2010 Total review time: 231 days Regulatory review time: 151 days	- Domestic clinical study results	32	Cellsorba E (Asahi Kasei Kuraray Medical Co., Ltd.)	Change	Instrument & apparatus 7 Purifie for blood cell removal	Application for a partial change to add a miniaturized column to the approved product "Cellsorba E (approval No.: 21300BZZ00440000)."A clinical study was conducted to evaluate the efficacy and safety of this product in patients with pediatric active ulcerative colitis.

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5	Sep. 14, 2010 Total review time: 487 days Regulatory review time: 255 days	- Domestic clinical study results	33	PTEG Kit (Akita Sumitomo Bakelite Co., Ltd.)	Approval	Instrument & apparatus 51 Enteral feeding kit for long-term use	An enteral feeding tube and its insertion kit used in a procedure for percutaneous trans-esophageal insertion and placement of a catheter in the gastrointestinal tract to provide enteral feeding and decompression to patients for whom it is difficult to perform gastrostomy. A clinical study was conducted to evaluate the efficacy and safety of percutaneous trans-esophageal gastro-tubing (PTEG) in patients receiving enteral feeding or decompression.
5	2010/10/21 Total review time: 325 days Regulatory review time: 200 days	- Domestic clinical study results	34	Toraylight NV (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow fiber dialyzer. Because equivalence to the approved products was not demonstrated with regard to the semipermeable membrane material, a clinical study was conducted to evaluate its efficacy and safety.
5	Dec. 1, 2010 Total review time: 404 days Regulatory review time: 248 days	- Domestic clinical study results	35	Maxiflux (Nipro Corporation)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter. Because equivalence to the approved products was not demonstrated with regard to the semipermeable membrane material and performance profile, a clinical study was conducted to evaluate its efficacy and safety.
5	Feb. 2, 2011 Total review time: 687 days Regulatory review time: 344 days	- Domestic clinical study results	36	Fibroscan (InterMedical Co., Ltd.)	Approval	Instrument & apparatus 12 Versatile ultrasound diagnostic imaging device	A device to measure non-invasively liver stiffness using ultrasonic waves, etc. A clinical study was conducted to evaluate whether it could qualitatively measure the stiffness of the liver.
6-1	Sep. 14, 2010 Total review time: 837 days Regulatory review time: 329 days	Sep. 5, 2002 Domestic clinical study results	37	Trabecular Metal Modular Acetabular System (Zimmer K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	A locking ring used to fix a titanium alloy acetabular cup and liner that are used at the pelvic side to replace the function of the hip joint during hip replacement arthroplasty (including revision hip replacement arthroplasty). The outer surface is coated with a consecutive 3-D dodecahedron porous structure made from tantalum to ensure direct fixation to the bone. A clinical study was conducted to evaluate the efficacy and safety of this device with this novel surface structure.
6-1	Nov. 9, 2010 Total review time: 855 days Regulatory review time: 237 days	Jul. 19, 2001 Feb. 12, 2002 Domestic clinical study results	38	Trabecular Metal Monoblock (Zimmer K.K.)	Approval	Medical products 4 Artificial knee joint, patellar and tibial component	A tibia component to be implanted at the tibial side to reconstruct the function of the knee joint and a patellar component to be implanted in the patella during knee replacement arthroplasty (including revision knee replacement arthroplasty). While the shape and size of this product are equal to those of the approved product, a metal part and ultrahigh molecular weight polyethylene part are compressed to form an integrated architecture. In addition, improved bone fixation and reduced stress shielding on bone are expected because of a new raw material (consecutive 3-D dodecahedron porous structure made from tantalum) used in this product. A clinical study was conducted to evaluate the efficacy and safety of this device with improved structure, etc.
6-2	Jan. 6, 2011 Total review time: 1011 days Regulatory review time: 496 days	- Domestic clinical study results	39	Biohesive (Alcare Co., Ltd.)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	A wound dressing and protecting material used to protect wound reaching subcutaneous adipose tissue, maintain a moist environment, promote healing and relieve pain. With hydrocolloid material as a base material, this product contains sulfadiazine silver 0.05% to improve hygiene inside the dressing material. Since equivalence to the approved product was not demonstrated with regard to this structure, a clinical study was conducted to evaluate its efficacy and safety.
8	Feb. 23, 2011 Total review time: 208 days Regulatory review time: 67 days	- Domestic clinical study results	40	Visceral Fat Area Measurement Device HDS-2000 (Omron Healthcare Co., Ltd.)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A body constituent analysis instrument that estimates and shows a cross-sectional area of visceral fat based on bioelectrical impedance level and major axis and minor axis of cross-sectional area of the abdomen. It is indicated for secondary screening (detection of cross-sectional area of visceral fat $\leqq$ 100 cm^2) of patients who are tested positive according to the diagnostic criteria using abdominal circumference, one of the diagnostic criteria for metabolic syndrome. A clinical study was conducted to evaluate the estimation precision of the cross-sectional area of visceral fat in relation to correlation with the cross-sectional area of visceral fat obtained from CT images.

Table 2. Products Approved in FY 2009: New Medical Devices

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 28, 2009 Total review time: 876 days Regulatory review time: 621 days	- Domestic clinical study results	1	Ortho-K (Alpha Corporation Inc.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	The first orthokeratology contact lens in Japan for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct unaided vision after removal of the lens.
1	May 22, 2009 Total review time: 1669 days Regulatory review time: 615 days	Oct. 17, 2003 Overseas clinical study results	2	Allegretto Wave (Wavelight Laser Technologie AG)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Jul. 1, 2009 Total review time: 96 days Regulatory review time: 91 days	May 23, 2003 No clinical study results	3	VISX Excimer Laser System (AMO Japan K.K.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism and remove corneal opacities by laser ablation of corneal tissue. (Application for change from a foreign exceptional approval to a regular marketing approval in the reexamination period)
1	Jul. 3, 2009 Total review time: 51 days Regulatory review time: 50 days	- No clinical study results	4	Ortho-K (Alpha Corporation Inc.)	Change	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and to correct unaided vision after removal. The addition of a manufacturing site. (A partial change in the reexamination period)
1	Jul. 24, 2009 Total review time: 186 days Regulatory review time: 131 days	Nov. 8, 2006 Overseas clinical study results	5	Excimer Laser Corneal Surgery System EC-5000CXIII (Nidek Co., Ltd.)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia, hyperopia or astigmatism, remove corneal surface opacities, or smooth corneal irregularities by laser ablation of corneal tissue. A partial change for the objectives including the addition of correction of hyperopia to the indications. (A partial change in the reexamination period)
1	Aug. 13, 2009 Total review time: 394 days Regulatory review time: 142 days	Oct. 1, 2001 No clinical study results	6	O_2 Optics (Ciba Vision K.K.)	Change	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A silicone hydrogel contact lens indicated for daily or up to 1 month extended wear. Addition of a supplementary fluid and a manufacturing site. (A partial change in the reexamination period)
1	Dec. 17, 2009 Total review time: 28 days Regulatory review time: 20 days	- No clinical study results	7	α Ortho-K (Alpha Corporation Inc.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct the unaided vision after removal. (Addition of a brand name to Ortho-K in the reexamination period) (The original product is in a reexamination period)
1	Feb. 2, 2010 Total review time: 1771 days Regulatory review time: 524 days	Dec. 22, 2005 Domestic clinical study results	8	ICL (STAAR Japan Inc.)	Approval	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	An intraocular lens to be implanted in the posterior chamber of the phakic eye (in front of the human crystalline lens) to correct refractive errors in the eye (myopia).
3-1	April 27, 2009 Total review time: 55 days Regulatory review time: 48 days	Sep. 22, 2006 No clinical study results	9	Angioguard XP (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	The first device in Japan to prevent distal emboli with a polyurethane filter to capture and remove embolic substances including thrombi released while a stent is placed in the carotid artery. Application for a partial change to alter the materials. (A partial change in the reexamination period)
3-1	Aug. 25, 2009 Total review time: 265 days Regulatory review time: 251 days	Jul. 12, 2007 No clinical study results	10	Precise for Carotid Artery (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for the carotid artery	The first stent for the carotid artery in Japan to dilate carotid stenosis and prevent restenosis. Change for addition of RX type. (A partial change in the reexamination period)
3-1	Jan. 8, 2010 Total review time: 589 days Regulatory review time: 229 days	Jul. 2, 2008 Domestic and overseas clinical study results	11	XIENCE V Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease.
3-1	Jan. 8, 2010 Total review time: 589 days Regulatory review time: 229 days	Jul. 2, 2008 Domestic and overseas clinical study results	12	PROMUS Drug-Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease.
3-1	Jan. 8, 2010 Total review time: 283 days Regulatory review time: 236 days	Oct. 2, 2008 Overseas clinical study results	13	Endeavor Sprint Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with zotarolimus coating used for dilating and maintaining the stenotic site of the coronary artery in symptomatic ischemic heart diseases, with a different delivery catheter from the original product. (The original product is in a reexamination period)
3-1	Jan. 25, 2010 Total review time: 285 days Regulatory review time: 73 days	Oct. 10, 2008 No clinical study results	14	TAXUS Liberté Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Application for a partial change to alter the test method for raw materials. (A partial change in the reexamination period)

