Products Approved in FY 2013: 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
1	May 21, 2013 Total review time: 193 days Regulatory review time: 77 days	- (About these changes) No clinical study results	1	Baerveldt Glaucoma Implant (AMO Japan K.K.)	Change	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the anterior or posterior chamber to the episclera to decrease intraocular pressure. Application for a partial change to add raw material to be used in the elbow of pars plana insertion type. (A partial change during the reexamination period)
1	Sep. 20, 2013 Total review time: 245 days Regulatory review time: 161 days	- Foreign clinical study results	2	MED-EL EAS Hearing Implant System (MED-EL Elektro-Medizinische Ger äte GmbH)	Approval	Medical products 4 Cochlear implant system	A cochlear implant system for perceiving information such as supporting hearing by acoustic stimulation to the low-frequencies and electric stimulation to the high-frequencies in patients with ski-slope hearing loss, in which there is good hearing for lower frequencies who have not responded sufficiently to wearing hearing aids. This product consists of an audio processor (an audio signal processing device) and an implant (an electrode and a stimulator). Of the sound signals picked up by the microphone embedded the audio processor, the high-frequency sounds are perceived by electric stimulation generated from the electrode in the same way as an existing cochlear implant, while the low-frequency sounds are amplified to be perceived by acoustic stimulation through the ear canal. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with ski-slope hearing loss. [Priority review]
1	Nov. 5, 2013 Total review time: 228 days Regulatory review time: 74 days	- (About these changes) No clinical study results	3	Alcon Ex-PRESS Glaucoma Filtration Device (Alcon Japan Ltd.)	Change	Medical products 4 Intraocular drain	A stainless-steel glaucoma filtration device intended to create an aqueous humor outflow tract between the anterior chamber and extraocular segment and to lower the intraocular pressure by puncture and placement from the limbus into the anterior chamber under the scleral flap with this device. An application for a partial change to change the Ex-PRESS delivery system (EDS) to the improved ESD in which an Ex-PRESS body hardly fall off from the EDS wire during transport. (A partial change during the reexamination period)
1	Dec. 20, 2013 Total review time: 255 days Regulatory review time: 81 days	- Clinical evaluation report	4	HOYA CTR (HOYA Corporation)	Approval	Medical products 4 Ophthalmic intracapsular ring	A blue C-shaped polymethyl methacrylate open ring used for patients whose cataract surgery is expected to carry risks associated with its completion and to be difficult to perform due to a brittleness or rupture of Zinn's Zonule. The ring, inserted into a capsule of crystalline lens, holds the capsule during surgery by making the subluxated capsule produce an extension from the inside. Shape of the ring is a single or a multiple circle. The multiple-circle ring has one or two sewing hooks which is used for anchoring to the sclera by suture thread. The hook is designed to come out from the anterior capsule and a suture thread which passes through the hook is anchored to the sclera. A clinical evaluation report was submitted to confirm that efficacy and safety of this device are equivalent to foreign similar devices, based on domestic and overseas long-term usage histories of the foreign similar devices of which indication and operative procedure had already been established. [Priority review]

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1	Mar. 28, 2014 Total review time: 583 days Regulatory review time: 237 days	Nov. 12, 1993 Clinical evaluation report	5	Ahmed Glaucoma Valve (Japan Focus Company, Ltd.)	Approval	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the inside of the eye to decrease intraocular pressure. It consists of a silicone plate and tube, and a polypropylene valve system with silicone membrane sheet. The components include only an anterior chamber insertion type. A major differences from the original product “Baerveldt Glaucoma Implant (Approval No. 22300BZX00370000)” are that this product is smaller and has a valve system. A clinical evaluation report summarizing the results of literature search on overseas clinical studies and experience of this product was submitted to evaluate its safety and efficacy in decreasing intraocular pressure.
3-1	May 1, 2013 Total review time: 418 days Regulatory review time: 116 days	Nov. 7, 2012 Domestic and foreign clinical study results	6	SMART CONTROL Stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A device that is identical to the approved product Smart Stent for Iliac Artery (Approval No.21700BZY00247000). A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in intervention therapy) and a delivery system to deliver the stent to the site of the lesion, for the treatment of stenosis or occlusion of the vessels in the superficial femoral artery region in addition to the treatment of iliac artery which is the applicable scope of the approved product. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out treatment. (The original product is in a reexamination period)
3-1	May 1, 2013 Total review time: 418 days Regulatory review time: 116 days	Nov. 7, 2012 Domestic and foreign clinical study results	7	SMART stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in intervention therapy) and a delivery system to deliver the stent to the site of the lesion, for the treatment of stenosis or occlusion of the vessels in the superficial femoral artery region. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out treatment. (The original product is in a reexamination period)
'3-1	Jun. 26, 2013 Total review time: 425 days Regulatory review time: 329 days	Feb. 17, 2012 Domestic and foreign clinical study results	8	Resolute Integrity SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a 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 stent is coated with zotarolimus with a cytostatic effect to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. A clinical study was conducted to evaluate the efficacy and safety of this product. (The original product is in a reexamination period)
3-1	Jun. 19, 2013 Total review time: 182 days Regulatory review time: 156 days	- (About these changes) No clinical study results	9	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a 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 stent is coated with everolimus with an immunosuppression to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. Application for a partial change to alter the product specification of the kinetic drug release of everolimus. (A partial change during the reexamination period)
3-1	Jul. 23, 2013 Total review time: 400 days Regulatory review time: 250 days	- Domestic clinical study results	10	SeQuent Please Drug Eluting Balloon Catheter (Nipro Corporation)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for coronary angioplasty	The first balloon-dilating catheter for coronary angioplasty with a paclitaxel-coated balloon in Japan to inhibit restenosis during revascularization for restenotic lesion in coronary artery stent. A clinical study was conducted to evaluate the efficacy and safety of this product for coronary in-stent restenosis.

