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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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)

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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]
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.

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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 external 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)
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."

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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)
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)

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.

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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.
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.

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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.
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.

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. 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.
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.

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
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.

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 & 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.

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. 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.
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.

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	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.
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.

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	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.
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.

Notes

1.

"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
Robotic, ICT, and other devices (not classified as other categories)	Mainly innovative medical devices utilizing robotics and advanced ICT 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.

2.

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.

3.

"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,

4.

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