Products Approved in FY 2018: New Medical Devices

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

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

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

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

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

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

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

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

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

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

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

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

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 20, 2018 Total review time: 266 days Regulatory review time: 130 days	- Clinical evaluation report	24	Okamoto Condoms VG (Okamoto Industries, Inc.)	Approval	Hygiene products 2 Contraceptive condom for males	A contraceptive condom for males intended to help contraception and prevention of sexually transmitted diseases. The product is composed of a condom itself and dressing agent (anti-adhesion agent, lubricant). The lubricant contains 0.5% of SPL7013. Regarding the safety evaluation for SPL7013, a clinical evaluation report that mainly includes the overseas clinical study data of SPL7013 gel for bacterial vaginosis, which has not been approved in Japan, was submitted.
Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 7, 2019 Total review time: 195 days Regulatory review time: 145 days	Mar. 18, 2016 Clinical evaluation report	25	FibroScan 530 Compact (Echosens)	Change	Instrument & apparatus 12 Versatile ultrasound diagnostic imaging device	A Versatile ultrasound diagnostic imaging device that provides qualitative information by measuring liver stiffness non-invasively. The application was submitted to add a measuring function of controlled attenuation parameter (CAP) level that quantitatively measures the liver fat volume. A clinical evaluation report on the evaluation of fatty liver grade using the CAP level in liver biopsy was submitted.
Ophthalmology and Otorhinolaryngology	Jul. 10, 2018 Total review time: 270 days Regulatory review time: 132 days	— Japanese clinical study results	26	Neo Sight One Day Aero (Aire Inc.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Daily wear, single-use, colored contact lenses for correction of visual acuity. The lens is composed of silicone hydrogel with a moisture content of 45% and an oxygen permeability (Dk) of 58.5. Due to the novelty of the raw material, a Japanese clinical study was conducted to confirm the efficacy and safety of the product as a contact lens for visual correction.
Ophthalmology and Otorhinolaryngology	Aug. 17, 2018 Total review time: 268 days Regulatory review time: 224 days	— Japanese clinical study results	27	Lentis Comfort (Santen Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct far and intermediate vision of an aphakic eye. The improved points are that the product has a refractive multifocal mechanism with two regions with different curvature radius of the optic zone, a pair of plate supports, and that it uses new raw materials. A Japanese clinical study was conducted to confirm the clinical efficacy and safety of the product including visual function as a multifocal posterior chamber lens.
Ophthalmology and Otorhinolaryngology	Aug. 21, 2018 Total review time: 266 days Regulatory review time: 212 days	Dec. 16, 2009 Clinical evaluation report	28	da Vinci Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery). A clinical evaluation report, which summarized a Japanese clinical study and a US clinical study in patients with oropharyngeal cancer, hypopharyngeal cancer, laryngeal cancer, etc., and foreign literatures, was submitted to evaluate the efficacy and safety of the product in transoral head and neck surgery.
Ophthalmology and Otorhinolaryngology	Aug. 21, 2018 Total review time: 266 days Regulatory review time: 212 days	Dec. 16, 2009 Clinical evaluation report	29	da Vinci Si Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, and gynecology, to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of head and neck surgery (limited to transoral surgery). A clinical evaluation report, which summarized a Japanese clinical study and a US clinical study in patients with oropharyngeal cancer, hypopharyngeal cancer, laryngeal cancer, etc., and foreign literatures, was submitted to evaluate the efficacy and safety of the product in transoral head and neck surgery.

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

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

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

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

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.