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3-1	Dec. 25, 2013 Total review time: 187 days Regulatory review time: 144 days	- Domestic clinical study results	11	Misago (Terumo Corporation)	Change	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent used for bail-out treatment (for acute or impending occlusion caused by failure in percutaneous angioplasty) and a delivery system to deliver the stent to the site of the lesion, for the treatment of symptomatic arterial diseases in the superficial femoral artery region. An application for a partial change to add longer stents (120 mm and 150 mm) than the approved ones. A domestic clinical study was conducted to evaluate the efficacy and safety of additional lengths of stents. (A partial change during the reexamination period)
3-2	Apr. 12, 2013 Total review time: 848 days Regulatory review time: 356 days	Dec. 16, 2002 Foreign clinical study results	12	DC Bead (Eisai Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A hydrophilic microsphere (spherical particulate) composed of polyvinyl alcohol polymer with a bridged structure. This product is used in transcatheter arterial embolization for patients with hepatocellular carcinoma. A clinical study was conducted to evaluate the efficacy and safety of the transcatheter arterial chemoembolization using this product for patients with unresectable hepatocellular carcinoma.
3-2	May 1, 2013 Total review time: 254 days Regulatory review time: 203 days	・ Reperfusion catheter Type 2b, type 3b: Nov. 23, 2011 ・ Separator Flex (Nitinol) type 1-4: May 21, 2010 Type 2b: Nov. 23, 2011 No clinical study results	13	Penumbra System (Medico's Hirata Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system is used to suck and remove a thrombus in patients with acute-phase cerebral infarction in combination with Penumbra Aspiration Pump (Approval No. 22300BZX00268000). Application for a partial change to add a separator of Nitinol type, a type of reperfusion catheter and a size of aspiration tube. (A partial change during the reexamination period)
3-2	Jun. 21, 2013 Total review time: 478 days Regulatory review time: 287 days	・ Hypervascular tumor and arteriovenous malformation: Apr. 26, 2000 ・ Uterine myoma: Nov. 22, 2002 Domestic and foreign clinical study results	14	Embosphere (Nippon Kayaku Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	Embosphere is a microbead for arterial embolization. It is hydrophilic, non-absorbable, and biocompatible spherical particles, which are impregnated and coated with porcine-derived gelatin to acrylic copolymers. A clinical study was conducted to evaluate the efficacy and safety of this product for patients with hypervascular tumor and arteriovenous malformation.
'3-2	Jun. 21, 2013 Total review time: 357 days Regulatory review time: 189 days	Nov. 7, 2006 Domestic clinical study results	15	Hepasphere (Nippon Kayaku Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	Hepasphere is a microbead for arterial embolization. It is biocompatible, hydrophilic, non-bioabsorbable, swellable, compressible, and deformable spherical particles composed of vinyl alcohol/sodium acrylate copolymers. A clinical study was conducted to evaluate the efficacy and safety of this product for patients with hypervascular tumor and arteriovenous malformation.
'3-2	Jun. 21, 2013 Total review time: 455 days Regulatory review time: 264 days	— Domestic and foreign clinical study results	16	Sapien XT (Edwards Lifescience Corporation)	Approval	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic heart valve (balloon expandable bovine pericardial valve) system is used for transcatheter valve implantation for patients with severe symptomatic aortic stenosis attributed to sclerosis and degeneration of the cusp of native aortic valve, for whom surgery cannot be performed and receiving the treatment with this product is considered the best treatment. A clinical study was conducted to evaluate the efficacy and safety of this product and to ensure the feasibility of the procedure.
3-2	Jul. 2, 2013 Total review time: 48 days Regulatory review time: 27 days	- No clinical study results	17	Neuroform Stent (Stryker Japan K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	An intracranial artery stent (for treatment of cerebral aneurysm) used to prevent coil migration in coil embolization for wide-necked cerebral aneurysm. An application for partial changes for addition of a manufacturing site. (A partial change during the reexamination period)

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3-2	Jul. 5, 2013 Total review time: 371 days Regulatory review time: 259 days	- Clinical evaluation report	18	Codman Enterprise VRD (Johnson & Johnson K.K.)	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 embolic coils from protrude and/or dropout into the parent artery during coil embolization. An application for partial changes to add the jailing technique that is widely used in clinical practice and to add a no-tip type without a distal marker located at the tip of delivery wire. A clinical evaluation report was submitted to evaluate the efficacy and safety of the jailing technique using this device. (A partial change during the reexamination period)
3-2	Jul. 5, 2013 Total review time: 72 days Regulatory review time: 51 days	- No clinical study results	19	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 polyvinyl alcohol polymer with a bridged structure. This product is used in transcatheter arterial embolization for patients with hepatocellular carcinoma. An application for partial changes for addition of a manufacturing site. (A partial change during the reexamination period)
3-2	Nov. 22, 2013 Total review time: 434 days Regulatory review time: 145 days	Aug. 3, 2005 Domestic clinical study results	20	Wingspan stent (Stryker Japan K.K.)	Approval	Instrument & apparatus 7 Cerebral artery stent	A self-expanding cerebral artery stent used in patients who have a dissection of the vessel or acute or impending occlusion caused by failure in percutaneous angioplasty for intracranial arterial stenosis with balloon angioplasty catheter or who require the re-treatment with no other effective treatment option. A domestic clinical study was conducted in patients with drug-resistant transient ischemic attack or cerebral apoplexy caused by intracranial artery stenosis to evaluate the safety and performance under domestic medical environments. [Priority review]
3-2	Dec. 20, 2013 Total review time: 424 days Regulatory review time: 294 days	Mar. 2, 2012 Foreign clinical study results	21	Solitaire FR Revascularization Device (Covidien Japan, Inc.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A multi-cell retriever intended to restore blood flow by removing thrombus for patients in acute phase of ischemic cerebral infarction who are ineligible for intravenous t-PA or who failed to restore blood flow with intravenous t-PA therapy. A clinical study was conducted to evaluate that safety and efficacy of this device substantially equal to the existing approved devices.
3-2	Mar. 28, 2014 Total review time: 456 days Regulatory review time: 175 days	Type I: Aug. 3, 2012, Type II: Oct. 31, 2012 Foreign clinical study results	22	Trevo Pro Clot Retriever (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	An emboli-removal catheter in the central circulatory system 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. A clinical study was conducted to evaluate that safety and efficacy of this device substantially equal the existing approved device, “Merci retriever” (Approval No. 22200BZX00596000).
4	Apr. 12, 2013 Total review time: 308 days Regulatory review time: 212 days	Mar. 27, 2009 Clinical evaluation report	23	Activa RC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Electrical brain stimulation device for tremor	Activa RC is an implantable electrical stimulation device used to reduce tremor associated with Parkinson's disease, essential tremor, etc. that are adequately controlled with medication. The device stimulates the deep brain (thalamus, subthalamic nucleus or internal globus pallidus), unilaterally or bilaterally. A partial change was applied for additional indications to treat for movement disorder caused by Parkinson's disease and dystonia that are not adequately controlled with medication. A clinical evaluation report summarizing results of foreign clinical studies and literatures, etc. was submitted for evaluating the efficacy and safety of this product for Parkinson's disease and dystonia.

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4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	24	Tendril MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	An implantable defibrillator/pacemaker lead used for long-term the heart rhythm regulation by cardiac stimulation in combination with an implantable cardiac pacemaker, etc. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	25	Accent MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 557 days Regulatory review time: 161 days	− Clinical evaluation report	26	Accent MRI RF (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. The patients implanted with the device can undergo an MRI scan under specific conditions. A clinical evaluation report summarizing the results of the foreign clinical studies of this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	27	Nuance MRI (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Application for addition of brand name to "Accent MRI" (Approval No. 22500BZX00241000). (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	28	Nuance MRI RF (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Application for addition of brand name to "Accent MRI RF" (Approval No. 22500BZX00242000). (The original product is in a reexamination period)
4	Jun. 7, 2013 Total review time: 74 days Regulatory review time: 73 days	− No clinical study results	29	Tendril MRI J (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	Application for addition of brand name to "Tendril MRI" (Approval No. 22500BZX00240000). (The original product is in a reexamination period)
4	Jun. 24, 2013 Total review time: 222 days Regulatory review time: 211 days	− Clinical evaluation report	30	Solia JT (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker lead	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. This device was newly applied as a pacemaker lead which is compatible with MRI. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)

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4	Jun. 28, 2013 Total review time: 59 days Regulatory review time: 47 days	– No clinical study results	31	DuralHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which cardiac transplantation is indicated, show 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 heart transplant. It was revealed after the approval that the electrostatic discharge resistance is not sufficient when using a protect cover (supportive tool that ensures the connection of the power supply to the controller and prevents unintended disconnection); it may cause the occurrence of anomalies. Application for a partial change that the diameter of the speaker hole of the protect cover is expanded and non-conductive coating is included on the surface of the protect cover in order to improve resistance to electrostatic discharge and secure electromagnetic compatibility of the system. (A partial change during the reexamination period) [Orphan device]
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	32	Lumax 740 ICD Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	33	Linox Smart Pro S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	34	Linox Smart Pro SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 449 days Regulatory review time: 276 days	- Clinical evaluation report	35	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 364 days Regulatory review time: 239 days	- Clinical evaluation report	36	Lumax 740 CRT-D Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with a defibrillator function intended for the treatment of ventricular tachycardia. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 364 days Regulatory review time: 239 days	- Clinical evaluation report	37	Corox Pro OTW BP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)

