Products Approved in FY 2017: New Medical Devices

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

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

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 16, 2018 Total review time: 359 days Regulatory review time: 286 days	Jun. 26, 2017 No clinical study results	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)	Change	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 application was submitted for changes including an addition of an aberration correction method in patients in whom the existing aberration correction method is inadequate, addition of a treatment mode for radiation output control based on cavitation that is detected during therapy. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 31, 2017 Total review time: 154 days Regulatory review time: 102 days	Aug. 5, 2015 Foreign clinical study results	Hot AXIOS System (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Prosthesis for pancreatic fistulation	A system intended to form a fistula in the wall of the gastrointestinal tract and cyst through the gastrointestinal tract with endoscopic ultrasound for treatment of the cyst with accumulation of exudate and necrotic material in a pancreatic pseudocyst or walled-off necrosis associated with acute pancreatitis including acute exacerbation of chronic pancreatitis. The system consists of a prosthesis for pancreatic fistulation and a delivery system. The results of a foreign clinical study for investigation of the efficacy and safety of the device in patients in whom endoscopic drainage is indicated were submitted.
Ophthalmology and Otorhinolaryngology	Dec. 15, 2017 Total review time: 168 days Regulatory review time: 127 days	— Japanese clinical study results	TITANBRIDGE (Nobelpharma Co., Ltd.)	Approval	Medical products 4 Fixture for thyroid cartilage	A hinge-type titanium bridge made of titanium is used to fix the thyroid cartilage with the incision gap made during type II thyroplasty to improve symptoms of adductor spasmodic dysphonia. While there has been no relatively less invasive and permanent treatment for adductor spasmodic dysphonia, the product realized the treatment based on a novel principle and its development for early commercialization was anticipated in Japan ahead of the rest of the world. Therefore, the product has been designated as an item to be reviewed under the sakigake designation fast-track review system. The results of an investigator-initiated clinical study conducted in Japan were submitted to evaluate the safety and clinical efficacy of the product. [SAKIGAKE designation, Orphan device]

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	Jun. 20, 2017 Total review time: 356 days Regulatory review time: 135 days	Aug. 12, 2016 Foreign clinical study results	EDWARDS INTUITY Elite Valve System (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 7 Bovine pericardial valve	This device is a system to surgically deliver a biological valve to the aortic valve position, and has a structure added with cloth-covered frame for fixation to the company's approved product "Carpentier-Edwards Bovine Pericardial Biological Valve Magna EASE ThermaFix Process" (Approval No. 22300BZX00320000) to enable the valve to be transplanted with fewer sutures than existing valves for conventional aortic valve replacement (AVR). The results of a clinical study conducted in the United States were submitted to evaluate the efficacy and safety of the device in patients with aortic stenosis or aortic stenosis with insufficiency, both requiring AVR.
Cardiopulmonary Circulation	Jul. 28, 2017 Total review time: 357 days Regulatory review time: 144 days	Apr. 1, 2016 Foreign clinical study results	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An ablation system utilizing laser for performing percutaneous transluminal myocardial ablation to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The system consists of a balloon catheter, console, endoscope fiber, solution to expand balloon catheter and accessories. The results from a US clinical study conducted to verify the efficacy and safety of this product in patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation and compared with the safety and efficacy of a radiofrequency ablation catheter were submitted.
Cardiopulmonary Circulation	Aug. 22, 2017 Total review time: 116 days Regulatory review time: 93 days	Sep. 28, 2012 No clinical study results	S-ICD Lead (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A subcutaneous implantable cardioverter-defibrillator (S-ICD) lead used in patients at a high risk of sudden cardiac death caused by ventricular tachyarrhythmias. This application was submitted to add in-house model in order to optimize its design and manufactureing. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Aug. 31, 2017 Total review time: 114 days Regulatory review time: 92 days	Jun. 22, 2015 No clinical study results	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets, and who are unable to undergo surgery. The application was submitted to add raw materials for the capsule, shaft and in-line sheath of the delivery catheter system. (A "partial change" application submitted during the post-market performance review period)