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-1	Jan. 25, 2010 Total review time: 285 days Regulatory review time: 73 days	Mar. 4, 2004 No clinical study results	15	TAXUS Express2 Stent (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Application for a partial change to alter the test method for raw materials. (A partial change in the reexamination period)
3-1	Feb. 15, 2010 Total review time: 374 days Regulatory review time: 155 days	Oct. 23, 2008 Overseas clinical study results	16	Carotid Wallstent Monorail (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	A stent made of cobalt-chromium alloy used for dilating and holding a stenotic site of the cartoid artery in cartoid stenosis. (The original product is in a reexamination period)
3-1	Feb. 15, 2010 Total review time: 374 days Regulatory review time: 155 days	Dec. 14, 2006 Overseas clinical study results	17	FilterWire EZ (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli with a polyurethane filter to capture and remove embolic substances including thrombi released while a stent is placed in the carotid artery. (The original product is in a reexamination period)
3-2	Apr. 9, 2009 Total review time: 714 days Regulatory review time: 243 days	Jun. 5, 2008 Overseas clinical study results	18	TALENT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysms used to prevent blood flow into the aneurysm and aneurysm rupture. (The original product is in a reexamination period)
3-2	May 1, 2009 Total review time: 56 days Regulatory review time: 52 days	- No clinical study results	19	Triplex (Terumo Corporation)	Change	Instrument & apparatus 7 Artificial blood vessel for the central circulation system	An artificial blood vessel consisting of a triple layer structure containing a non-porous layer held between 2 polyester stockinette layers; together these layers form a tubular body. This does not require sealing with biological materials. Application for a partial change to alter the materials. (A partial change in the reexamination period)
3-2	May 27, 2009 Total review time: 187 days Regulatory review time: 181 days	Jul. 21, 2005 No clinical study results	20	ONYX Liquid Embolic System LD (ev3 Inc.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	The first liquid embolic material in Japan used to occlude the flow of blood as pretreatment for surgical resection of arteriovenous malformations (bAVM's). A change of adding description concerning compatible catheters. (A partial change in the reexamination period)
3-2	Nov. 25, 2009 Total review time: 215 days Regulatory review time: 139 days	Nov. 7, 2008 No clinical study results	21	GORE TAG Thoracic Aortic Stent Graft System (Japan Gore-Tex Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysm used to prevent blood flow into the aneurysm and its rupture. Application for a partial change to add a delivery system. (A partial change in the reexamination period)
3-2	Jan. 8, 2010 Total review time: 302 days Regulatory review time: 179 days	May 8, 2007 Domestic and overseas clinical study results	22	Codman Enterprise VRD (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A cylindrical, mesh-like vascular reconstruction device to be deployed in the parent artery in order to prevent the embolic coils from protrude and/or dropout into the parent artery during coil embolization of wide-neck intracranial aneurysms, which are difficult to treat with surgery. [Orphan device]
4	May 27, 2009 Total review time: 106 days Regulatory review time: 94 days	Dec. 9, 1997 (12Fr) Sep. 4, 1998 (14Fr/16Fr) Jan. 25, 2002 (16Fr SLSII) May 2, 2002 (12/14FrSLSII) No clinical study results	23	Excimer Laser Cardiac Lead Removal System (DVx Inc.)	Change	Instrument & apparatus 7 Pacemaker/defibrillator lead removal kit	The first extraction laser sheath in Japan used at removal of chronically implanted pacing or defibrillator leads to ablate binding tissue around the circumference of leads using the laser energy delivered from a dedicated excimer laser system. Addition of a manufacturing site. (A partial change in the reexamination period)
4	Nov. 18, 2009 Total review time: 2091 days Regulatory review time: 200 days	May 31, 2001 Domestic and overseas clinical study results	24	Implantable Ventricular Assist Device HeartMate XVE LVAS (Nipro Corporation)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	An implantable diaphram left ventricular assist device intended for use to improve the circulation in patients with end-stage heart failure who are difficult to survive despite the conventional short-term, mechanically-assisted circulation and maximum medical management, and are considered to be difficult to be rescued without heart transplantation. The efficacy and safety of this product for the target patients were evaluated in the clinical studies using the previous model. [Orphan device]
4	Jan. 8, 2010 Total review time: 423 days Regulatory review time: 192 days	Jun. 16, 1997 Overseas clinical study results	25	Vagus Nerve Stimulation (VNS) System (Nihon Kohden Corporation)	Approval	Instrument & apparatus 12 Vagus nerve stimulation device with anti-seizure effects	An electrical stimulation device to stimulate vagus nerve as an adjuvant therapy for patients with drug-resistant epilepsy who have refractory epileptic seizures. Clinical studies were conducted to confirm the efficacy and safety of this product in the target patients. [Priority review]
5	Aug. 6, 2009 Total review time: 427 days Regulatory review time: 188 days	Jan. 15, 2002 No clinical study results	26	Dornier Epos Ultra (Dornier MedTech Japan Co. Ltd.)	Change	Instrument & apparatus 12 Extracorporeal shock wave pain therapy system	A low-energy extracorporeal shock wave therapy system for orthopedic use with reduced output of the conventional electromagnetic induction-type extracorporeal shock wave lithotripter applied for pain relief therapy. Application for a partial change for the objectives including for addition of the ultrasonic imaging device used to position the affected area. (A partial change in the reexamination period)
5	Sep. 1, 2009 Total review time: 679 days Regulatory review time: 413 days	Oct. 22, 2004 Overseas clinical study results	27	MR-Guided Focused Ultrasound Surgery System ExAblate 2000 (GE Healthcare Japan Corporation)	Approval	Instrument & apparatus 12 Ultrasound hyperthermia system	A focused ultrosonic surgery system used for treatment of symptomatic uterine fibroid while monitoring the tissue temperature with MR in order to improve the symptoms.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Jan. 8, 2010 Total review time: 283 days Regulatory review time: 84 days	May 6, 2005 Domestic clinical study results	28	Cryosurgical Unit CryoHit (Hitachi Medical Corporation)	Approval	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical system used to kill renal tumor cells of small diameter by utilizing Joule-Thompson effect of high-pressure argon gas to cool the tip end of probe or needle (-100°C or lower) under Magnetic Resonance (MR) Image guidance.
5	Jan. 15, 2010 Total review time: 703 days Regulatory review time: 254 days	Sep. 24, 2001 Domestic clinical study results	29	Deflux (Q-Med AB)	Approval	Medical products 4 Filling material for the treatment of vesicoureteral reflux	A device with injectable material consisting of dextranomer microspheres which is a bulge forming material and solution of stabilized hyaluronate sodium in phosphate buffered saline filled in a disposable syringe equipped with a tip cap, used for treatment of patients with vesicoureteral reflux grade II - IV.
6	Nov. 2, 2009 Total review time: 584 days Regulatory review time: 273 days	Oct. 10, 2003 Domestic clinical study results	30	V.A.C. ATS Therapy System (KCI KK)	Approval	Medical products 4 Negative Pressure Wound Therapy System	A therapy system used for protection of the wounds, maintaining a healing environment, and promoting and shortening the time of wound healing in patients with intractable traumatic wounds or dehisced wounds, post-operative open wounds or skin defect wounds, post-operative wounds after dismemberment of extremities due to diabetics, etc. The novelty of this product is the capability of the system to control the treatment mechanically while the conventional simple suction therapy was performed by individual physicians using a prepared set of tools. A clinical study was conducted in Japan to evaluate its clinical efficacy and safety.
6	Dec. 24, 2009 Total review time: 462 days Regulatory review time: 142 days	May 25, 2004 Clinical evaluation report	31	Stryker SpinePlex Bone Cement (Stryker Japan K.K.)	Approval	Medical products 4 Orthopedic bone cement	An acrylic bone cement used for pain relief in percutaneous vertebroplasty for painful vertebral body fracture caused by malignant spine tumor such as metastatic bone tumor and myeloma which are not responsive to conventional therapies. A clinical evaluation report summarizing the Japanese clinical study results and the literature research data on the use results of this and similar products in foreign countries was submitted to verify the safety and efficacy. [Priority review]
6	Feb. 5, 2010 Total review time: 651 days Regulatory review time: 368 days	Jul. 2, 1998 Domestic and overseas clinical study results	32	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Approval	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system to be used in percutaneous kyphosis correction performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief in spinal compression fracture. The novelty of this product is the capability to fill the bone cement safely after restoration of the physical vertebral height by forming a cavity in the fractured vertebral body in comparison with the conventional vertebroplasty. A clinical study was conducted in Japan to evaluate its efficacy and safety. In addition, results from overseas clinical studies were submitted.
6	Feb. 5, 2010 Total review time: 651 days Regulatory review time: 347 days	Apr. 1, 2004 Domestic and overseas clinical study results	33	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Orthopedic bone cement	A therapeutic spine bone cement used in percutaneous kyphosis correction in spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. The novelty of this product is the capability to fill the bone cement safely after restoration of the physical vertebral height by forming a cavity in the fractured vertebral body in comparison with the conventional vertebroplasty. A clinical study was conducted in Japan to evaluate its efficacy and safety.In addition, results from overseas clinical studies were submitted.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 205 days	Apr. 29, 2005 Overseas clinical study results	34	da Vinci Surgical System (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 12 Surgical robot, operational unit	A device to assist a surgeon in controlling endoscopic instruments attached to three arms of the patient cart with master-slave control in order to perform cutting, coagulating and suturing the tissue by manipulating the master controller on the surgeon console.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 232 days	Apr. 29, 2005 Overseas clinical study results	35	EndoWrist Bipolar Instrument (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 25 Reusable active endotherapy device using radio frequency	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping,suturing etc.and to cut and coagulate the tissue by using radiofrequency electrosurgery current under endoscopic visualization.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 232 days	Apr. 29, 2005 Overseas clinical study results	36	EndoWrist Monopolar Instrument (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 25 Reusable active endotherapy device using radio frequency	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping etc. and to cut and coagulate the tissue by using radiofrequency electrosurgery current under endoscopic visualization.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 235 days	Apr. 29, 2005 Overseas clinical study results	37	EndoWrist Instrument (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 25 Reusable active endotherapy device	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping, suturing, ligation etc. under endoscopic visualization.

Note: Products submitted for application in 2003 and before are included.

Table 3. Products Approved in FY 2009: Improved Medical Devices (with Clinical Data)