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4	Jul. 2, 2013 Total review time: 197 days Regulatory review time: 177 days	- Clinical evaluation report	38	Ilest 7 ICD Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. This product was developed based on the approved product “Lumax 740 ICD” (Approval No.22400BZX00162000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, and MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	39	Ilesto 7 CRT-D Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An Implantable biventricular pacing pulse generator with a defibrillator function intended for the treatment of ventricular tachycardia. This product was developed based on the approved product “Lumax 740 CRT-D” (Approval No.22400BZX00161000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, and MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	40	Ilest 7 ICD DF4 Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator intended for the treatment of ventricular tachycardia or ventricular fibrillation. This product was developed based on the approved product “Lumax 740 ICD” (Approval No.22400BZX00162000). The major improvements from the approved product include downsizing of the product, a newly added automatic threshold monitoring function in the right atrium, MRI compatibility under specific conditions, and an equipped DF4 connector port. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 189 days Regulatory review time: 171 days	- Clinical evaluation report	41	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. This product was developed based on the company's approved product “Linox Smart SD” (Approval No.22200BZX00751000). The major modifications from the approved product include a change to the DF4 connector port and the MRI compatibility under specific conditions. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Jul. 2, 2013 Total review time: 81 days Regulatory review time: 79 days	- No clinical study results	42	Protego Pro SD (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for additional brand name for “Linox Smart Pro DF4 SD”. (The original product is in a reexamination period)
4	Jul. 18, 2013 Total review time: 211 days Regulatory review time: 137 days	- No clinical study results	43	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which cardiac transplantation is indicated, show 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 heart transplant. After the approval, multiple events due to failure to maintain normal rotation mode of the pump (magnetic suspension) were reported in Japan and overseas. A detailed investigation confirmed that some wires in the percutaneous cable were disconnected, which occurred in the connector area close to a pump. This application for partial change to extend a strain relief of the cable as a measure against the failure due to the fracture of the percutaneous cable. (A partial change during the reexamination period) [Orphan device]

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4	Jul. 23, 2013 Total review time: 287 days Regulatory review time: 177 days	Aug. 17, 2009 Foreign clinical study results	44	LifeVest Wearable Defibrillator (ZOLL Lifecor Corporation)	Approval	Instrument & apparatus 12 Wearable defibrillator	The first wearable defibrillator in Japan to monitor and analyze electrocardiograms of the patients wearing this device continuously, and to deliver electric shock for defibrillation automatically if ventricular tachycardia or ventricular fibrillation requiring defibrillation is detected. A clinical study was conducted to evaluate the success rate of defibrillation for arrhythmia which requires defibrillation and the risk of inappropriate electric shock delivery due to false detection of arrhythmia. [Priority review]
4	Aug. 7, 2013 Total review time: 156 days Regulatory review time: 147 days	- No clinical study results	45	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for partial changes to alter the cannula (alterations in its surface processing and shape) in hope of inhibition of wedge thrombus formation to reduce the risk of cerebral infarction, which has been frequently reported in ongoing cases in the clinical trials and post-marketing surveillance. (A partial change during the reexamination period) [Orphan device]
4	Aug. 7, 2013 Total review time: 131 days Regulatory review time: 113 days	Jan. 26, 2011 Clinical evaluation report	46	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 electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). This device has already been approved for use in reduction of tremors associated with Parkinson's disease, essential tremor, etc. that are not controlled with medication. A partial change has been approved for additional indications to treat movement disorder caused by Parkinson's disease and dystonia that are not adequately controlled with medication. A clinical evaluation report summarizing results of foreign clinical studies and published literatures, etc. was submitted for evaluating the efficacy and safety of this product for Parkinson's disease and dystonia. (The original product is in a reexamination period)
4	Aug. 27, 2013 Total review time: 419 days Regulatory review time: 192 days	- Clinical evaluation report	47	Evia HF-T Pro (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable biventricular pacing pulse generator without a defibrillator function intended for the treatment of bradycardia. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Sep. 6, 2013 Total review time: 205 days Regulatory review time: 51 days	Oct. 12, 2010 No clinical study results	48	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. An application for partial change to change raw materials of a coating agent for a central venous catheter having a perfusion balloon. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	49	Evia T Series Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)

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
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	50	Evia Series Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	51	Solia T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 6, 2013 Total review time: 162 days Regulatory review time: 151 days	- No clinical study results	52	Solia S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 17, 2013 Total review time: 116 days Regulatory review time: 59 days	Aug. 24, 2012 No clinical study results	53	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 electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). A partial change has been approved for addition of type of a stimulator with no coating applied on its shield case. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	54	Corox Pro OTW BP (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	55	Linox Smart Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	56	Linox Smart Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)

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
4	Sep. 18, 2013 Total review time: 71 days Regulatory review time: 61 days	- No clinical study results	57	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	58	Ilest 7 CRT-D Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with a defibrillator function (CRT-D) intended for the treatment of ventricular tachycardia. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 60 days	- No clinical study results	59	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 60 days	- No clinical study results	60	Protego Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable defibrillator/pacemaker lead. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	61	Ilest 7 ICD DF4 Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator (ICD) intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 70 days Regulatory review time: 66 days	- No clinical study results	62	Ilest 7 ICD Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	An automatic implantable defibrillator (ICD) intended for the treatment of ventricular tachycardia or ventricular fibrillation. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Sep. 18, 2013 Total review time: 20 days Regulatory review time: 20 days	Aug. 24, 2012 No clinical study results	63	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 electrical stimulus to the deep brain (thalamus, subthalamic nucleus, or internal globus pallidus). A partial change has been approved for addition of type of a stimulator with no coating applied on its shield case. (A partial change during the reexamination period)
4	Sep. 20, 2013 Total review time: 266 days Regulatory review time: 95 days	- Domestic clinical study results	64	PD Laser BT (Panasonic Healthcare Co., Ltd.)	Approval	Instrument & apparatus 31 PDT semiconductor laser	A laser irradiation device designed for photodynamic therapy. This device is to be used in combination with “Laserphyrin 100mg for Injection” (Approval No. 21500AMZ00509000) as an oncotropic photo-sensitizer, targeting primary malignant brain tumor as an additional treatment to the surgical resection. A clinical trial was conducted to confirm the efficacy and safety of photodynamic therapy for primary malignant brain tumor using this device and the concomitant drug. [Orphan medical 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
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 389 days	- Foreign clinical study results	65	Libra Single 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	A deep brain stimulation device is indicated for patients with essential tremor, various symptoms of Parkinson's disease or dystonia that have not responded sufficiently to drug therapy. This product is used for alleviation of essential tremor, movement disorders associated with Parkinson’s disease, and dystonia symptoms. A clinical study was conducted to evaluate the efficacy and safety of this product for Parkinson’s disease and dystonia. (The original product is in a reexamination period)
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 385 days	- Foreign clinical study results	66	Brio Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	A deep brain stimulation device is indicated for patients with essential tremor, various symptoms of Parkinson's disease or dystonia that have not responded sufficiently to drug therapy. This product is used for alleviation of essential tremor, movement disorders associated with Parkinson’s disease, and dystonia symptoms. A main body of implantable stimulator is rechargeable. A clinical study was conducted to evaluate the efficacy and safety of this product for Parkinson’s disease and dystonia. (The original product is in a reexamination period)
4	Oct. 30, 2013 Total review time: 48 days Regulatory review time: 42 days	- No clinical study results	67	Evia HF-T Pro (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable biventricular pacing pulse generator without a defibrillator function used to improve symptoms of cardiac failure. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Oct. 30, 2013 Total review time: 124 days Regulatory review time: 112 days	- No clinical study results	68	Solia JT (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead connected with an implantable cardiac pacemaker. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change conditions for MRI compatibility. (A partial change during the reexamination period)
4	Nov. 22, 2013 Total review time: 1390 days Regulatory review time: 301 days	- Domestic and foreign clinical study results	69	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	An axial-flow implantable ventricular assist device system to be used to improve the blood circulation until heart transplant is performed in patients who have severe cardiac failure for which heart transplant is indicated, show 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 heart transplant. A clinical study was conducted in the U.S. to evaluate the efficacy and safety of this product, and a domestic clinical study was conducted to evaluate the efficacy and safety in Japan where healthcare environments are different from those in the U.S. [Orphan device]
4	Nov. 29, 2013 Total review time: 410 days Regulatory review time: 74 days	- Clinical evaluation report	70	Ingenio MRI (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	71	Fineline Ⅱ PU (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)