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	Sep. 7, 2017 Total review time: 106 days Regulatory review time: 100 days	- No clinical study results	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing a high-frequency current to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to modify the specifications for the performance and safety, in association with the change of the upper limit of the preset temperature for “SATAKE HotBalloon Generator” (Approval No. 22700BZX00356000), add a stirring tube different in length , and confirm the conformance to the latest specifications for leakage current. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Oct. 27, 2017 Total review time: 231 days Regulatory review time: 183 days	— No clinical study results	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted to correct discrepancies in descriptions of the shape, structure, and principles, raw materials, and specifications for performance and safety in the approval document. (A "partial change" application submitted during the reexamination period)
Cardiopulmonary Circulation	Oct. 31, 2017 Total review time: 368 days Regulatory review time: 222 days	May 10, 2016 Foreign and Japanese clinical study results	MitraClip NT System (Abbot Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	The system is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The results of a foreign clinical study comparing the percuntaneous reduction by this system with surgery in operable patients, and Japanese and foreign clinical studies in patients with severe MR who have been determined to be at high risk for mitral valve surgery were submitted.
Cardiopulmonary Circulation	Nov. 8, 2017 Total review time: 167 days Regulatory review time: 104 days	Jul. 8, 2016 No clinical study results	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add activation of the remote monitoring function and adjust the descriptions on details of approved items. (A "partial change" application submitted during the post-market performance review period)