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Jul. 24, 2009 Total review time: 401 days Regulatory review time: 161 days	Apr. 5, 2005 Clinical evaluation report	1	Relieva Sinus Balloon Catheter Set (Medico's Hirata Inc.)	Approval	Instrument & apparatus 51 Endoscopic dilatation catheter	A catheter set used to drain the pus by dilating narrowed natural openings of the frontal sinus, sphenoid sinus, and maxillary sinus with balloons for the treatment of sinusitis. A clinical evaluation report based on the overseas post-marketing clinical research was submitted to evaluate its efficacy and safety.
1	Dec. 9, 2009 Total review time: 588 days Regulatory review time: 384 days	- Domestic clinical study results	2	Menicon 1day Flat Pack (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	A daily disposable soft contact lens for myopia and hyperopia. A copolymer of HEMA and GMA is used as lens materials. Clinical studies were conducted to evaluate the efficacy and safety.
1	Mar. 4, 2010 Total review time: 769 days Regulatory review time: 418 days	Mar. 3, 2008 Overseas clinical study results	3	1-Day Acuvue TruEye (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	A daily disposable soft contact lens for myopia, hyperopia, astigmatism, or presbyopia. A copolymer of HEMA, OH-mPDMS, and DMA is used as lens materials. Clinical studies were conducted to evaluate the efficacy and safety.
2	Jan. 15, 2010 Total review time: 697 days Regulatory review time: 447 days	- Domestic clinical study results	4	Neobone (Covalent Materials Corporation)	Change	Medical products 4 Artificial bone implant	An artificial bone implant material consisting of granular and shaped (e.g. rectangular cuboid) products to be used for filling bone defect and for supporting bone regeneration. Application for a partial change to add spherical granular product and to add granular products for use in dental field to the indication in addition to its use in the orthopedic field. Clinical studies were conducted to evaluate its efficacy as bone filler for dental use.
3-1	Apr. 20, 2009 Total review time: 641 days Regulatory review time: 427 days	- Overseas clinical study results	5	Palmaz Genesis for Renal Artery (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent used for dilating and holding a stenotic site in renal artery stenosis. Clinical studies were conducted to evaluate its clinical efficacy in renal artery stenosis.
3-1	Aug. 6, 2009 Total review time: 1989 days Regulatory review time: 859 days	Jul. 29, 2002 Clinical evaluation report	6	HydroCoil Embolic System (Terumo Corporation)	Approval	Instrument & apparatus 51 Sterilized tube and catheter for vascular treatment	A delivery pusher for platinum alloy coil intended to block the blood flow into brain aneurysm and for guiding the coil to the implanting site. The coil is coated with swellable hydrogel. Clinical evaluation data to evaluate its efficacy and safety were submitted.
3-1	Jan. 8, 2010 Total review time: 226 days Regulatory review time: 182 days	- Overseas clinical study results	7	Cypher Select+ Stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with drugs to inhibit the neointimal proliferation and a delivery catheter. Clinical studies were conducted to evaluate its efficacy and safety.
3-2	Aug. 21, 2009 Total review time: 549 days Regulatory review time: 482 days	Apr. 7, 2005 Overseas clinical study results	8	DuraSeal Blue Spray (Tyco Healthcare Japan Inc.)	Approval	Medical products 4 Absorbable tissue reinforcement material	An absorbable prosthetic material for dura mater applied as an adjunct to suturing, on the dural gap, sutured site of dura mater, and the gap between the duraplasty material and dura mater. A clinical study was conducted to evaluate its efficacy and safety.
4	Apr. 16, 2009 Total review time: 533 days Regulatory review time: 195 days	May 7, 2007 Overseas clinical study results	9	Promote 36 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT (treatment method to improve cardiac failure symptoms, which synchronizes ventricular contraction by stimulating cardiac muscles of both ventricles electrically for a long time), with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Apr. 16, 2009 Total review time: 533 days Regulatory review time: 243 days	Sep. 11, 2007 Overseas clinical study results	10	Promote RF 36 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Apr. 24, 2009 Total review time: 238 days Regulatory review time: 137 days	Sep. 11, 2007 Overseas clinical study results	11	Promote RF 30 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Jul. 7, 2009 Total review time: 439 days Regulatory review time: 335 days	Nov. 12, 2003 Overseas clinical study results	12	Endo-PAT2000 (CCI Corporation)	Approval	Instrument & apparatus 21 Regional body plethysmograph	A device to determine the vascular endothelium-mediated changes by measuring the volume pulse waves before and after 5-minute occlusion of the brachial artery with a cuff applied on the upper arm. Overseas clinical study results were used to evaluate the safety.
4	Aug. 5, 2009 Total review time: 383 days Regulatory review time: 299 days	Apr. 23, 2008 D970003/S096 Apr. 30, 2008 D970003/S097 Overseas clinical study results	13	Altrua 60DR (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. A clinical study was conducted to evaluate its Automatic Capture feature capability, which automatically adjusts the ventricular pacing output.
4	Aug. 5, 2009 Total review time: 352 days Regulatory review time: 268 days	Apr. 23, 2008 D970003/S096 Apr. 30, 2008 D970003/S097 Overseas clinical study results	14	Altrua 60SR (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. A clinical study was conducted to evaluate its Automatic Capture feature capability, which automatically adjusts the ventricular pacing output.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Aug. 10, 2009 Total review time: 510 days Regulatory review time: 290 days	Mar. 16, 2007 Overseas clinical study results	15	Cool Path Ablation System (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used for the electrophysiological study of the heart and for creating endocardial lesions to treat typical atrial flutter with radiofrequency current. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to avoid increasing tip electrode-tissue interface temperature.
4	Oct. 19, 2009 Total review time: 327 days Regulatory review time: 200 days	- Overseas clinical study results	16	Cool Path Duo Irrigation Catheter (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used for the electrophysiological study of the heart and for creating endocardial lesions to treat typical atrial flutter with radiofrequency current. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to avoid increasing tip electrode-tissue interface temperature.
4	Oct. 28, 2009 Total review time: 485 days Regulatory review time: 313 days	May 7, 2007 Overseas clinical study results	17	OptiSense S (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the pulse generator (PG).
4	Oct. 28, 2009 Total review time: 485 days Regulatory review time: 313 days	Oct. 1, 2009 Overseas clinical study results	18	OptiSense Optim (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the PG.
4	Oct. 28, 2009 Total review time: 467 days Regulatory review time: 309 days	Oct. 1, 2009 Overseas clinical study results	19	OptiSense Optim Lead (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the PG.
4	Nov. 12, 2009 Total review time: 332 days Regulatory review time: 204 days	Nov. 21, 2001 Overseas clinical study results	20	Genesis Single 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief to be applied to patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. Clinical studies were conducted to evaluate the constant current stimulation that is generally used for electrical tissue stimulation and used in this product, while the constant voltage stimulation is used in conventional approved products.
4	Dec. 2, 2009 Total review time: 278 days Regulatory review time: 202 days	Mar. 28, 2008 Overseas clinical study results	21	EON Mini Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief to be applied to patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. It can be charged non-invasively from outside the body. Clinical studies were conducted to evaluate the constant current stimulation that is generally used for electrical tissue stimulation and applied in this product.
4	Mar. 26, 2010 Total review time: 847 days Regulatory review time: 410 days	Feb. 4, 2005 Overseas clinical study results	22	ZOLL AED Pro Semi-Automatic Defibrillator (ZOLL Medical Corporation)	Approval	Instrument & apparatus 12 Semi-automatic defibrillator	A semi-automatic external defibrillator using biphasic defibrillator waveform dedicated for use by healthcare professionals, equipped with a pad with an acceleration sensor to enable the display of the rate and depth of chest compression during cardiopulmonary resuscitation. A clinical study was conducted to confirm the efficacy and safety of defibrillator function using biphasic waveform.
5	Jun. 2, 2009 Total review time: 736 days Regulatory review time: 303 days	Jun. 29, 2001 Domestic clinical study results	23	Monosyn (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 2 Polyglyconate suture	An absorbable synthetic monofilament suture made of glycolide/trimethylene carbonate/ε-caprolactone. A clinical trial was conducted to evaluate the efficacy and safety because the combination and amount of the polymers are different from the precedented approved product's.
5	Jun. 8, 2009 Total review time: 619 days Regulatory review time: 383 days	- Domestic clinical study results	24	Fuji IR (Fuji Latex Co., Ltd.)	Approval	Hygienic products 2 Contraceptive condom for males	A condom made chiefly from polyisoprene rubber used to cover the penis for the purpose of contraception and as an adjunct in the prevention of sexually transmitted diseases. A clinical study was conducted to compare its efficacy and safety with those of commercially available condoms (condom made from natural rubber latex).
5	Nov. 10, 2009 Total review time: 375 days Regulatory review time: 297 days	Dec. 4, 2006 Overseas clinical study results	25	WallFlex Duodenal Stent (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Gastroduodental stent	The device consists of a metal stent intended for dilatation and to maintain the patency in gastroduodenal obstructions produced by malignant neoplasms, and a delivery system for endoscopic implantation of the stent. Clinical studies were conducted to evaluate its efficacy for improvement of QOL for a certain period and the safety.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Nov. 20, 2009 Total review time: 624 days Regulatory review time: 433 days	Jan. 8, 2002 Clinical evaluation report	26	Gynemesh (Johnson & Johnson K.K.)	Approval	Medical products 4 Nonabsorbable prosthetic material for hernia, chest wall, and abdominal wall	A mesh used for repair of pelvic organ prolapse, with limited intended use and shape and structure, while manufactured in the same way from the same materials as "Prolene Mesh (polypropylene)" (Approval No. 20400BZY00787000). A clinical evaluation report discussing the efficacy and safety through the defined algorithm for the literature survey was submitted.
5	Feb. 3, 2010 Total review time: 406 days Regulatory review time: 262 days	- Domestic clinical study results	27	Hemodialysis Monitoring Equipment TR-3000MA (Toray Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodialysis equipment	A hemodialysis monitoring equipment with additional functions to "TR-3000M (Approval No. 21500BZZ00045000),"of assisting priming, blood return, blood taking with diahysate, as well as rapid substitution and manual substitution. Clinical studies were performed in Japan to confirm its efficacy and safety.
6	May 8, 2009 Total review time: 2907 days Regulatory review time: 791 days	- Domestic clinical study results	28	Care Sheet "SS" (SSP Co., Ltd.)	Approval	Medical products 4 Hydrocolloid material	A wound dressing and protecting material using hydrogel in a form of poultice. A clinical study was conducted to evaluate its efficacy and safety.
6	Jun. 29, 2009 Total review time: 732 days Regulatory review time: 451 days	Aug. 5, 2004 Domestic clinical study results	29	OIC PEEK Interbody Cage (Stryker Japan K.K.)	Approval	Medical products 4 Spinal cage	A spinal cage made from a novel material polyetheretherketone (PEEK) resin. A pair of these products with bone graft packed inside are intervertebrally inserted and fixed by pressure using another intervertebral fixation system. Clinical studies were performed in Japan to confirm its efficacy and safety.
6	Aug. 6, 2009 Total review time: 934 days Regulatory review time: 487 days	- Domestic clinical study results	30	Blend-E (Nakashima Medical Co., Ltd.)	Approval	Medical products 4 Artificial knee joint, patellar and tibial component	A tibial insert and patellar component made from ultrahigh molecular weight polyethylene. The shape and structure are the same as the approved products of the company, but dl-α-Tocopherol, a kind of vitamin E, has been added to this product in order to give the antioxidative potential to the material and to improve the resistance to wear. Clinical studies were performed in Japan to confirm its efficacy and safety.
8	Oct. 30, 2009 Total review time: 1688 days Regulatory review time: 554 days	Jun. 15, 1999 Overseas clinical study results	31	Medtronic MiniMed CGMS-Gold (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 Glucose monitoring system	A glucose monitoring system to keep continuous record of glucose level in the interstitial fluid which is considered to change in parallel with the blood glucose level, intended for use to obtain information on the fluctuation pattern of blood glucose values necessary to optimize the diabetic treatment. A clinical trial was conducted to compare the correlation between the glucose level in blood and that in the interstitial fluid in order to confirm the clinical performance of this product.
8	Nov. 20, 2009 Total review time: 1169 days Regulatory review time: 677 days	- Domestic clinical study results	32	Ultrasound Bone Densitometer LD-100 (OYO Electric Co., Ltd.)	Approval	Instrument & apparatus 12 Ultrasound bone densitometer	A device to measure the bone density using ultrasound. This product calculates the bone density based on the measurement of arrival times and attenuations of fast wave and slow wave that propagate the radius and arrival times of the reflected waves, while conventional ultrasound bone densitometers measure the speed or attenuation of ultrasonic pulse that propagates the calcaneus. Clinical studies were performed in Japan to confirm its efficacy and safety.