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
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	72	Fineline Ⅱ EZ PU (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	73	Fineline Ⅱ Sterox (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 29, 2013 Total review time: 99 days Regulatory review time: 60 days	- (About these changes) Clinical evaluation report	74	Fineline Ⅱ Sterox EZ (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead to regulate the heart rhythm by long-term cardiac stimulation, which is used in conjunction with an implantable cardiac pacemaker. An application for a partial change to enable patients with the device to conditionally undergo MRI scans. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 185 days	Dec. 17, 2010 Foreign clinical study results	75	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A long, flexible, steerable catheter is used as an adjunctive device in the endocardial treatment of paroxysmal atrial fibrillation. This product is to be used in conjunction with “Arctic Front Advance Cardiac Cryoablation Catheter” (simultaneously submitted). It is used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites, or creation of an ablation line between the inferior vena cava and the tricuspid valve. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 166 days	Dec. 10, 2010 Foreign clinical study results	76	Medtronic CryoConsole (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical unit to be used for the treatment of arrhythmia. The device is for the exclusive use of Medtronic cryoablation catheters. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]
4	Feb. 19, 2014 Total review time: 300 days Regulatory review time: 204 days	Apr. 12, 2012 Foreign clinical study results	77	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon catheter used for cardiac cryoablation to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. A clinical study was conducted to evaluate the efficacy and safety of this product when it is applied for patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. [Priority review]
4	Feb. 28, 2014 Total review time: 851 days Regulatory review time: 685 days	- Domestic clinical study results	78	Coopdech i-Cool (Daiken Medical Co., Ltd.)	Approval	Instrument & apparatus 12 Temperature management system	A system used to lower the brain temperature by bringing a cuff in which temperature-controlled physiological saline circulates into contact with parts of pharyngeal and esophagus of the patients who require therapeutic hypothermia following cardiac arrest. A domestic clinical study was conducted to confirm that brain temperature becomes lower early in therapeutic hypothermia by cooling pharyngeal with this device, that it does not worsen outcomes in the patients significantly, and that the risks are acceptable.

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
4	Feb. 28, 2014 Total review time: 77 days Regulatory review time: 15 days	Jan. 17, 2014 (Approval of application corresponding to the present partial change) No clinical study results	79	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 catheterballoon in which a perfusion fluid (physiological saline) circulates in patients who need fever control. An application for a partial change to change the manufacturing site. (A partial change during the reexamination period)
4	Mar. 26, 2014 Total review time: 272 days Regulatory review time: 183 days	Feb. 1, 2001 Clinical evaluation report	80	Nykanen RF Wire (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	A wire used for puncture of atrial septum or membranous atresia of pulmonary artery in patients with severe congenital heart diseases by delivering radiofrequency energy. A clinical evaluation report based on published literatures in foreign countries was submitted without conducting a domestic or foreign clinical study. [Priority review]
4	Mar. 26, 2014 Total review time: 91 days Regulatory review time: 71 days	Jan. 15, 2013 No clinical study results	81	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. An application for a partial change to change the conditions of usable MRI devices. (A partial change during the reexamination period)
4	Mar. 26, 2014 Total review time: 90 days Regulatory review time: 68 days	- Clinical evaluation report	82	Protego Pro S (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable electrode lead with a screw-shaped tip having a quadrupolar connector (DF4-Standard). It is used for the treatment of ventricular tachycardia, with being connected to ICD or CRT-D. This lead, having one defibrillation electrode, was developed based on the main body of “Protego Pro SD (Approval No. 22500BZX00295A01).” The patients with the device can conditionally undergo an MRI scan. A clinical evaluation report was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
5	Apr. 12, 2013 Total review time: 197 days Regulatory review time: 97 days	−(No application for this indication) Clinical evaluation report	83	Histoacryl (B. Braun Aesculap Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels	An n-butyl-2-cyanoacrylate is injected for endoscopic vascular embolization for gastric varices. This product has been already used in and out of Japan as material for endoscopic vascular embolization. Based on the current situation, a clinical evaluation report was submitted to evaluate the efficacy and safety of this product. [Priority review]
5	Jun. 21, 2013 Total review time: 396 days Regulatory review time: 192 days	− Domestic clinical study results	84	Magnetic Stimulator TMU-1100 (Nihon Kohden Corporation)	Approval	Instrument & apparatus 12 Magnetic stimulation device for treatment of urinary incontinence	A magnetic stimulation device to improve symptoms of overactive bladder with urinary incontinence. This product is used for adult female patients with overactive bladder who are not responsive to or cannot use therapeutic agents for urinary incontinence. Pulse current flowing in a stimulation coil under the sealing surface of a chair-shaped stimulation unit generates magnetic energy through the upper portion of the sealing surface. The variable magnetic fields induce eddy currents in the body of the patient who is seated on the stimulation unit. The eddy currents primarily stimulate the nerves in the pelvic floor area of the patient. A clinical study was conducted to evaluate the efficacy and safety of this product in female patients with overactive bladder with urinary incontinence.
5	Jul. 5, 2013 Total review time: 43 days Regulatory review time: 12 days	- No clinical study results	85	CryoSeal CS-1 (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Apparatus for blood component separation	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. An application for a partial change to change the manufacturing sites. (A partial change during the reexamination period)