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

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

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

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

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Jun. 27, 2017 Total review time: 256 days Regulatory review time: 176 days	Sep. 17, 2010 Japanese clinical study results	V.A.C. Ulta Wound Therapy System (KCI KK)	Approval	Medical products 4 Negative pressure wound therapy system	V.A.C. Ulta Therapy System is a negative pressure wound therapy (NPWT) system with wound cleaning function to be used for patients with refractory wounds which have not responded to and/or are considered unlikely to respond to the conventional NPWT. This device can also be used for wounds with local infection using its function to instill wound-cleansing solutions automatically and periodically to optimize the wound surface environment and clean wounds. Furthermore, it can also be used as a local NPWT without using the function of periodic and automatic instillation. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety in patients with refractory wounds associated with contamination or local infection.
Orthopedic and Plastic Surgery	Aug. 21, 2017 Total review time: 263 days Regulatory review time: 110 days	Jan. 23, 2009 Japanese clinical study results	BC Corkscrew FT Anchor (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament fixation made of poly-L-lactic acid/β-tricalcium phosphate composite used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. There have been no Japanese approvals of medical devices using the raw material. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using this device and “BC SwiveLock Screw” for which an application was made simultaneously, were submitted as clinical study data.
Orthopedic and Plastic Surgery	Aug. 22, 2017 Total review time: 264 days Regulatory review time: 125 days	Jan. 7, 2011 Japanese clinical study results	BC SwiveLock Screw (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament fixation used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. As a raw material for the absorbable screw, poly-L-lactic acid/β-tricalcium phosphate composite is adopted. Until now, there have been no approvals of products for which β-tricalcium phosphate is added to poly-L-lactic acid. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using this device and “BC Corkscrew FT Anchor” for which an application was made simultaneously, were submitted as clinical study data.
Orthopedic and Plastic Surgery	Aug. 31, 2017 Total review time: 125 days Regulatory review time: 91 days	Sep. 15, 2011 Japanese clinical study results	BC SwiveLock Tenodesis Screw (Arthrex Japan G.K.)	Approval	Medical products 4 Absorbable ligament fixation	An absorbable ligament anchor made of poly-L-lactic acid/β-tricalcium phosphate composite used to attach the stump of soft tissues, such as ligaments and tendons, or artificial ligaments to bones. There have been no Japanese approvals of medical devices using the raw material. Therefore the results from a Japanese open study conducted to evaluate the safety and efficacy for rotator cuff repair using the company’s similar devices “BC SwiveLock Screw” and “BC Corkscrew FT Anchor” which use the raw material, were submitted as clinical study data.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Oct. 16, 2017 Total review time: 108 days Regulatory review time: 79 days	Aug. 5, 2005 Clinical evaluation report	Compress System (Zimmer Biomet G.K.)	Approval	Medical products 4 Artificial material for lower limb reconstruction	An artificial material for lower limb reconstruction intended to reconstruct lower limb function with prosthesis of the defective part of the bone, in patients who had undergone extensive bone resection, due to conditions such as malignant tumor. The structure of the system provides compressive stress on the bone-implant interface, and reduces stress shielding which is caused by the placement of implant. The device does not include a stem, and is therefore available for use in patients where necessary length of the stem for bone implant cannot be ascertained. A clinical assessment report including the results of a clinical study with follow-up in the U.S., and reports from foreign clinical literature, were submitted to demonstrate similar efficacy and safety of the product to existing artificial joints for cancer patients.
Orthopedic and Plastic Surgery	Dec. 7, 2017 Total review time: 90 days Regulatory review time: 55 days	Mar. 2, 2015 Clinical evaluation report	Mpact DM Acetabular Component (Medacta Japan Co., Ltd.)	Approval	Medical products 4 Artificial hip joint, acetabular component	The acetabular component for an artificial hip intended to replace or restore the acetabulum during hip replacement (including reimplantation), consisting of a stainless steel cup and liner made of ultra-high molecular weight polyethylene. The contact surface of the cup and acetabular roof is treated with pure titanium flame spray, and the liner is treated with crosslinking. Since the device is the first double mobility system of this company with sliding surfaces both on the in- and outside of the liner, a clinical assessment report based on a foreign clinical study of the device and foreign clinical literature on the previous generation of the product, demonstrating equivalence to this device, were submitted to confirm that the product has similar efficacy and safety to a conventional artificial hip.
Orthopedic and Plastic Surgery	Dec. 26, 2017 Total review time: 364 days Regulatory review time: 75 days	Nov. 9, 2010 Clinical evaluation report	CO2RE Carbon Dioxide Laser with Fractional Mode (Syneron Candela K.K.)	Approval	Instrument & apparatus 31 Carbon dioxide laser	A carbon dioxide laser intended for ablation of soft tissue for skin resurfacing. The device has a computer-controlled scanner by which uniform ablation is feasible based on the pattern that is selected by the physician in advance. It also has a mode of fine fractional laser irradiation. Improved points include improved safety compared to the conventional laser scalpel by smaller spots ablation instead of larger area ablation on the skin, to expand its applications to various purposes including cosmetic improvement. The product is equipped with a mode that allows its use for other purposes as a laser scalpel, similarly to conventional carbon dioxide lasers. A clinical assessment report, consisting of the results of a foreign clinical study of the device and clinical papers of similar products was submitted to evaluate that the performance of the product on skin resurfacing as well as complications due to the product are acceptable for a medical device for cosmetic use.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Feb. 2, 2018 Total review time: 310 days Regulatory review time: 114 days	May 17, 2009 Foreign clinical study results	Prontosan (B. Braun Medical AG)	Approval	Medical products 4 Antibacterial wound dressing	Antibacterial gel dressing for wounds reaching the subcutaneous adipose tissue (excluding third-degree burns) to "protect wounds," "moisten wound bed," "accelerate healing," and "alleviate pain." Ingredients of the product include polyhexanide, which has been used as a disinfectant in clinical practice, in expectation of the effect of preventing bacterial infection and diffusion in the wounds. The results of a foreign clinical study were submitted to confirm the efficacy and safety of the product as a wound dressing consisting of new raw materials, and the absence of delayed healing due to the polyhexanide content.
Orthopedic and Plastic Surgery	Feb. 28, 2018 Total review time: 258 days Regulatory review time: 178 days	Aug. 24, 2012 Clinical evaluation report	Trabecular Metal Ankle System (Zimmer Biomet G.K.)	Approval	Medical products 4 Total ankle prosthesis	A hinge-type titanium bridge made of titanium is used to fix the thyroid cartilage with the incision gap made during type II thyroplasty to improve symptoms of adductor spasmodic dysphonia. While there has been no relatively less invasive and permanent treatment for adductor spasmodic dysphonia, the product realized the treatment based on a novel principle and its development for early commercialization was anticipated in Japan ahead of the rest of the world. Therefore, the product has been designated as an item to be reviewed under the sakigake designation fast-track review system. The results of an investigator-initiated clinical study conducted in Japan were submitted to evaluate the safety and clinical efficacy of the product. [SAKIGAKE designation, Orphan device]
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 26, 2017 Total review time: 270 days Regulatory review time: 181 days	Jul. 9, 2015 Foreign clinical study results	SCS External Stimulation Device (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Stimulation device for pain relief	A stimulation device used in Spinal Cord Stimulation which allows physicians to locate stimulus and patients to subjectively evaluate the therapeutic effect. The application was submitted to establish a new stimulation mode (A "partial change" application). The results of a foreign clinical study using a similar product, “Prodigy MRI Dual 8 Neurostimulator” designed to demonstrate the non-inferiority to the existing stimulation mode were submitted to evaluate the efficacy and safety of the new stimulation mode which is not included in the existing system.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 30, 2017 Total review time: 209 days Regulatory review time: 108 days	Oct. 18, 2016 Foreign clinical study results	Proclaim Elite MRI Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief used in patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. The patients implanted with the device can conditionally undergo an MRI scan. The application was submitted to add a stimulation mode, namely “Surgical mode,” which is provided as one of safety measures when the patient has to have whole-body MRI with electrosurgical units (A "partial change" application). The results of a foreign clinical study using a similar product, “Prodigy MRI Dual 8 Neurostimulator” designed to demonstrate the non-inferiority to the existing stimulation mode were submitted to evaluate the efficacy and safety of the new stimulation mode which is not included in the existing system.