Note: Products submitted for application in 2003 and before are included.

Table 2. FY 2008 List of Approved Products: New Medical Devices

Category	Approval Date Review time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 9, 2008 Total review time: 1107 days Regulatory review time: 320 days	Aug. 11, 2006 Domestic clinical study results	1	Excimer Laser System MEL80 (Carl Zeiss Meditec Co., Ltd.)	Approval	Instrument & apparatus 31 Other laser surgical instrument and laser coagulator (ophthalmic excimer laser surgical instrument)	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Jun. 25, 2008 Total review time: 56 days Regulatory review time: 46 days	May 23, 2003 No clinical study results	2	Star S4 IR Excimer Laser (AMO Manufacturing USA, LLC)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism and remove corneal opacities by laser ablation of corneal tissue. The addition of the manufacturing site. (A partial change during the reexamination period)
1	Dec. 22, 2008 Total review time: 574 days Regulatory review time: 162 days	Apr. 14, 2000 (For myopia) Oct. 11, 2006 (For hyperopia) Domestic and overseas clinical study results	3	Excimer Laser Corneal Surgery System EC-5000 (Nidek Co., Ltd.)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia, hyperopia or astigmatism, remove corneal surface opacities, and smooth corneal irregularities by laser ablation of corneal tissue. A partial change for the objectives including the addition of correction of hyperopia to the indications.
3-1	Sep. 26, 2008 Total review time: 1276 days Regulatory review time: 601 days	Jul. 21, 2005 Overseas clinical study results	4	ONYX Liquid Embolic System LD (ev3, K.K.)	Approval	Instrument & apparatus 51 Other tube and catheter related auxiliary devices (vascular embolization system)	The first liquid embolic material in Japan used to occlude the flow of blood as pretreatment for surgical resection of arteriovenous malformations(bAVM's). [Priority review]
3-1	Jan. 28, 2009 Total review time: 303 days Regulatory review time: 195 days	Oct. 10, 2008 Overseas clinical study results	5	Taxus Libertè Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating to be used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. (The original product is in a reexamination period)
3-1	Mar. 24, 2009 Total review time: 685 days Regulatory review time: 367 days	Feb. 1, 2008 Domestic and overseas clinical study results	6	Endeavor Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with zotarolimus coating to be used for dilating and holding the stenotic site of the coronary artery in symptomatic ischemic heart diseases.
3-2	Jul. 22, 2008 Total review time: 481 days Regulatory review time: 421 days	Dec. 20, 2002 No clinical study results	7	Excluder Bifurcated Stent Graft System (Japan Gore-Tex Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm to be deployed in the lesion in order to prevent the enlargement and rupture of aneurysm by blocking the blood flow into the aneurysm. A change of the manufacturing site and the addition of the applicable size. (A partial change during the reexamination period)
3-2	Dec. 26, 2008 Total review time: 848 days Regulatory review time: 517 days	May 14, 2003 Amplatzer Duct Occluder Amplatzer Delivery System Apr. 25, 2007 Amplatzer TorqVue Delivery System Overseas clinical study results	8	PDA Occlusion Set (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	The first device in Japan dedicated for the closure of patent ductus arteriosus (PDA) by the deployment of the duct occluder in the PDA site percutaneously using the delivery system.
4	Apr. 4, 2008 Total review time: 175 days Regulatory review time: 137 days	May 12, 2006 No clinical study results	9	Concerto C154DWK (Medtronic Japan Co., Ltd)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT (treatment method to improve cardiac failure symptoms, which synchronizes ventricular contraction by stimulating cardiac muscles of bilateral ventricles electrically for a long time), with the function of a defibrillator. (A partial change during the reexamination period)
4	May 7, 2008 Total review time: 138 days Regulatory review time: 117 days	Mar. 17, 2008 Overseas clinical study results	10	Consulta CRT-D (Medtronic Japan Co., Ltd)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. (The original product is in a reexamination period)

Category	Approval Date Review time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Jul. 1, 2008 Total review time: 489 days Regulatory review time: 79 days	Dec. 9, 1997 (12 Fr) Sep. 4, 1998 (14 Fr/16 Fr) Jan. 25, 2002 (16 Fr SLSⅡ) May 2, 2002 (12/14 Fr SLSⅡ) Overseas clinical study results	11	Excimer Laser Cardiac Lead Removal System (DVx Inc.)	Approval	Instrument & apparatus 7 Pacemaker / defibrillator lead extraction kit	The first extraction laser sheath in Japan used at removal of chronically implanted pacing or defibrillator leads to ablate binding tissue around the circumference of leads using the laser energy delivered from the dedicated excimer laser system. [Priority review]
4	Jan. 26, 2009 Total review time: 395 days Regulatory review time: 353 days	－ No clinical study results	12	Intravascular OCT ImageWire (Goodman Co., Ltd.)	Change	Instrument & apparatus 51 Intravascular optical tomographic catheter	A catheter utilizing optical coherence tomography (OCT) for monitoring of the vascular lumen and the vascular wall surface in the coronary artery. A change in the shape of the joint with the dedicated OCT diagnostic imaging instrument. (A partial change during the reexamination period)
4	Jan. 26, 2009 Total review time: 395 days Regulatory review time: 351 days	－ No clinical study results	13	Intravascular OCT Imaging System (Goodman Co., Ltd.)	Change	Instrument & apparatus 12 OCT diagnostic imaging instrument	An optical coherence tomography (OCT) diagnostic imaging instrument for monitoring of the vascular lumen and the vascular wall surface in the coronary artery. The addition of a unit for connection with the dedicated catheter, and a change in the pullback speed. (A partial change during the reexamination period)
5	Sep. 2, 2008 Total review time: 1257 days Regulatory review time: 267 days	－ Domestic clinical study results	14	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Adsorption apheresis device	The Adacolumn is an adsorptive type extracorporeal leukocyte apheresis device. An indication is added for the promotion of remission in patients with moderate to severe active Crohn's disease who are refractory to conventional treatment methods. [Orphan device]
5	Sep. 8, 2008 Total review time: 602 days Regulatory review time: 266 days	Sep. 14, 2007 Domestic clinical study results	15	Olympus Capsule Endoscope System (Olympus Medical Systems Corp.)	Approval	Instrument & apparatus 25 Capsule electronic endoscope system	An endoscopic system comprised of a capsule endoscope (26 x 11 mm) and a monitoring unit. To be used for monitoring and diagnosis of the small bowel. (The original product is in a reexamination period)
6	Dec. 22, 2008 Total review time: 208 days Regulatory review time: 71 days	Aug. 18, 2004 Overseas clinical study results	16	VEPTR System (Synthes K. K.)	Approval	Medical products 4 Internal fixation system	An implantable device made of standard medical grade titanium to be used in patients with thoracic insufficiency syndrome to stabilize their thorax while correcting chest wall malformations in order to help the growth of their thorax and lungs. [Priority review]

Table 3. FY 2008 List of Approved Products: Medical Devices Approved with Clinical Data (Other Than New Medical Devices)

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Sep. 8, 2008 Total review time: 992 days Regulatory review time: 343 days	Mar. 22, 2004 Domestic clinical study results	1	Bausch & Lomb Microkeratome System (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 34 Electric keratome	An electric keratome used in ophthalmic surgeries such as laser *in-situ* keratomileusis (LASIK) for lamellar corneal incisions. A clinical study was conducted to evaluate the safety of this product in LASIK.
1	Aug. 5, 2008 Total review time: 594 days Regulatory review time: 228 days	Sep. 14, 2005 (Colorless); Dec. 16, 2005 (Yellow) Overseas clinical study results	2	Alcon AcrySof Toric Single Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	An intraocular lens with its posterior face having a cylindrical optical power for correcting corneal astigmatism. Clinical studies were conducted to evaluate the efficacy and safety of this astigmatic (toric) intraocular lens.
1	Aug. 5, 2008 Total review time: 461 days Regulatory review time: 209 days	- Domestic clinical study results	3	Tecnis Multifocal IOL (AMO JAPAN K. K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal intraocular lens with its anterior face having an aspheric mechanism and the posterior face having a diffractive multifocal mechanism. Clinical studies were conducted to evaluate the efficacy and safety of this multifocal intraocular lens.
1	Oct. 31, 2008 Total review time: 283 days Regulatory review time: 251 days	Nov. 22, 2006 Domestic clinical study results	4	Proclear 1 Day (CooperVision Japan, Inc.)	Approval	Instrument & apparatus 72 Single use colored contact lenses for correcting visual acuity	A daily disposable soft contact lens for myopia, hyperopia, astigmatism, or presbyopia. A copolymer of HEMA and MPC is used as lens material. A clinical study was conducted to evaluate the efficacy and safety of this product.
1	Nov. 28, 2008 Total review time: 561 days Regulatory review time: 264 days	Oct. 30, 2007 Overseas clinical study results	5	Tecnis 1-Piece IOL (AMO Japan K. K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	An one-piece intraocular lens utilizes the raw materials of the optical zone of the existing intraocular lens in the haptic zone as well. Clinical studies were conducted to evaluate the efficacy and safety of this product including the performance of the haptic zone.
2	Jan. 29, 2009 Total review time: 427 days Regulatory review time: 331 days	- Domestic clinical study results	6	µ-one HA Implant (Yamahachi Dental MFG, Co.)	Approval	Medical products 4 Intraosseous dental implant	An intraosseous dental implant made of titanium with a hydroxyapatite (HA) coating (1 - 2 µm). Clinical studies were conducted to evaluate the efficacy and safety of this product coated with HA.
3-1	Jul. 4, 2008 Total review time: 463 days Regulatory review time: 334 days	Sep. 10, 2004 Overseas clinical study results	7	MULTI-LINK Mini Vision Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent for reference vessel diameters ranging from 2.25 mm to 2.5 mm.Clinical trials were conducted to evaluate the efficacy and safety of the stent for bailout use in small vessels.
3-1	Mar. 26, 2009 Total review time: 1945 days Regulatory review time: 553 days	- Domestic clinical study results	8	Coroflex (B. Braun Aesculap Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent	A stainless-steel balloon-expandable coronary stent. Clinical studies were conducted to evaluate the clinical performance (e.g. restenosis rate) of the stent.
3-2	Aug. 25, 2008 Total review time: 858 days Regulatory review time: 599 days	Sep. 26, 2006 Overseas clinical study results	9	Arista AH (Senko Medical Trading Co.)	Approval	Medical products 4 Bioresorbable local hemostatic device	An absorbable hemostat consisting of microporous polysaccharide hemospheres (MPHs) to be used for the local management of bleeding wounds. Clinical studies were conducted to evaluate the hematostatic ability and safety of this product compared with a similar product.
4	Jul. 11, 2008 Total review time: 280 days Regulatory review time: 150 days	Nov. 21, 2007 Overseas clinical study results	10	Medtronic Reveal DX (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 ECG monitor	An insertable cardiac monitor to be implanted under the skin in patients for whom the diagnosis was not made from the test(s) the physician considered necessary. The device is intended for use in patients with unexplained syncope for the purpose of recording and storing the ECGs for diagnosis. The documents on clinical evaluation were submitted concerning the efficacy and safety of electrocardiography using this product.
4	Jul. 16, 2008 Total review time: 610 days Regulatory review time: 140 days	Feb. 10, 2000 Domestic clinical study results	11	INOvent (Air Water Inc.)	Approval	Instrument & apparatus 6 Nitric oxide management system	A device to be used for patients with respiratory failure to allow the dilution of nitric oxide inhalant to a certain concentration and its stable supply to the patient. Clinical studies were conducted to compare the predefined concentration of nitric oxide and the concentration of inhaled nitric oxide and to evaluate the concentration of inhaled nitrogen dioxide.