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
5	Sep. 20, 2013 Total review time: 386 days Regulatory review time: 126 days	Mar. 14, 2011 Domestic and foreign clinical study results	86	InterStim II Neurostimulator for Sacral Neuromodulation (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for bladder and bowel control	An implantable nerve stimulation system to improve fecal incontinence by electrical stimulation to sacral nerves for the patients with fecal incontinence who have not responded or cannot apply to conservative treatment. Clinical studies were conducted to evaluate therapeutic effect of this device for fecal incontinence and the safety during a test stimulation period and an implantation period.
5	Feb. 19, 2014 Total review time: 72 days Regulatory review time: 19 days	- No clinical study results	87	Cryoseal Disposable Kit (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Blood component separation kit	Blood component separation kit to be used to isolate/collect blood components in a sterile state when preparing a biological tissue adhesive from autologous plasma. Patients are to undergo preoperative autologous blood donation. An application for a partial change of approval application for medical device to change manufacturing sites. (A partial change during the reexamination period)
6-1	Sep. 20, 2013 Total review time: 756 days Regulatory review time: 371 days	May 14, 2004 (stem, etc.) Mar. 16, 2005 (baseplate, etc.) Jul. 20, 2006 (baseplate long post, etc.) Clinical evaluation report	88	Aequalis Reversed Shoulder Prosthesis (Tornier S.A.S.)	Approval	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system in a reversed form of the conventional, anatomically-structured shoulder prosthesis with a spherical glenoid component and a humeral head component that is a concave hemispherical shell. Since there was no similar device in Japan, a clinical evaluation report was submitted to confirm the efficacy and safety of this device equivalent to similar devices based on overseas usage history and publications of this device and the similar devices by taking into account that the indication and operative procedure had already been established by its long-term usage history overseas.
6-1	Oct. 30, 2013 Total review time: 1038 days Regulatory review time: 666 days	Dec. 19, 2005 Clinical evaluation report	89	Trabecular Metal Reverse Shoulder System (Zimmer K.K.)	Approval	Medical products 4 Total shoulder prosthesis	A total shoulder prosthesis having the concept of a reversed shoulder prosthesis system in which the anatomical structure is reversed. It is used for cases of having difficulty in elevetion of a shoulder with an unreconstructible rotator cuff function such as a massive rotator cuff tear. When it can not be used in reversed combination for the reason that a base plate can not be applied during surgery, it can be emergently combined in an anatomical shape. Trabecular metal is applied to portions contacting bone on a humeral stem and a reversed base plate. A clinical evaluation report was submitted to confirm the efficacy and safety of this device is equivalent to the existing approved devices based on overseas usage histories and publications of this device and similar devices. (The original product is in a reexamination period)
6-2	Oct. 11, 2013 Total review time: 416 days Regulatory review time: 112 days	Feb. 20, 2013 Foreign clinical study results	90	Natrelle 410 Breast Implant (Allergan Japan K. K.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled artificial breast for restoring or forming the shape of a breast after the insertion into the application site. It is used for breast reconstruction surgery or augmentation mammaplasty. It is improved compared with the approved "Natrelle Breast Implant (Approval No. 22400BZX00354000)".The improvements are that it is designed with an anatomical shape that mirrors a woman's real breast and the gel with increased degree of crosslinking makes the breast harder. A clinical study was conducted to evaluate the performance as an artificial breast and adverse events in breast reconstruction surgery or augmentation mammaplasty. (The original product is in a reexamination period)
Cellular and tissue-based products	Jul. 30, 2013 Total review time: 75 days Regulatory review time: 40 days	- No clinical study results	91	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This is an autologous-cultured epidermis processed from epidermal cells and multiple animal origin-materials for severe burn injury. This application for partial changes to add a new supplier of bovine serum used in the processes of this product and to change the preparation method of culture medium.

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	Mar. 17, 2014 Total review time: 109 days Regulatory review time: 39 days	- No clinical study results	92	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This is an autologous-cultured epidermis processed from epidermal cells and multiple animal origin-materials for severe burn injury. An application for partial changes to change and add raw materials of this product, and to change storage period of the intermediates.
Specified partial change	Jan. 16, 2014 Total review time: 83 days Regulatory review time: 37 days	Feb. 13, 2014 No clinical study results	93	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system used in percutaneous coronary stent placement. The stent is coated with everolimus with immunosuppression. An application for a partial change of approval application for medical device to add everolimus with a different manufacturing number. (A partial change during the reexamination period)
Specified partial change	Mar. 11, 2014 Total review time: 62 days Regulatory review time: 29 days	- No clinical study results	94	Cryoseal Disposable Kit (Asahi Kasei Medical Co.,Ltd.)	Change	Instrument & apparatus 7 Blood component separation kit	Blood component separation kit to be used to isolate/collect blood components in a sterile state when preparing a biological tissue adhesive from autologous plasma. Patients are to undergo preoperative autologous blood donation. An application for a partial change of approval application for medical device to add new raw materials of the components for stabilizing supply of the materials. (A partial change during the reexamination period)

Products Approved in FY2013: 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	Apr. 8, 2013 Total review time: 299 days Regulatory review time: 141 days	Jun. 5, 2012 Foreign clinical study results	1	Biotrue Oneday (B.L.J. Company, Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lens for correcting visual acuity	A single use soft contact lens with 78% water content and oxygen permeability (Dk) of 42 composed of nesofilcon A. It is integrally colored light blue and contains an ultraviolet absorber. Because the product has novel raw materials, but not a novel design, a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Aug. 27, 2013 Total review time: 382 days Regulatory review time: 207 days	Apr. 15, 2013 Foreign clinical study results	2	Tecnis Toric 1-Piece (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A one-piece monofocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery accompanied with corneal astigmatism. The same raw materials as those of “Tecnis one-piece (Approval No. 22000BZX01610000)” are used. A cylindrical frequency was newly added to the front of the lens to correct corneal astigmatism, which is difference from the existing approved product. A clinical study was conducted to evaluate the clinical efficacy and safety of this product with the newly added correcting function of corneal astigmatism.
1	Jan. 14, 2014 Total review time: 491 days Regulatory review time: 141 days	- Domestic clinical study results	3	HOYA iSert Micro Toric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	A posterior chamber lens with an injector in which a monofocal posterior chamber lens is preloaded to insert it into an aphakic eye with corneal astigmatism after cataract surgery. The raw materials of the lens are the same as those of “HOYA iSert Micro (Approval No. 22200BZX00615000).” A cylindrical power is newly added to one side of the lens to correct corneal astigmatism, which is the difference from the existing approved product. A domestic clinical study was conducted to evaluate the clinical efficacy and safety of this lens with the newly added correcting function of corneal astigmatism.
1	Jan. 15, 2014 Total review time: 292 days Regulatory review time: 227 days	- Domestic clinical study results	4	Alcon Acrysof IQ Restor Toric Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal toric intraocular lens to be inserted into an aphakic eye with corneal astigmatism. This product has an aspheric, diffractive, and multifocal structure on the anterior optical surface and a toric structure on the posterior surface. The each optical design is identical to that of the company’s approved product. In addition, the raw material and basic structure of the lens are also identical to those of the company’s approved product. A domestic clinical study was conducted to evaluate that this device corrects corneal astigmatism and provides adequate multifocal function, compared to clinical study results of the approved single-function lenses of multifocal or toric.
1	Mar. 3, 2014 Total review time: 213 days Regulatory review time: 150 days	- Clinical evaluation report	5	ICL KS-AquaPORT (STAAR Japan Inc.)	Approval	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	A one-piece intraocular lens to correct refractive errors. It is designed to be implanted in the posterior chamber of a phakic eye (in front of the human crystalline lens). A through-hole is added to the center of the optical zone of the company’s approved product “ICL (Approval No. 22200BZY00001000),” which makes laser iridotomy, required as a preoperative procedure in the original product, unnecessary. A clinical evaluation report was submitted to evaluate the effects on the change on visual function and corneal endothelial cells, and the presence or absence of increased ocular pressure associated with the absence of laser iridotomy.