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

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

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

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Nov. 2, 2017 Total review time: 258 days Regulatory review time: 209 days	Jul. 15, 2016 Foreign clinical study results	Tecnis Symfony Toric (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye with corneal astigmatism. The posterior optical zone has the same diffractive multifocal mechanism as the company's approved product, "Tecnis Symfony" (Approval No. 22900BZX00006000). The anterior optical zone has an aspherical surface similar to the company's approved product, "Tecnis Toric One-piece" (Approval No. 22500BZX00363000). The improved point is that it has combined optical functions of the company's approved products.
Ophthalmology and Otorhinolaryngology	Nov. 24, 2017 Total review time: 269 days Regulatory review time: 107 days	— Japanese clinical study results	Noninvasive Transtympanic Pressure Device EFET01 (Daiichi Medical Co., Ltd.)	Approval	Instrument & apparatus 12 Transtympanic pressure device	A device intended to inhibit vertiginous attacks due to Meniere's disease and delayed endolymphatic hydrops by non-invasively adding pressure to the middle ear cavity through the external auditory canal to facilitate excretion of endolymphatic fluid that has accumulated in the inner ear, consisting of an air pressure generating device, a tube with ear plugs to add pressure and a power supply. The improved point is increased reproducibility of the waveform by detailed specification of the parameters of the air pressure wave to efficiently add pressure to the middle ear space, compared to certified tympanum massagers.
Ophthalmology and Otorhinolaryngology	Nov. 27, 2017 Total review time: 262 days Regulatory review time: 199 days	— Japanese clinical study results	Clareon Aspherical Hydrophobic Acryl Intraocular Lens (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A monofocal posterior chamber lens to be inserted as a substitute for a crystalline lens in the posterior chamber to correct visual acuity of an aphakic eye. The shape of the product is a one-piece type, consisting of the same raw materials in the optic and haptic. The product is a cross-linked acrylic copolymer containing the same ultraviolet and blue light-absorbing agents as the company's approved product, "Alcon AcrySof Natural Single Piece" (21800BZY10066000). The improved point is that flexibility and maneuverability are increased by changing the composition of the major component monomers.
Ophthalmology and Otorhinolaryngology	Dec. 7, 2017 Total review time: 261 days Regulatory review time: 141 days	— Clinical evaluation report	Menicon Rose K-T (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	An oxygen-transmissible daily wear hard contact lens intended to correct visual acuity in patients with keratoconus and associated myopia and hyperopia. The improved points are that the lens blanks of products made of the same raw materials as the company's approved product, "Menicon Tinu," (21800BZZ10125000) are formed to enable patients with keratoconus to wear the lenses, and that indications are made clear in the intended use.
Ophthalmology and Otorhinolaryngology	Feb. 27, 2018 Total review time: 263 days Regulatory review time: 212 days	— Japanese clinical study results	Aktis Toric (Nidek Co., Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The product is a single-piece-type monofocal posterior chamber lens intended to be inserted into the aphakic eye of patients with corneal astigmatism after cataract surgery. The shape other than the optic is similar to the company's approved product, "Nex-Acri AA 1P" (Approval No. 22100BZX00945000). The improved points are the change of raw material compositions and the addition of cylindrical power for the correction of corneal astigmatism. The results of a Japanese clinical study were submitted to evaluate the clinical efficacy, including an astigmatism correction function, and safety of the device.