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Jul. 16, 2008 Total review time: 181 days Regulatory review time: 141 days	Apr. 7, 2009 Overseas clinical study results	12	Attain Ability Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	Over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as cardiac resynchronization therapy defibrillator (CRT-D). The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Jul. 16, 2008 Total review time: 166 days Regulatory review time: 121 days	Dec. 7, 2006 Overseas clinical study results	13	Lumax 300 HF-T (BIOTRONIK Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers cardiac resynchronization therapy (CRT), with the function of a defibrillator. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Jul. 16, 2008 Total review time: 166 days Regulatory review time: 121 days	Dec. 7, 2006 Overseas clinical study results	14	Lumax 340 HF-T (BIOTRONIK Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Oct. 14, 2008 Total review time: 459 days Regulatory review time: 316 days	Nov. 17, 2004 (V-343) Jun. 30, 2004 (V-340) Overseas clinical study results	15	Atlas + HF (St. Jude Medical Japan CRMD)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT (treatment method to improve cardiac failure symptoms, which synchronizes ventricular contraction by stimulating cardiac muscles of bilateral ventricles electrically for a long time), with the function of a defibrillator. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Oct. 14, 2008 Total review time: 459 days Regulatory review time: 316 days	Nov. 17, 2004 (V-337) Jun. 30, 2004 (V-338) Overseas clinical study results	16	Epic HF (St. Jude Medical Japan CRMD)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Dec. 15, 2008 Total review time: 410 days Regulatory review time: 227 days	Nov. 5, 2004 Overseas clinical study results	17	Navistar Thermocool (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used in myocardium with radiofrequency current and for the electrophysiological study of the heart to treat type I atrial flutter. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to aviod increasing tip electrode-tissue interface temperature.
4	Jan. 29, 2009 Total review time: 482 days Regulatory review time: 353 days	Jul. 25, 2007 Overseas clinical study results	18	QuickFlex (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as CRT-D for CRT. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Feb. 10, 2009 Total review time: 215 days Regulatory review time: 166 days	Jun. 13, 2008 Overseas clinical study results	19	Attain StarFix Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as CRT-D for CRT. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Mar. 17, 2009 Total review time: 404 days Regulatory review time: 251 days	Zephyr DR: Mar. 29, 2007 Zephyr XL DR: Mar. 29, 2007 Overseas clinical study results	20	Zephyr DR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 17, 2009 Total review time: 404 days Regulatory review time: 251 days	Zephyr SR: Mar. 29, 2007 Zephyr XL SR: May 9, 2007 Overseas clinical study results	21	Zephyr SR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A single-chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 24, 2009 Total review time: 358 days Regulatory review time: 260 days	Apr. 29, 2005 Overseas clinical study results	22	Frontier II (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Mar. 30, 2009 Total review time: 364 days Regulatory review time: 264 days	Apr. 29, 2005 Overseas clinical study results	23	Frontier CRT-P (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Mar. 24, 2009 Total review time: 397 days Regulatory review time: 257 days	- Overseas clinical study results	24	Emprise SR+ (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A single chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 24, 2009 Total review time: 397 days Regulatory review time: 257 days	- Overseas clinical study results	25	Emprise DR+ (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
5	May 7, 2008 Total review time: 894 days Regulatory review time: 489 days	- Domestic clinical study results	26	Asahi Hollow Fiber Hemodiafilter (Asahi Kasei Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hemodialfilter using hollow fibers made of polysulfone resin to remove metabolites in blood during hemodiafiltration for patients with acute and chronic renal failure. Clinical studies were conducted because it was the first time to use polysulfone resin as a raw material of hollow fibers for hemodialfilter, although it had been approved for hemodialyzer.
5	Dec. 18, 2008 Total review time: 875 days Regulatory review time: 519 days	- Domestic clinical study results	27	Flow Star (JMS Co., Ltd.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A hemofilter used for treatment and purification of body fluid in patients with acute renal failure accompanying acute hepatic insufficiency, acute on chronic renal failure, perioperative period, sepsis, multiple organ failure, acute respiratory failure, or acute circulation failure. Clinical studies were conducted because it was the first time to use polyethersulfone (PES) as a raw material of hollow fibers.
6	May 22, 2008 Total review time: 2586 days Regulatory review time: 376 days	Mar. 1, 1996 Overseas clinical study results	28	Integra Dermal Regeneration Template (Century Medical, Inc.)	Approval	Medical products 4 Other surgical or orthopedic materials (dermal regeneration graft)	A two-layered matrix consisting of a cross-linking layer of bovine-derived collagen and shark-derived glycosaminoglycan and a silicone layer. To be indicated for the postexcisional treatment of full-thickness or partial-thickness thermal injuries. The product contains glycosaminoglycan, which is a novel feature unseen in existing products. Clinical studies were conducted to evaluate the efficacy and safety of this product.
6	Sep. 17, 2008 Total review time: 504 days Regulatory review time: 253 days	Mar. 14, 2007 Domestic clinical study results	29	Super Fixsorb MX30 (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation screw	Absorbable screws composed of poly L-lactide and hydroxyapatite. A partial change for the addition of the skull to the target site of Super Fixsorb MX30. Clinical studies were conducted to evaluate the efficacy and safety concerning the added target site.
6	Sep. 17, 2008 Total review time: 37 days Regulatory review time: 28 days	Mar. 14, 2007 No clinical study results	30	Osteotrans Plus 30 Screw (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation screw	A partial change for application of another brand name of Super Fixsorb MX30.
6	Sep. 17, 2008 Total review time: 491 days Regulatory review time: 240 days	Mar. 14, 2007 Domestic clinical study results	31	Super Fixsorb MX40 (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation plate	Absorbable plate composed of poly L-lactide and hydroxyapatite. A partial change for the addition of the skull to the target site of Super Fixsorb MX40. Clinical studies were conducted to evaluate the efficacy and safety concerning the added target site.
6	Sep. 17, 2008 Total review time: 37 days Regulatory review time: 28 days	Mar. 14, 2007 No clinical study results	32	Osteotrans Plus 40 Plate (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation plate	A partial change for application of another brand name of Super Fixsorb MX40.
6	Mar. 23, 2009 Total review time: 682 days Regulatory review time: 509 days	- Domestic clinical study results	33	Neobone X (MMT Co., Ltd.)	Approval	Medical products 4 Artificial bone implant	A composite type of synthetic hydroxyapatite bone substitute made of interconnected porous and solid parts. The product is used with the inner and outer fixation devices at the load bearing site. Clinical studies were conducted to evaluate its efficacy and safety in patients with cortical bone defect.

Table 2. FY2007 List of Approved Products: New Medical Devices

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Oct. 1, 2007 Total review time: 458 days Regulatory review time: 231 days	1	Excimer Laser Corneal Surgery System EC-5000CXIII (Nidek Co., Ltd.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism, remove corneal surface opacities, and smooth corneal irregularities by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Jan. 21, 2008 Total review time: 1060 days Regulatory review time: 717 days	2	O_2OPTIX and 8 other trade names (CIBA Vision K.K.)	Change	Instrument & apparatus 72 Soft contact lenses	Oxygen-permeable soft contact lenses using silicone hydrogel, which are indicated for the correction of visual acuity (myopia and hyperopia). Partial change application to add a new intended use of up to 30-day extended wear, which is the first in Japan, to the approved use of daily wear with a 1 month replacement schedule.
1	Feb. 28, 2008 Total review time: 76 days Regulatory review time: 52 days	3	Menicon Lifely (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Oxygen-permeable hard contact lenses, which are indicated for daily or up to 30-day extended wear (trade name divisional application of Menicon Tinu, the original product). (The original product is in a reexamination period)
1	Mar. 6, 2008 Total review time: 1742 days Regulatory review time: 650 days	4	Technolas Excimer Laser System (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 31 Other laser surgical instrument and laser coagulator (ophthalmic excimer laser surgical instrument)	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Mar. 6, 2008 Total review time: 541 days Regulatory review time: 219 days	5	VISX Excimer Laser System (AMO Manufacturing USA, LLC)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgery instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism and remove corneal opacities by laser ablation of corneal tissue. Laser-assisted in situ keratomileusis (LASIK) indication was added to previously approved indications, photorefractive keratectomy (PRK) and phototherapeutic keratectomy (PTK). (The original product is in a reexamination period)
3-1	Sep. 28, 2007 Total review time: 457 days Regulatory review time: 245 days	6	ANGIOGUARD XP (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	The first device in Japan to prevent distal emboli with a polyurethane filter to capture and remove embolic substances including thrombi released while a stent is placed in the carotid artery. The effect on the prevention of distal embolization with the use of the stent and the operability were evaluated in clinical studies. [Priority review]
3-1	Sep. 28, 2007 Total review time: 457 days Regulatory review time: 268 days	7	PRECISE for the Carotid Artery (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	The first stent for the carotid artery in Japan to dilate carotid stenosis and prevent restenosis.The incidence of complications after treatment was evaluated in a clinical study comparing with surgical therapy. [Priority review]
3-2	Oct. 31, 2007 Total review time: 2638 days Regulatory review time: 1045 days	8	SEAMDURA, NEOSEAM (GUNZE Limited)	Approval	Medical products 4 Bioabsorbable artificial dural substitutes	The first bioabsorbable artificial dural substitutes in Japan to compensate for the dural defect. Their clinical performance as dural substitutes was evaluated in clinical studies.
3-2	Feb. 5, 2008 Total review time: 736 days Regulatory review time: 525 days	9	Powerlink Stent Graft System (Cosmotec Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm to prevent blood flow into the aneurysm and its rupture. The incidence of adverse events after treatment was mainly evaluated in clinical studies. (The original product is in a reexamination period)