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	Jan. 23, 2014 Total review time: 391 days Regulatory review time: 188 days	Jun. 30, 2004 Domestic and foreign clinical study results	6	Straumann Implant (SLActive) TL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	The first dental implant in Japan that enables earlier loading than conventional loading. This device is sealed into vial filled with normal saline to keep hydrophilic nature of titanium until just before use, which accelerates osteointegration. A domestic clinical study on an implant of 4.1mm in diameter was conducted to evaluate its efficacy and safety in early loading compared to in conventional loading. In addition, results of foreign clinical studies on a thinner implant of 3.3mm in diameter were submitted.
3-1	Jul. 10, 2013 Total review time: 349 days Regulatory review time: 233 days	Dec. 21, 2012 Foreign clinical study results	7	XIENCE Xpedition Drug Eluting Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent composed of a drug-eluting stent used for treatment of patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 32mm or less) with a reference vessel diameter of 2.50-3.75mm and a delivery catheter used to implant a stent to the coronary stenosis site. The device has a different stent delivery system from the company's approved product “XIENCE PRIME Drug Eluting Stent (Approval No. 22400BZX00145000).” A new stent diameter of 3.25mm is added. Results from clinical studies on “XIENCE PRIME Drug Eluting Stent” were submitted to confirm the efficacy and safety of this product.
3-1	Sep. 26, 2013 Total review time: 300 days Regulatory review time: 205 days	Oct. 15, 2009 Clinical evaluation report	8	Hyperform/Hyperglide Occlusion Balloon Catheter (Covidien Japan, Inc.)	Change	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for cerebral aneurysm. An application for a partial change to change the intended use and the operation procedures to enable this product to be used in coil embolization for wide-neck cerebral aneurysm as an assisting balloon, in addition to an indication as an occlusion balloon. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Dec. 9, 2013 Total review time: 404 days Regulatory review time: 265 days	Feb. 22, 2013 Foreign clinical study results	9	Resolute Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a 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. Application for a partial change to add a product with a stent length of 34mm and 38mm to the existing products for extending the target lesion length from 27mm to 35mm and change the specification of drug content uniformity. A clinical study was conducted to evaluate the efficacy and safety of the product for patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 35mm or less).
3-1	Jan. 30, 2014 Total review time: 265 days Regulatory review time: 192 days	- Clinical evaluation report	10	Kaneka Assistant Balloon Catheter NE-N3 (Kaneka Corporation)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	A intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for cerebral aneurysm. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Feb. 4, 2014 Total review time: 221 days Regulatory review time: 112 days	Feb. 22, 2012 Foreign clinical study results	11	AbsolutePro Vascular Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A self-expanding stent and stent delivery system inserted and placed at the site of new lesions or restenotic lesions of symptomatic atherosclerosis in the iliac artery (common iliac artery and external iliac artery) to secure intravascular lumen. A clinical study was conducted to evaluate that the efficacy and safety of the product are not inferior compared to the results from past clinical studies.

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
3-1	Feb. 28, 2014 Total review time: 182 days Regulatory review time: 76 days	Jul. 31, 2012 Foreign clinical study results	12	Omnilink Elite Vascular Stent (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A balloon-expanding stent and stent delivery system inserted and placed at the site of new lesions or restenotic lesions of symptomatic atherosclerosis in the iliac artery (common iliac artery and external iliac artery) to secure intravascular lumen. A clinical study was conducted to evaluate that the efficacy and safety of the product are not inferior compared to the results from past clinical studies.
3-1	Mar. 26, 2014 Total review time: 363 days Regulatory review time: 129 days	Mar. 19, 2013 Clinical evaluation report	13	Guidezilla Extension Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter to enhance access to the stenotic site of the coronary artery and facilitate placement of interventional devices including a guidewire. A clinical evaluation report was submitted to evaluate that the device has equal efficacy and safety to those of the approved devices.
3-1	Mar. 28, 2014 Total review time: 361 days Regulatory review time: 147 days	- Clinical evaluation report	14	Nipro Guiding Catheter B (Nipro Corporation)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter providing back-up support for insertion of a therapeutic device. It is inserted into the coronary artery when it is difficult for a guidewire or an intravascular therapeutic device to reach a target lesion or pass a lesion in percutaneous transluminal coronary angioplasty. A clinical evaluation report was submitted to evaluate that the device has equal efficacy and safety to those of the approved devices.
3-2	Jul. 19, 2013 Total review time: 618 days Regulatory review time: 389 days	Nov. 9, 2006 Foreign clinical study results	15	Gore Propaten Vascular Graft (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel using heparin	An artificial blood vessel used in vascular replacement, bypass grafting, hemodialysis or other vascular techniques for patients with occlusive diseases or aneurysms or trauma patients who require vascular replacement. It has a basic structure of a stretched polytetrafluoroethylene (PTFE) tube. Heparin bonded covalently to the luminal surface of the graft is expected to produce a local and long-term antithrombotic effect and improve the 1-year patency rate and limb salvage rate after peripheral vascular bypass surgery for patients with peripheral artery occlusive disease. A clinical study was conducted to evaluate its efficacy and safety in above-knee femoropopliteal artery bypass surgery for vascular occlusive diseases.
3-2	Sep. 27, 2013 Total review time: 434 days Regulatory review time: 254 days	Aug. 23, 2011 Foreign clinical study results	16	GORE CTAG Thoracic Endoprosthesis (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for endovascular treatment of thoracic aortic aneurysm. The product consists of a stent graft and delivery catheter. The main differences from the approved product “GORE TAG Thoracic Endoprosthesis (Approval No. 22000BZX00185000)” include a shape change of the stent graft (removal of flare parts at both ends of a stent graft), an increase in the stent wire diameter, a change of the apex number of the stent, an addition of a new stent graft size, and a position change of adhesive tape, etc. These changes enhanced compression resistance of the stent graft and followability to an implanted vessel so that the product is applicable to more diversified blood vessel diameters. A clinical study was conducted to evaluate its efficacy and safety in cases with thoracic aortic aneurysm.
3-2	Oct. 11, 2013 Total review time: 178 days Regulatory review time: 148 days	Apr. 16, 2013 Foreign clinical study results	17	ENDURANT II Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system used for endovascular treatment of infrarenal abdominal aortic aneurysm. The product consists of a stent graft and delivery system. An application for a partial change to add AUI (aorta uni-iliac) configuration. Results from a clinical study using the first generation product were submitted to evaluate the efficacy and safety of the AUI configuration for infrarenal abdominal aortic aneurysm.

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
3-2	Dec. 6, 2013 Total review time: 595 days Regulatory review time: 380 days	Dec. 1, 2011 Clinical evaluation report	18	GuideLiner Catheter (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Coronary recanalization catheter	A coronary recanalization catheter providing back-up support for insertion of the therapeutic device. It is inserted into the coronary artery when it is difficult for a guidewire or an intravascular therapeutic device to reach a target lesion or pass a lesion in percutaneous transluminal coronary angioplasty. A clinical evaluation report was submitted to confirm the efficacy and safety when this device is used as a slave catheter.
3-2	Jan. 30, 2014 Total review time: 456 days Regulatory review time: 419 days	- Domestic clinical study results	19	J Graft Open Stent Graft (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic open stent graft used for the treatment of diseases which require aorta replacement from the distal aortic arch to the proximal descending aorta. This product is capable of being fixed securely on the central side in a similar suturing way with a conventional synthetic graft, and is fixed on the peripheral side by the spring force of the stent graft without suture which provide one-stage, low invasive treatment for a widespread lesion. A clinical study was conducted to confirm the efficacy and safety of this device for diseases requiring aorta replacement.
3-2	Feb. 6, 2014 Total review time: 132 days Regulatory review time: 99 days	- Clinical evaluation report	20	BA Soft Balloon Catheter (Fuji Systems Corporation)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization in the central circulation system used for a temporary interruption of blood flow in percutaneous intravascular surgery or as an adjunct of coil embolization for a cerebral aneurysm to prevent a coil body from protruding or being disengaged toward the parent artery. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-2	Feb. 24, 2014 Total review time: 594 days Regulatory review time: 366 days	OTW System (Jan. 31, 2007) DV System (Sep. 19, 2007) Clinical evaluation report	21	AERO Hybrid Stent for Airway Stenosis (Sugan Co., Ltd.)	Approval	Instrument & apparatus 7 Tracheal stent	A tracheal stent used to secure an airway for tracheal or bronchial stenosis caused by malignant tumors. Since this stent made of nitinol is fully covered with polyurethane film, it has the advantage of both metal stent which can be inserted by rigid or flexible endoscope and silicon stent which has low complication rates in granulation, tumor infiltration and so on. A clinical study report was submitted to confirm the efficacy and safety of this device for tracheal and bronchial stenosis caused by malignant tumors.
3-2	Feb. 28, 2014 Total review time: 1428 days Regulatory review time: 167 days	Aug. 30, 2008 Foreign clinical study results	22	ATS 3f Aortic Bioprosthesis (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Equine pericardial valve	The ATS 3f Aortic Bioprosthesis is used for replacement as an alternative to dysfunctional aortic valve. Its leaflets are made of equine pericardium. This aortic bioprosthetic valve is designed as a tubular structure without a stent, which allows the valve to open and close like a native valve. A clinical study was conducted to confirm the efficacy and safety of this device when it was implanted in patients with aortic stenosis.
3-2	Feb. 28, 2014 Total review time: 730 days Regulatory review time: 270 days	Jan. 7, 2010 Foreign clinical study results	23	Floseal (Baxter Limited)	Approval	Medical products 4 Gelatin-based local absorbable hemostatic material with human thrombin	A local absorbable hemostatic material used in surgical procedures (other than in ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. A clinical study was conducted to evaluate its performance and safety for a bleeding area in cardiac, vascular and spine/spinal surgery.
3-2	Mar. 28, 2014 Total review time: 302 days Regulatory review time: 153 days	Sep. 11, 2008 Foreign clinical study results	24	NAV 6 Filter (Abbott Vascular Japan Co.,Ltd.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device is used to prevent distal emboli by capture and removal of obstructing materials such as thrombi during carotid artery stent procedure. It is percutenously and temporarily placed in the distal sites from stenotic region in the cervical part of carotid artery. A clinical study was conducted to confirm the effectiveness and safety when this device is used during CAS.