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	Jun. 9, 2017 Total review time: 221 days Regulatory review time: 107 days	Apr. 28, 2017 Foreign clinical study results	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a zotarolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm and a delivery catheter to place the stent at the site of stenosis. The deliverability was improved by reducing the thickness of the stent strut to lower crossing profile as compared to that of the previous product “Resolute Integrity Coronary Stent System (Approval No. 22400BZX00176000)”. To maintain radiopacity, platinum-iridium alloy was used for inner core of the strut. The results of clinical studies conducted in the United States were submitted to evaluate the efficacy and safety in patients with symptomatic ischemic cardiac disease.
Cardiopulmonary Circulation	Aug. 1, 2017 Total review time: 412 days Regulatory review time: 277 days	- Foreign clinical study results	BioFreedom Drug-Coated Stent (Biosensors Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a biolimus-coated stent and a delivery catheter for the treatment of patients with symptomatic ischemic heart disease, with de novo coronary lesions of a lesion length of 33 mm or less, and with a reference vessel diameter of 2.25-4.0 mm in size. Without the use of polymer, biolimus A9 is directly coated to the stainless steel which has a selectively micro-structured surface. The drug is absorbed in about 1 month, after which becomes a bare metal stent. This stent was developed to allow discontinuation of dual antiplatelet therapy in one month, similarly to bare metal stents. The results from Japanese and foreign clinical studies were submitted to evaluate the efficacy and safety of this device.
Cardiopulmonary Circulation	Aug. 14, 2017 Total review time: 255 days Regulatory review time: 98 days	Jul. 1, 2014 Nov. 12, 2014 Clinical evaluation report	COOK Evolution RL Controlled-Rotation Dilator Sheath Set (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Pacemaker/ defibrillator lead removal kit	A pacemaker/defibrillator lead removal kit used for transvenous lead removal of implantable pacemaker leads, implantable defibrillator leads, etc. It was developed based on the approved product “COOK Lead Extraction System” (Approval No. 22700BZX00054000). Changes were made to unidirectional or bidirectional rotation of the inner sheath by handle operation and to a stainless-steel tip on the end of the inner sheath. A clinical evaluation report summarizing foreign literatures reporting this device or the previous generation device was submitted to evaluate the efficacy and safety of this device.
Cardiopulmonary Circulation	Aug. 31, 2017 Total review time: 262 days Regulatory review time: 72 days	Jul. 31, 2017 Foreign clinical study results	Avalus Bioprosthesis (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve to be used to substitute for the function of a malfunctioning native or prosthetic aortic valve. The biological valve has a frame made of polyetheretherketone and a valve leaflet treated with alpha-amino oleic acid for anticalcification. It was developed aiming at the safety of MRI and reductions of permanent deformations and corrosion risk when assuming future valve in valve procedures are performed, by using non-metallic components. The results of clinical studies conducted in EU, US, and Canada were submitted to evaluate the efficacy and safety of this product in patients with aortic valve stenosis requiring aortic valve replacement.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Nov. 2, 2017 Total review time: 247 days Regulatory review time: 135 days	Oct. 25, 2016 Foreign clinical study results	Claria MRI CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. It is a higher-end model of the company's approved product, "Amplia MRI CRT-D Series" (Approval No. 22800BZX00219000). The major differing point is an additional feature whereby the device evaluates the efficacy of pacing with CRT during atrial fibrillation (AF), and adjusts the pacing rate based on the evaluation results (EffectivCRT during AF feature). The results of a foreign clinical study were submitted to evaluate the efficacy and safety of the EffectivCRT during AF feature.
Cardiopulmonary Circulation	Jan. 19, 2018 Total review time: 374 days Regulatory review time: 157 days	— Global clinical trial	Orsiro Sirolimus Eluting Coronary Stent System (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 26 mm or less) with a reference vessel diameter of 2.25 mm to 4.0 mm and a delivery catheter to place the stent at the site of stenosis. The stent platform made of cobalt chromium is coated with hydrogenated amorphous silicon carbide that inhibits metal ion release. The drug coating layer is composed of sirolimus and bioabsorbable PLLA. The results of Japanese and foreign clinical studies were submitted to evaluate the efficacy and safety of this device.
Cardiopulmonary Circulation	Jan. 24, 2018 Total review time: 239 days Regulatory review time: 140 days	Dec. 21, 2017 Foreign clinical study results	BSC OI Ablation Catheter (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A catheter designed to be inserted percutaneously into the heart through a blood vessel to deliver radiofrequency energy to the electrophysiologically identified target site of arrhythmia to treat drug-refractory recurrent symptomatic paroxysmal atrial fibrillation as well as sustained or recurrent type I atrial flutter. The device is intended for the treatment of arrhythmia by an increase in tissue temperature due to the delivery of radiofrequency energy, leading to ablation in the myocardial tissue. The application was submitted to expand the indication to drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. The results of a foreign clinical study that evaluated the efficacy and safety of the device on drug-refractory recurrent symptomatic paroxysmal atrial fibrillation were submitted.

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.

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.