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-2	Mar. 12, 2008 Total review time: 492 days Regulatory review time: 248 days	10	GORE TAG Thoracic Endoprosthesis System (Japan Gore-Tex Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	The first stent graft for thoracic aortic aneurysm in Japan to prevent the blood flow into the aneurysm and its rupture. The incidence of adverse events after treatment was evaluated in a clinical study comparing with surgical therapy. [Priority review]
4	Apr. 13, 2007 Total review time: 71 days Regulatory review time: 55 days	11	SynchroMed EL Pump (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 74 Programmable implantable drug infusion pump	Addition of N'Vision as an applicable programmer to the drug infusion pump indicated for intrathecal baclofen therapy. (Partial change during the reexamination period)
4	May 29, 2007 Total review time: 279 days Regulatory review time: 167 days	12	Concerto C154DWK (Medtronic Japan Co., Ltd)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 285 days	13	QuickSite (St. Jude Medical CRMD)	Approval	Instrument & apparatus 7 Implantable pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 290 days	14	Epic HF (St. Jude Medical CRMD)	Approval	Instrument & apparatus 12 Other defibrillator and related devices (implantable biventricular pacing pulse generator with defibrillator function)	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 290 days	15	Atlas + HF (St. Jude Medical CRMD)	Approval	Instrument & apparatus 12 Other defibrillator and related devices (implantable biventricular pacing pulse generator with defibrillator function)	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Sep. 7, 2007 Total review time: 309 days Regulatory review time: 136 days	16	SynchroMed II Pump (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 74 Programmable implantable drug infusion pump	Drug infusion pump indicated for intrathecal baclofen therapy. (The original product is in a reexamination period)
4	Sep. 28, 2007 Total period: 605 days Regulatory review time: 326 days	17	Intravascular OCT ImageWire (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Intravascular optical tomographic catheter	An intravascular optical tomographic catheter that irradiates the vascular wall with near infrared light through internal optical fibers and images for testing the lumens and superficial walls of the coronary arteries by optical coherence tomography (OCT). This is the first medical device in Japan to use OCT for intravascular observation.
4	Sep. 28, 2007 Total review time: 605 days Regulatory review time: 326 days	18	Intravascular OCT Imaging System (Goodman Co., Ltd.)	Approval	Instrument & apparatus 12 OCT diagnostic imaging instrument	A diagnostic imaging system using near infrared light as a light source that images for testing the lumens and superficial walls of the coronary arteries by OCT. This is the first medical device in Japan to use OCT for intravascular observation.

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Dec. 7, 2007 Total review time: 308 days Regulatory review time: 163 days	19	Concerto C174AWK (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Dec. 27, 2007 Total review time: 202 days Regulatory review time: 83 days	20	Novacor Left Ventricular Assist System (Edwards Lifesciences LLC)	Change	Instrument & apparatus 7 Implantable ventricular assist device	Partial change application to add a new battery because of discontinued battery production and change the controller accordingly. (A partial change during a reexamination period)
4	Feb. 26, 2008 Total review time: 333 days Regulatory review time: 173 days	21	ACUITY Steerable (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (The original product is in a reexamination period)
4	Feb. 28, 2008 Total review time: 183 days Regulatory review time: 180 days	22	QuickSite (St. Jude Medical CRMD)	Change	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (Partial change application for extension for shelf life) (The original product is in a reexamination period)
5	Apr. 13, 2007 total review time: 437 days Regulatory review time: 236 days	23	Cool-tip RF System (Tyco Healthcare Japan, Inc.)	Change	Instrument & apparatus 29 Therapeutic electrosurgical unit	A device to coagulate/ablate nonresectable liver tumors using a radiofrequency current (480 kHz). Partial change application mainly to make the generator conform to IEC60601-1-2 (2001). (A partial change during the reexamination period)
5	Apr. 23, 2007 Total review time: 1103 days Regulatory review time: 384 days	24	Given Diagnostic Imaging System (Given Imaging Ltd.)	Approval	Instrument & apparatus 25 Other medical endoscope (capsule electronic endoscope system)	A small intestinal image recording system that consists mainly of a capsule-shaped image transmitter, a sensor array for receiving image data, an image data recorder, and a RAPID workstation for reviewing recorded image data. This is the first medical device in Japan to provide diagnostic images of the small intestinal mucosa through a capsule swallowed by the patient.
6	Mar. 25, 2008 Total review time: 2281 days Regulatory review time: 437 days	25	Dornier Epos Ultra (Dornier MedTech Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Other therapeutic or surgical instruments (electromagnetic induction-type extracorporeal shock wave therapy system)	A low-energy extracorporeal shock wave therapy system for orthopedic use. This is the first device in Japan to relieve the pain of chronic plantar fasciitis with reduced output of the conventional electromagnetic induction-type extracorporeal shock wave lithotripter.
Office of Biologics II	Oct. 29, 2007 Total review time: 1118 days Regulatory review time: 540 days	26	JACE (Japan Tissue Engineering Co., Ltd.)	Approval	Medical products 4 Other surgical/orthopedic materials (autologous cultured epidermis)	Autologous cultured keratinocytes using Green's technique in which keratinocytes derived from the patient's own skin tissue are co-cultured with irradiated 3T3-J2 cells derived from mouse fetuses as a feeder to form a sheet in approximately three to seven layers thick. This is indicated for the treatment of serious large burns that cannot be provided with a sufficient area of donor skin for autologous skin grafting, and of burns in which the total area of deep second-degree (deep dermal) and third-degree (full-thickness) burn is 30% or more of the total body surface area. It is the first medical device of processed human cellullar/tissue product in Japan. [Priority review]

Table 3. FY2007 List of Approved Products: Medical Devices Approved with Clinical Data (Other Than New Medical Devices)

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	May 22, 2007 Total review time: 475 days Regulatory review time: 347 days	1	SEED UV-1 (SEED Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Hard contact lenses that are made mainly of methacrylate monomers and that are indicated for daily or up to 1-week extended wear. These lenses have been specially designed to ensure sufficient oxygen permeability and strength. They use a new raw material constituted of a new combination of four already-approved monomers in a new ratio. Clinical studies were mainly conducted to evaluate the safety of these lenses in the eyes.
1	Jun. 19, 2007 Total review time: 627 days Regulatory review time: 335 days	2	Alcon AcrySof ReSTOR Single-Piece (Alcon Japan Ltd.)	Approval	Instrument and apparatus 72 Multifocal posterior chamber lens	Foldable multifocal posterior chamber lens with 12 toric diffraction regions in the anterior center. A new lens design with a diffraction structure that diffracts the incident light into near and far fields is used, and the lens has two focal points. Clinical studies were conducted to evaluate whether the structure provides the expected performance, efficacy, and safety of this product.
1	Jun. 28, 2007 Total review time: 1651 days Regulatory review time: 711 days	3	Moistear and 5 other trade names (Koken Co., Ltd)	Approval	Medical products 4 Other ophthalmic products and related products (punctal plug)	A punctal plug made of atelocollagen to retain tear volume by lacrimal duct occlusion as a symptomatic treatment for aqueous tear deficiency (dry eye). Unlike the conventional silicone plug, the atelocollagen solution is the first medical device intended to achieve embolization by gelatinizing the solution injected into the lacrimal duct at body temperature. Clinical studies were conducted to evaluate the efficacy of this product and the safety of atelocollagen in the eyes.
1	Feb. 5, 2008 Total review time: 427 days Regulatory review time: 302 days	4	O_2OPTIX 2-Week (CIBA VISION K.K.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Soft contact lenses indicated for daily or up to 2-week extended wear, made of a new raw material, silicone hydrogel, with a new combination of the raw materials used in the approved product O_2OPTIX (approval no., 21600BZY00383000) for higher water content. Both spherical and toric lens designs were used. Because a new raw material is used, comparative clinical studies were conducted to evaluate the safety of this product.
1	Feb. 25, 2008 Total review time: 1083 days Regulatory review time: 503 days	5	HiResolution Bionic Ear System (Nihon Bionics Co., Ltd.)	Approval	Instrument & apparatus 7 Other sensory assisting instrument (cochlear implant system)	A cochlear implant system with a new sound processing strategy (HiRes) with higher stimulation rates. Clinical studies were mainly conducted to evaluate the efficacy of HiRes and the safety of this implant whose material and shape differ from those of the conventional product.
1	Mar. 3, 2008 Total review time: 987 days Regulatory review time: 539 days	6	Cataract Surgery INFINITI Vision System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 12 Cataract and vitreous surgery instrument	A surgical system used for extracapsular cataract extraction and anterior vitrectomy that performs various functions such as irrigation, aspiration, phacoemulsification, vitrectomy, and cauterization or coagulation. This product is a system that adds the AquaLase function which delivers balanced saline solution (BSS) to fragment cataracts with fluidic pulses to the approved Ultrasonic Cataract Surgery INFINITI Vision System (approval No. 21500BZY00342000). Because the AquaLase function was introduced for the first time in Japan, clinical studies were conducted to evaluate its clinical use.
1	Mar. 25, 2008 Total review time: 795 days Regulatory review time: 578 days	7	HOYA Airy One month (HOYA Corporation)	Approval	Instrument & apparatus 72 Reusable colored contact lens for correction of visual acuity	Silicone hydrogel soft contact lenses made of a new silicone-containing monomer that are indicated for daily or up to 30-day extended wear. Lenticular lens designs were used. Clinical studies were mainly conducted to evaluate the safety of the lenses made of a new raw material.
3-1	Jun. 7, 2007 Total review time: 1224 days Regulatory review time: 329 days	8	Angio-Seal STS PLUS (Getz Bros. Co., Ltd. [Japan])	Approval	Medical products 4 Bioresorbable local hemostatic device	A device to achieve hemostasis at the femoral artery puncture site after percutaneous catheterization by sandwiching the vascular wall between the anchor from the inside of the punctured vascular wall and the collagen sponge and bioresorbable suture from the outside. This product improves ease of use and suture knotting than the conventional product. Clinical studies were mainly conducted to evaluate whether the device has a hemostatic effect comparable to that of the conventional product.
3-1	Jul. 11, 2007 Total review time: 378 days Regulatory review time: 228 days	9	Express LD Vascular Stent (Boston Scientific Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac arteries	A balloon-expandable stent for iliac arteries. Delivery of this stent is easier because the delivery catheter of this stent has a smaller diameter than those of the conventional products of other companies. The clinical performance (including restenosis rate) of the stent was evaluated in clinical studies.