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4	Jul. 18, 2013 Total review time: 335 days Regulatory review time: 193 days	Jan. 29, 2013 Global clinical trials	25	Viva CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. The device is newly equipped with AdaptivCRT technology developed to automatically control CRT parameters (AV and VV delays) based on patients' conduction and CardioSync Optimization supporting CRT parameter control by measuring patients' electric conduction property at follow-up visits, with which the approved product “Protecta XT CRT-D (Approval No. 22200BZX00913000)” was equipped. There are six models of the products having different shapes of connectors of lead connection parts and different mounting functions. A clinical study was conducted to evaluate the efficacy and safety of the AdaptivCRT function.
4	Aug. 9, 2013 Total review time: 696 days Regulatory review time: 280 days	Aug. 14, 2008 Foreign clinical study results	26	Watch PAT (Philips Respironics GK)	Approval	Instrument & apparatus 21 Sleep evaluation device	A medical device used as an adjunct in evaluation and diagnosis of sleep-disordered breathing events and sleep stages in patients suspected of sleep-disordered breathing. The wrist-worn device records PAT (Peripheral Artery Tonometry) signal (finger plethysmogram), $Sp0_2$, snoring, and body position and motion during sleep. Results from clinical studies on the precedent device equipped with the same software as this device were submitted to examine whether the software of this device can evaluate sleep disorder.
4	Sep. 12, 2013 Total review time: 265 days Regulatory review time: 172 days	- Global clinical trials	27	Viva Quad CRT-D Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. One of the IS-1 connector ports of the original product “Viva CRT-D Series (Approval No. 22500BZX00320000)” is changed to a IS4 connector port capable of being adopted to a left ventricle (LV) lead that has four independent pacing electrodes. There are three models of the products having different mounting functions. It also has VectorExpress, a support function to be used for selecting a pacing vector, which provides automatic measurement of the capture threshold based on impedance and pulse width of 16 types of LV vector and relative battery life. A clinical study was conducted to evaluate the efficacy and safety of AdaptivCRT technology.
4	Sep. 30, 2013 Total review time: 536 days Regulatory review time: 382 days	- Foreign clinical study results	28	DBS 4 contacts lead (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrode lead placed on the deep brain in deep brain stimulation therapy. It transmits electric stimulus generated from an implanted stimulation device. The product consists of an electrode lead and its accessories. It is used in conjunction with “Libra Single 8 Neurostimulator (Approval No. 22500BZX00450000)” and “Brio Dual 8 Neurostimulator (Approval No. 22500BZX00451000).” A clinical study was conducted to evaluate the efficacy and safety of product in Parkinson’s disease and dystonia.
4	Jan. 28, 2014 Total review time: 1033 days Regulatory review time: 401 days	Sep. 24, 2003 Domestic clinical study results	29	AB5000 Ventricle (Medix Japan, Inc.)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	An pneumatic ventricular support system that is placed external to the patient. A domestic clinical trial was conducted to evaluate its adaptability to domestic medical circumstances. Results of a post-marketing surveillance submitted to the US FDA were reviewed as reference data.
4	Jan. 28, 2014 Total review time: 944 days Regulatory review time: 314 days	Aug. 1, 2006 Foreign clinical study results	30	Endovenous Closure System (Covidien Japan Inc.)	Approval	Instrument & apparatus 29 Therapeutic electrosurgical device	An electrosurgical device used for the treatment of primary varicose veins of lower extremities. It generates a laser in the veins to obstruct saphenous veins. It thermally coagulates the main saphenous vein to cause vascular obstruction. This device is composed of a generator which generates high-frequency current and a catheter which is connected to the generator. The catheter, to the tip of which a heating coil is attached, is inserted via the skin and lumina to an objective lesion region (the main saphenous vein). The heating coil obstructs a vascular vessel. A clinical study in which it is compared to the domestically approved product “ELVeS Laser (Approval No. 22200BZX00660000)” was conducted to evaluate its clinical efficacy and safety.

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4	Feb. 28, 2014 Total review time: 375 days Regulatory review time: 252 days	Apr. 4, 2012 Foreign clinical study results	31	Protecta XT CRT-D (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. An application for a partial change to add NYHA class II (mild) cardiac function to the current indications of class III or IV (moderate or severe) for extending its indication. A clinical study was conducted to confirm the validity of the new indication. In addition, results from evaluations of multiple clinical studies were submitted as a clinical evaluation report.
4	Mar. 7, 2014 Total review time: 345 days Regulatory review time: 167 days	Nov. 17, 2011 Foreign clinical study results	32	INCEPTA Plus CRT-D (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable defibrillator with a biventricular pacing function. An application to add NYHA class II (mild) cardiac function to the current indications of class III (moderate) or IV (severe). A clinical study was conducted to evaluate the validity of the new indication.
4	Mar. 7, 2014 Total review time: 245 days Regulatory review time: 172 days	- Domestic clinical study results	33	ELVeS Laser 1470 (Integral Corporation)	Approval	Instrument & apparatus 31 Diode laser	A laser treatment device used for varicose veins of lower extremities. It generates a laser in the veins to obstruct saphenous veins. A domestic clinical study was conducted to confirm that this device provides a similar degree of interruption of blood flow to the original product “ELVeS Laser” and that it is less associated with postoperative pains than the original.
4	Mar. 11, 2014 Total review time: 326 days Regulatory review time: 160 days	Jun. 11, 2001 Clinical evaluation report	34	Subcutaneous Implantable Lead System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A subcutaneously implanted lead with a defibrillation coil electrode for ICD and CRT-D. This product is used for patients with a high defibrillation threshold in whom it is difficult for a normal transvenous defibrillation lead to work effectively. A clinical evaluation report summarizing results of foreign clinical studies was submitted to confirm the efficacy and safety of this device.
5	Apr. 17, 2013 Total review time: 279 days Regulatory review time: 240 days	- (About these changes) Clinical evaluation report	35	Dornier Delta II (Dornier Medtech Japan Co., Ltd.)	Change	Instrument & apparatus 12 Extracorporeal lithotripter	An electromagnetic lithotripter used in bloodless treatment by radiating a shock wave from outside the body to a calculus to crush it into small fragments. The product consists of a shock wave generating device, a X-ray device, an ultrasonic device, ECG device, and a treatment table. An application for a partial change to add an indication for pancreatolithiasis to the conventional indication for calculus of the upper urinary tract and biliary calculus with no change of the product itself. A clinical evaluation report summarizing literature cited in three domestic guidelines on treatment of pancreatolithiasis and literature on clinical use of this product.
5	May 21, 2013 Total review time: 294 days Regulatory review time: 142days	- Clinical evaluation report	36	Niti-S Colorectal Stent (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Colonic stent	A biliary stent used to relieve obstructive symptoms before surgery for stricture of the large intestine caused by malignant tumors or for palliation in patients with unresectable malignant tumors or who are not expected to respond to other treatments. A clinical study report, which summarizes literature information using technical success of stent placement, improvement of obstructive symptoms after the placement, and the incidence of adverse events as evaluation items, was submitted to confirm the efficacy and safety of this device when it is used for relief of obstructive symptoms before surgery or palliation.
5	Jun. 5, 2013 Total review time: 125 days Regulatory review time: 114 days	- Domestic clinical study results	37	PEPA Hemodiafilter GDF (Nikkiso Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has been markedly reduced due to chronic or acute renal failure, etc. Because equivalence to the approved haemodiafiltration device was not demonstrated with regard to the semipermeable membrane material, a clinical study was conducted to confirm the efficacy and safety.

