Products Approved in FY 2015: New Medical Devices

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

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

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

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

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 24, 2015 Total review time: 137 days Regulatory review time: 107 days	- No clinical study results	24	LVIS Stent (Terumo Corporation)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system to prevent the protrusion and/or dislodgement of embolic coils into/from the parent artery during coil embolization in patients who have a wide-neck cerebral aneurysm (defined as that with a neck of 4 mm or greater, or dome/neck ratio of less than 2) in the parent artery with a diameter of 2.0 to 4.5 mm, among the patients who have an unruptured aneurysm (with a maximum diameter of 5 mm or greater) which is difficult to treat surgically (including surgical clipping) or by coil embolization using an embolization coil alone. The application was submitted to add a LVIS stent (type 2) in which the stent weave density was changed to realize easier operability at the curvature of the vessels and in which the flare shape was changed for improved manufacturing efficiency. (A "partial change" application) (The original product is in a reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 2, 2015 Total review time: 341 days Regulatory review time: 200 days	Jan. 22, 2014 Foreign clinical study results	25	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft system consisting of a stent graft for treatment of the thoracic aorta and a delivery catheter used to deliver and implant the stent graft in the target site. The application was submitted for an additional indication of acute complicated Stanford type B aortic dissection (A "partial change" application). Results from clinical studies conducted in the United States to verify the efficacy and safety of the product for acute complicated Stanford type B aortic dissection were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 2, 2015 Total review time: 56 days Regulatory review time: 29 days	- No clinical study results	26	DC Bead (Eisai Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of cross-linked polyvinyl alcohol polymer. This product is used for vascular embolization in patients with hypervascular tumors or arteriovenous malformations. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 4, 2015 Total review time: 94 days Regulatory review time: 12 days	- No clinical study results	27	PD Laser BT (Panasonic Healthcare Co., Ltd.)	Change	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device designed for photodynamic therapy. This device is to be used in combination with "Laserphyrin 100 mg for Injection" (Approval No. 21500AMZ00050900) as an oncotropic photo-sensitizer, targeting primary malignant brain tumor as an additional treatment to surgical resection. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the reexamination period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2015 Total review time: 266 days Regulatory review time: 138 days	- No clinical study results	28	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Change	Instrument & apparatus 7 Aortic stent graft	A device consisting of a stent graft for treatment of thoracic aortic aneurysm and a delivery system used to deliver and implant the stent graft in the target site. The application was submitted for an additional type of delivery catheter with an effective sheath length of 950 mm and a compatible guidewire diameter of 0.035 inch. (A "partial change" application submitted during the reexamination period)

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

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

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

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

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

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

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

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

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

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

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

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
Cardiopulmonary Circulation	Jan. 12, 2016 Total review time: 817 days Regulatory review time: 179 days	Jun. 10, 2010 Foreign clinical study results	26	AtriCure Left Atrial Appendage Clip (Century Medical, Inc.)	Approval	Instrument & apparatus 30 Clip for cardiac tissue	A device used to occlude the left atrial appendage in patients with a risk of thromboembolism including atrial fibrillation and other conditions during an open-heart cardiovascular surgery. Results from foreign clinical studies conducted to evaluate the efficacy and safety of the device were submitted.
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	27	Durata ICD Screw-in Lead (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device consists of an implantable defibrillator/pacemaker lead and accessories that are connected to a pulse generator for use in the treatment of tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	28	Durata ICD Lead Single Coil (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device consists of an implantable defibrillator/pacemaker lead and accessories that are connected to a pulse generator for use in the treatment of tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	29	Ellipse ICD (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device consists of an implantable defibrillator and accessories. It is intended to be used for patients at high risk of sudden death due to ventricular tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
Cardiopulmonary Circulation	Feb. 2, 2016 Total review time: 347 days Regulatory review time: 276 days	- Clinical evaluation report	30	Ellipse Limited ICD (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device consists of an implantable defibrillator and accessories. It is intended to be used for patients at high risk of sudden death due to ventricular tachyarrhythmia. A clinical evaluation report was submitted to evaluate the safety of the device under MRI scans. The application was submitted to allow patients with a certain model of the device to undergo an MRI scan under predefined conditions. (A "partial change" application)
4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 108 days	- Clinical evaluation report	31	Assurity MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by delivering the electrical stimulus to myocardium for a long period. The patients implanted with the device can have an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies related to the device was submitted to evaluate the safety of the device on MRI scan.
4	Jun. 22, 2015 Total review time: 214 days Regulatory review time: 118 days	- Clinical evaluation report	32	Endurity MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	The device is an implantable cardiac pacemaker to regulate the heart rhythm by delivering the electrical stimulus to myocardium for a long period. The patients implanted with the device can have an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies related to the device was submitted to evaluate the safety of the device on MRI scan.

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

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

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

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

Review Categories of Medical Devices from October 1, 2015

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.

Review Categories of New/Improved Medical Devices until September 30, 2015

Review Category	Products
1	Mainly for Ophthalmology and otorhinolaryngology
2	Mainly for dentistry
3-1	Intervention devices mainly in cerebral, cardiovascular, respiratory, psychiatric, and neurological field (materials)
3-2	Non-intervention devices mainly in cerebral, cardiovascular, respiratory, psychiatric, and neurological field (materials)
4	Mainly for cerebral, cardiovascular, respiratory, psychiatric, and neurological field (appliances/machines)
5	Mainly for gastrointestinal and urinary systems, obstetrics and gynecology
6	Mainly for orthopedic/plastic surgery and dermatology
7	Mainly for laboratory tests (*in vitro* diagnostics)
8	Mainly for multicategory medical devices, advanced electronic medical devices, and other uncategorized medical devices
Bio-derived device (quality)	A "partial change" application related to the Standards for Biological Ingredients, viral safety, etc.