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-1	Oct. 23, 2007 Total review time: 337 days Regulatory review time: 256 days	10	NSE PTCA Balloon Catheter (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Balloon-expandable catheter for coronary angioplasty	A device in which slipping on balloon expansion is reduced by placing elements along the balloon of the PTCA balloon catheter. Clinical studies were conducted to evaluate the slipping-reducing effect of this product and the safety of the elements.
3-1	Jan. 18, 2008 Total review time: 505 days Regulatory review time: 336 days	11	AngioSculpt PTCA Balloon Catheter (USCI Japan Ltd.)	Approval	Instrument & apparatus 51 Balloon-expandable catheter for coronary angioplasty	A PTCA balloon catheter with a wire outside the balloon to reduce the slipping on expansion. The slipping-reducing effect and safety of the improved product were evaluated in clinical studies.
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 285 days	12	Aescula (St. Jude Medical CRMD)	Approval	Instrument & apparatus 7 Implantable pacemaker lead	Left ventricular lead with stylet used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy).
4	Jun. 4, 2007 Total review time: 349 days Regulatory review time: 290 days	13	Sleep Recorder SD-101 (Kenzmedico Co., Ltd.)	Approval	Instrument & apparatus 21 Instrument for sleep evaluation	A simple testing instrument for sleep apnea syndrome that records and analyzes respiratory waveforms during sleep. It can be used at home as well as in hospitals. It is placed on a mattress, detects subtle pressure changes in parts of the body surface associated with respiration, and expresses them as waveforms. It can measure pressure changes for up to 10 hours under unrestrained conditions. Because this product uses a novel method of detecting respiratory waveforms, it was compared in clinical studies with polysomnography (PSG), the standard test method for sleep apnea syndrome.
4	Jul. 9, 2007 Total review time: 830 days Regulatory review time: 279 days	14	IBI Cardiac Ablation System II (Getz Bros Co., Ltd.)	Approval	Instrument & apparatus 31 Medical cautery instrument	An instrument that electrophysiologically detects the abnormal conduction pathways in the heart with arrhythmia and that ablates these pathways. Major improvements in this product as compared to the conventional product include two temperature sensors for the ablation site to ensure safety and the ability increase the output up to 100 W. Clinical studies were conducted to evaluate the safety of the increased output.
4	Jul. 26, 2007 Total review time: 437 days Regulatory review time: 122 days	15	Revolution (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Intravascular ultrasonic catheter for the central circulatory system	A catheter for intravascular ultrasonic diagnostic imaging that incorporates an ultrasonic transducer for ultrasound imaging of the vascular lumen and wall. The ultrasonic frequency was improved to 45 MHz. Clinical results were submitted mainly to evaluate the adverse events associated with the use of this system.
4	Jul. 26, 2007 Total review time: 437 days Regulatory review time: 118 days	16	Volcano In-Vision Gold Imaging System (Goodman Co., Ltd.)	Approval	Instrument & apparatus 12 Cardiovascular ultrasonic diagnostic imaging instrument	A diagnostic imaging instrument intended to image and test the vascular lumen and wall using ultrasound. The ultrasonic frequency has been improved to 45 MHz. Clinical studies were mainly conducted to evaluate the adverse events associated with the use of this system.
4	Oct. 1, 2007 Total review time: 579 days Regulatory review time: 247 days	17	Navistar DS (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used in myocardial with radiofrequency current and for the electrophysiological examination of the heart to treat type I atrial flutter. It has one 8-mm tip electrode, two temperature sensors, and a maximum power output of 70 W. Clinical studies were conducted because both the electrode length and output in this product is different from that in the conventional product.
4	Nov. 21, 2007 Total review time: 307 days Regulatory review time: 148 days	18	Medtronic Virtuoso DR (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	Implantable defibrillator used to automatically detect and treat atrial fibrillation/tachycardia and ventricular fibrillation/tachycardia. Clinical study results were submitted to evaluate the MVP function (to give priority to self atrioventricular conduction and inhibit unnecessary ventricular pacing), atrial cardioversion function, and atrial antitachycardia pacing function.

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Nov. 7, 2007 Total review time: 854 days Regulatory review time: 522 days	19	Toraysulfone HDF (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hemodialysis filter	A hemodiafilter using hollow fibers made of polysulfone resin to remove metabolites (including urea, creatinine, water, etc.) in blood during hemodiafiltration for patients with acute and chronic renal failure. Clinical investigation was conducted to evaluate its efficacy and safety because it was the first time that polysulfone resin was used as a raw material of hollow fibers of hemodiafilter.
6	May 8, 2007 Total review time: 768 days Regulatory review time: 253 days	20	CentPillar TMZF Stem (Striker Japan K.K.)	Approval	Medical products 4 Hip prosthesis	A cementless stem made of a titanium alloy for use as a femoral component in hip replacement. The proximal portion of the stem is subjected to surface roughening by plasma spraying of pure titanium followed by plasma coating with hydroxyapatite. Because of the novelty of the raw material and special surface treatment method employed, clinical studies were conducted to evaluate the efficacy and safety of this product in clinical use.
6	Jun. 4, 2007 Total review time: 809 days Regulatory review time: 186 days	21	Trident HA Acetabular Cup System (Striker Japan K.K.)	Approval	Medical products 4 Hip prosthesis	A component system consisting of a shell, dome-hole plug, and ceramic liner used as a acetabular component in hip replacement. Beacuse of the novelty of the ceramic liner into which ceramic and metal layers are integrated and the special shell surface treatment employed, clinical studies were conducted to evaluate the efficacy and safety of this product in clinical use.
6	Jun. 11, 2007 Total review time: 1200 days Regulatory review time: 250 days	22	LactoSorb (Biomet Microfixation, Inc.)	Approval	Medical products 4 Bone setting assembly	An absorbable bone setting assembly made of the copolymer of L-lactate and glycolate. This product was given overseas manufacturing approval as screws, plates, and mesh used for bone setting and reconstruction to treat cranial and facial bone trauma. The improvement in this device is that an absorbable coplymer which has not yet been approved for use as a raw material is used as the raw material. Clinical studies were conducted to evaluate whether the absorption rate of this product is safe for clinical use.
6	Aug. 3, 2007 Total review time: 855 days Regulatory review time: 251 days	23	K-MAX AHT HIP System (Japan Medical Materials Corporation)	Approval	Medical products 4 Hip prosthesis	A system consisting of a titanium alloy stem, an outer cup (both cementless), and screws used for the total hip replacement, partial hip replacement, etc. The proximal portion of the stem and the surface of the outer cup are subjected to surface roughening by spraying pure titanium followed by alkaline heat treatment, and the screw heads are subjected to alkaline heat treatment. Because of the novelty of the surface treatment employed, clinical studies were conducted to evaluate whether this product is effective and safe for clinical use.
6	Oct. 1, 2007 Total review time: 1084 days Regulatory review time: 561 days	24	Aquacel Ag (Bristol-Myers Squibb K.K.)	Approval	Medical products 4 Antimicrobial material	An antimicrobial dressing consisting of 100% fibrous sodium carboxymethylcellulose and silver used to protect wounds deep into the subcutaneous fat tissue, while maintaining a moist environment, promoting healing, and relieving pain. Expected secondary effects include antimicrobial effect of the silver ion on the bacteria existing inside the dressing and at the wound contact area. Clinical studies were conducted to evaluate the antimicrobial activity, wound-healing effect, and safety of this product.
6	Nov. 21, 2007 Total review time: 1274 days Regulatory review time: 299 days	25	Sterile CFRP Cage (Medtronic Sofamor Danek, Co., Ltd.)	Approval	Medical products 4 Bone setting assembly	A spinal cage made of a carbon fiber-reinforced polymer (CFRP). Because the material used in this product is different from that in the approved product, which is made of a titanium alloy, clinical studies were conducted to evaluate whether the product is effective and safe for clinical use.
8	May 30, 2007 Total review time: 1098 days Regulatory review time: 406 days	26	Proton Beam Therapy System PROBEAT (PT-W01) (Hitachi, Ltd.)	Approval	Instrument & apparatus 83 Other medical charged-particle radication therapy system (Proton beam therapy system)	A radiotherapy system using high-energy proton beam. It can shape the dose distribution of proton beam emitted from a synchrotron accelerator (beam energy, 80–200 MeV) to conform three-dimensionally to the size and shape of the affected site, and irradiate the site horizontally and vertically. (On application, the original product is in a reexamination period)
8	Jan. 23, 2008 Total review time: 1784 days Regulatory review time: 944 days	27	Noninvasive Hemoglobin Analyzer R02M (Sysmex Corporation)	Approval	Instrument & apparatus 21 Other single-person bioinformation monitor and related instruments (noninvasive hemoglobin analyzer)	This device irradiates a finger with infrared to near-infrared light and noninvasively measures the amount of light absorption by hemoglobin in the peripheral blood. The pulse oxymeter uses a similar principle to show the oxygen saturation in the arterial blood, whereas the new device is intended for use in screening for severe and moderate anemia and uses a new indicator correlating with blood hemoglobin concentration to show hemoglobin levels in five levels. Clinical studies were conducted to evaluate whether it can be used in screening for anemia as an indicator of hemoglobin levels.

