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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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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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.

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	Oct. 26, 2016	28	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	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)
	Total review time: 244 days Regulatory review time: 103 days	Foreign clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Dec. 26, 2019	Apr. 23, 2019	29	Lotus Edge Valve System (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 7	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.
	Total review time: 301 days Regulatory review time: 145 days	Foreign and Japanese clinical study results				Transcatheter bovine pericardial valve	
Cardiopulmonary Circulation	Jan. 9, 2020	Jun. , 2017	30	Edwards SAPIEN 3 (Edwards Lifesciences Limited.)	Change	Instrument & apparatus 7	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.
	Total review time: 328 days Regulatory review time: 144 days	Foreign clinical study results				Transcatheter bovine pericardial valve	
Cardiopulmonary Circulation	Mar. 12, 2020	Jul. 8, 2010	31	Impella Controller (Abiomed, Inc.)	Change	Instrument & apparatus 7	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)
	Total review time: 168 days Regulatory review time: 114 days	No clinical study results				Controller of implantable pump catheter for ventricular support	
Cardiopulmonary Circulation	Mar.12,2020	Mar. 22, 2018	32	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51	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)
	Total review time: 168 days Regulatory review time: 72 days	No clinical study results				Implantable Pump Catheter for Ventricular Support	

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	Freestyle Libre (Abbott Japan Co., Ltd.)	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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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.

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.

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	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.

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 circulation 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).

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).

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.

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.

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.

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.)	Approval	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	

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, 2004).

4.

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