FY2006 List of Approved Products: New Medical Devices

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Note
1	25-Oct-06	1 Excimer Laser Corneal Surgery System EC-5000 (Nidek Co., Ltd.)	Approval	Other laser surgical instrument and laser coagulator (ophthalmic excimer laser surgical instrument)	A excimer laser surgical system used in ophthalmology to correct myopia with and without astigmatism, remove corneal opacity and smooth corneal surface irregularities, by laser ablation. Addition of a new intended use for Laser-assisted in situ Keratomileusis (LASIK) to the already approved uses for photorefrective keratectomy (PRK) and phototherapeutic keratectomy (PTK).
1	25-Oct-06	2 Menicon Tinu, and other 16 trade names (Menicon Co. Ltd.)	Approval	Hard contact lenses	Rigid gas permeable hard contact lenses, which are indicated for daily or up to 30 days extended wear for correction of visual acuity (myopia, hyperopia, and/or aphakia).
2	23-Jan-07	3 Carisolv (D-PAC Co., Ltd.)	Approval	Unclassified dental material (a supplemental solution for hand-held cutting instruments)	A supplemental solution with a main component of sodium hypochlorite that makes removal of caries easy by softening the carious dentin.
3	11-Jul-06	4 Cook Zenith AAA Endovascular Graft (Medico's Hirata Inc.)	Approval	Other artificial blood vessel (endovascular graft)	A synthetic vascular prosthesis with stents intended for use to prevent further growth and rupture of an abdominal aortic aneurysm by blocking the blood flow into the aneurysm.
3	18-Jul-06	5 Micro-Driver Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Coronary stent	A coronary stent, which is made from a new alloy (MP35N), indicated to treat small coronary arteries.
3	22-Jan-07	6 Excluder Bifurcated Stent Graft (Japan Gore-Tex, Inc.)	Approval	Other artificial blood vessel (stent graft)	An artificial blood vessel with stents intended for use to prevent further growth and rupture of an abdominal aortic aneurysm by blocking the blood flow into the aneurysm.
3	23-Jan-07	7 Triplex (Terumo Corporation)	Approval	Artificial blood vessel made from synthetic fibers	The graft is an artificial blood vessel consisting of a triple layer structure containing a non-porous layer held between 2 polyester stockinette layers; together these layers form a tubular body. This does not require sealing with biological materials.
3	15-Mar-07	8 Cypher Stent (Johnson & Johnson K.K.)	Partial	Coronary stent	A drug-eluting stent coated with sirolimus for use to prevent restenosis after percutaneous coronary intervention. （revision made during reexamination period）
3	15-Mar-07	9 ASD Closure Set (Japan Lifeline Co., Ltd.)	Partial	A prosthetic material used as artificial pericardium	A fine wire mesh device indicated for use to percutaneously close the atrial septal defect. （revision made during reexamination period）
3	30-Mar-07	10 TAXUS Express 2 Stent (Boston Scientific Japan K.K.)	Approval	Coronary stent	A coronary stent coated with paclitaxel intended to reduce arterial restenosis.
4	03-Apr-06	11 Attain OTW Lead (Medtronic Japan Co., Ltd.)	Partial	Implantable cardioverter defibrillator/pacemaker lead	OTW (Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy).
4	11-May-06	12 Heart Laser (Imatron Japan Inc.)	Approval	Carbon dioxide laser surgical instrument and laser coagulator	A laser surgical instrument and its accessories intended for use to treat severe ischemic heart diseases; the instrument irradiates carbon dioxide laser from the epicardial side to create a transmural channel through the cardiac muscle that facilitates revascularization of the muscle.

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Note
4	18-May-06	13 Medtronic InSync Ⅲ Marquis (Medtronic Japan Co., Ltd.)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	14 CONTAK RENEWAL 4 HE, and other 1 trade name (Guidant Corporation)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	15 CONTAK RENEWAL 4, other 1 trade name (Guidant Corporation)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.)	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	16 Easytrak 2 CS Lead (Guidant Corporation)	Approval	Other pacemaker (implantable defibrillator/pacemaker lead)	OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
4	31-Aug-06	17 Easytrak 2 Lead (Guidant Corporation)	Approval	Other pacemaker (implantable defibrillator/pacemaker lead)	OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
4	06-Sep-06	18 Medtronic InSync Ⅲ (Medtronic Japan Co., Ltd.)	Approval	Implantable biventricular pacing pulse generator without defibrillator function.	Implantable pulse generator that delivers CRT, without function of defibrillator.
4	26-Jan-07	19 SynchroMed EL Pump (Medtronic Japan Co., Ltd.)	Partial	Programmable drug infusion pump	Drug infusion pump indicated for intrathecal baclofen therapy in patients with severe spasticities resulted from cerebrospinal disorders.
4	09-Feb-07	20 Attain Bipolar OTW Lead (Medtronic Japan Co., Ltd.)	Approval	Implantable defibrillator/pacemaker lead	Bipolar OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
5	19-Oct-06	21 MucoUp (Seikagaku Corporation)	Approval	Other inactive therapeutic component used with endoscopes (sub-mucosal layer injection solution used with endoscopes)	Sub-mucosal layer injection solution used with endoscopes to improve the operativity of endoscopic mucosal resection and separation: by injecting the adequate dose into the sub-mucosal layer at the lesion, viscoelasticity of sodium hyaluronate solution exerts force to separate the sub-mucosal layer and muscle layer.
6	10-May-06	22 Super-Fixsorb MX30 (Takiron Co., Ltd.)	Approval	Osteosynthesis Material	Bioresorbable screws made of a composite of 30wt% hydroxyapatite particles and 70wt% poly-L- lactide.
6	10-May-06	23 Super-Fixsorb MX40 (Takiron Co., Ltd.)	Approval	Osteosynthesis Material	Bioresorbable plates made of a composite of 40wt% hydroxyapatite particles and 60wt% poly-L- lactide.

Table-19. A List of Approved Articles in 2005 (New Medical Devices)

Category	Date of Approval	Trade Name (Name of Company)	Approva /Partial	Classification Japanese Accepted Name	Notes
4	6-Jul-05	1 Contak CD, and another trade name (Guidant Japan KK)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	6-Jul-05	2 Contak CRTD, and another trade name (Guidant Japan KK)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	Same as above
4	6-Jul-05	3 Easytrack Lead, and another trade name (Guidant Japan KK)	Approva	Other heart pacemaker (iImplantable cardioverter defibrillator/pacemaker lead)	The first OTW(Over The Wire) type lead (used with CONTAK CD, etc., a chest implantable pulse generator for CRT)
4	6-Jul-05	4 Easytrack CS, and another trade name (Guidant Japan KK)	Approva	Other heart pacemaker (implantable cardioverter defibrillator/pacemaker lead)	Same as above
4	6-Jul-05	5 Attain OTW Lead (Medtronic Japan Co., Ltd.)	Approva	Lead for an implantable heart pacemaker	The first OTW (over the wire) type lead to be used with an implantable cardiac pacemaker with a port for a left ventricular lead
4	20-Jul-05	6 Medtronic InSync 8040 (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Addition of OTW type lead (Attain OTW lead) to list of leads usable with implantable heart pacemaker for CRT [Partial change during re-examination period]
4	15-Nov-05	7 Medtronic InSync ICD (Medtronic Japan Co., Ltd.)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	15-Nov-05	8 Attain Lead (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Medtronic InSync ICD is added to list of devices usable with this lead [Partial change during the re-examination period]
5	8-Dec-05	9 Cool-tip RF System (Tyco Healthcare)	Approva l	Electric surgical instrument	A device with a new indication for coagulating hepatic tumor by high-frequency current of the radio-frequency waves (480 kHz). Since the attached electrode is of the straight needle type with beveled tip, the intermittent high-frequency electrification as well as the internal electrode cooling mechanism are adopted in order to prevent an increase in temperature at the tip. [Prompt review]
5	9-Dec-05	10 Cool-tip RF System (Valleylab, a division of Tyco Healthcare Group LP)	Partial	Electric surgical instrument for treatment	Electric surgical instrument on high-frequency current of radio-frequency waves (480 kHz), the indication of which was changed to "for coagulating hepatic tumor" [Prompt review]
6	1-Mar-06	11 Super Fixsorb 30, and another trade (TAKIRON Co., LTD.)	Partial	absorbable osteosynthesis device	Addition of shapes (product with medium size, larger core diameter), dye (marker) and packaging materials to absorbable osteosynthesis devices (major ingredients: poly lactic acid, hydroxyapatite) [Partial change in the approved items during the re-examination period]

Table 19 A list of approved items in 2004 (new medical devices)

	Date of approval	Brand name (name of company)	Approval/ supplemental change	Generic name	Note
1	September 22, 2004	Kawasumi Potassium adsorption filter (Kawasumi Laboratories, Inc.)	Supplemental Change	Other blood collecting and transfusion device (Potassium adsorption filter)	Cation exchange column used for preventing hyperkalemia by adsorbing and eliminating excessive potassium ions in concentrated human erythrocyte fluid provided for transfusion. (Extension of validity period during re-assessment period)
2	January 12, 2005	Particle radiotherapy facilities (carbon ions / proton type) (Mitsubishi Electric Co.)	Supplemental Change	Other particle accelerator for radiotherapy (Particle radiotherapy facilities)	Equipment for particle radiotherapy with high-energy proton or carbon-ion beam accelerated for treating solid tumors and/or brain tumors. (First kind of apparatus in which carbon-ion beams are added as a beam type.) <Priority review>
3	January 24, 2005	Gelpart (Yamanouchi Pharmaceutical. Co., Ltd.)	Approval	Other surgical and orthopedics operating supplies (multiporous gelatine particles)	First equipment for arterial embolism used for transcatheter arterial embolization in patients with hepatocellular carcinoma.
4	January 24, 2005	MULTI-LINK PIXEL stent (Guidant Japan K.K.)	Approval	Stent	Stent designed for use in small vessels of less than 2.5mm for which coronary stents were not indicated till now. This stent is limited to the treatment of abrupt or threatened abrupt closure with failed interventional therapy of *de novo* and restenotic native coronary artery lesions with reference vessel diameter from 2.25 to

					2.5mm (lesion length, less than 25mm).
5	March 2, 2005	RFA system (Boston Scientific Japan K.K.)	Approval	Electrosurgical unit	RF ablation device which coagulates malignant hepatic tumors through the application of heat generated by radio frequency wave. Compared with devices already approved, the maximum output has been increased to 200W and an electrode with a larger expansion diameter (4cm) has been added.
6	March 25, 2005	JMS Dialysis console GC-110N (JMS Co., Ltd.)	Approval	Hemodialysis equipment	A hemodialysis equipment developed for the purpose of safer dialysis therapy, with the first system to have automated control functions for some processes such as priming of blood circuit and dialyzer, blood removal at initiation of dialysis, rapid fluid replacement during dialysis, and return of blood at the end of dialysis.
7	March 25, 2005	ASD closure set (Japan Lifeline Co Ltd.)	Approval	Vascular prosthesis (device for percutaneous atrial septal defect closure)	This is the first medical device for the percutaneous closure of secundum atrial septal defect by placing the main body (septal occluder) at the defect using the delivery system.
8	March 25, 2005	SynchroMed EL pump (Medtronic Japan Co., Ltd.)	Approval	Other infusion apparatus (Implantable pump)	This pump is indicated for intrathecal infusion of baclofen for severe spasticity of spinal or cerebral origin (limited to the patient for whom conventional therapy was not effective). <Orphan medical device>