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5	Jul. 3, 2013 Total review time: 400 days Regulatory review time: 115 days	- Clinical evaluation report	38	Niti-S Comvi Pyloric/Duodenal stent (Century Medical, Inc.)	Approval	Instrument & apparatus 7 Gastroduodenal stent	A gastroduodenal stent for patients with unresectable malignant gastroduodenal stenosis who cannot be managed by palliative surgical therapy and are not expected to achieve improvement with other treatments. The main difference from the approved product “Niti-S Gastroduodenal Stent (Approval No. 22300BZX00428000)” is that this product has a cover made of PTFE. A clinical study report was submitted summarizing results of literature research on clinical data to evaluate the efficacy and safety of this device compared to an uncovered stent.
5	Jul. 11, 2013 Total review time: 296 days Regulatory review time: 172 days	- Domestic clinical study results	39	PillCam COLON 2 Capsule Endoscopy System (Given Imaging K.K.)	Approval	Instrument & apparatus 25 Capsule electronic endoscope system	A capsule electronic endoscope system to take images of colorectal mucosa and provide the images when colonoscopy is required for diagnosis of colonic diseases but it is difficult to be performed. The main difference from the approved product “Given Capsule Endoscopy (Approval No. 22100BZX00363000)” is that this product is used for diagnosis of colonic diseases. A clinical study was conducted to evaluate the sensitivity of this device in subjects who were detected by colonoscopy to have diseases which require endoscopic or surgical therapy.
5	Sep. 12, 2013 Total review time: 295 days Regulatory review time: 164 days	- Domestic clinical study results	40	Prismaflex ST (Gambro K.K.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter to improve clinical conditions by performing continuous hemodiafiltration. It is used in patients with severe sepsis or septic shock, patients with acute renal failure accompanying diseases or conditions including sepsis, multi organ failure, acute hepatic failure, acute respiratory failure, acute cardiovascular failure, acute pancreatitis, burn injury, traumatic injury, postoperative diseases or patients with chronic renal failure who have unstable circulation dynamics associated with these diseases or conditions. This product is a filter used for slow continuous hemofiltation that is connected to a blood circuit. The main difference from the approved product “Hemofeel SH (Approval No. 21200BZZ00274000)” is that the product is indicated for patients with severe sepsis or septic shock. A clinical study was conducted to evaluate the efficacy and safety of this device in patients with severe sepsis or septic shock.
5	Sep. 12, 2013 Total review time: 295 days Regulatory review time: 164 days	- Domestic clinical study results	41	SepXiris (Gambro K.K.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A slow continuous hemofilter to improve clinical conditions by performing continuous hemodiafiltration. It is used in patients with severe sepsis or septic shock, patients with acute renal failure accompanying diseases or conditions including sepsis, multi organ failure, acute hepatic failure, acute respiratory failure, acute cardiovascular failure, acute pancreatitis, burn injury, traumatic injury, postoperative diseases or patients with chronic renal failure who have unstable circulation dynamics associated with the diseases or conditions. The main difference from the approved product “Hemofeel SH (Approval No. 21200BZZ00274000)” is that the product is indicated for patients with severe sepsis or septic shock. A clinical study was conducted to evaluate the efficacy and safety of this device in patients with severe sepsis or septic shock.
5	Jan. 14, 2014 Total review time: 264 days Regulatory review time: 162 days	- Domestic clinical study results	42	Fineflux (Nipro Corporation)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter used to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has been markedly reduced due to chronic or acute renal failure, etc. Cellulose triacetate, which has been conventionally used as a hollow fiber membrane raw material of a hemodialyzer, is adopted as a hollow fiber membrane raw material of the hemodiafilter. A clinical study was conducted to evaluate the efficacy and safety because the raw material of its semipermeable membrane was proved to be not equivalent to that of the 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
5	Jan. 28, 2014 Total review time: 152 days Regulatory review time: 113 days	- Clinical evaluation report	43	MucoUp (Seikagaku Corporation)	Change	Medical products 4 Submucosal filling material for endoscope	A submucosal filling material for an endoscope containing the active ingredient sodium hyaluronate. It is injected submucosally during endoscopic mucosal resection or endoscopic submucosal dissection to form a mucosal protrusion and maintain it. This application for a partial change for medical devices is to add an indication for the site of esophageal tumors. A clinical evaluation report summarizing literature information was submitted to evaluate the efficacy and safety when it is used in endoscopic mucosal resection/endoscopic submucosal dissection.
6-1	Jun. 12, 2013 Total review time: 957 days Regulatory review time: 260 days	- Clinical evaluation report	44	Biomet Biolox Delta Ceramic Liner (At the time of approval, Biomet Japan, Inc.; currently, Biomet Japan, LLC)	Approval	Medical products 4 Artificial hip joint, acetabular component	A liner made of zirconia-toughened alumina ceramic composites used in combination with the company's approved product "Biomet Biolox Delta Ceramic Head (Approval No. 22400BZX00141000)." Because the combination of the company's liner material and head material was an unprecedented combination, a clinical evaluation report summarizing its efficacy and safety based on foreign use results and published literature was submitted.
6-1	Sep. 6, 2013 Total review time: 134 days Regulatory review time: 107 days	- Clinical evaluation report	45	Adler BIOLOX delta Ceramic System (Robert Reid Inc.)	Approval	Medical products 4 Total hip prosthesis	A femoral stem-head and an acetabulum-forming liner made of alumina-zirconia ceramics composite used in hip replacement used in combination with the approved products "Alder prosthetic hip joint system (Approval No. 22500BZX00017000)," "HYDRA Femoral Component (Approval No. 22500BZX00018000)," and "BIOLOX delta Ceramic Head (Approval No. 22500BZX00019000)." Because combination of the company's head and liner made of the raw material was unprecedented, a clinical evaluation report evaluating the incidence of repeat replacements and the incidence of defects based on foreign use results and published literature was submitted.
6-1	Jan. 28, 2014 Total review time: 144 days Regulatory review time: 62 days	- Clinical evaluation report	46	R3 Delta Ceramic Liner (Smith & Nephew Orthopaedics KK)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for total hip replacement. It is made of zirconia-toughened alumina (BIOLOX delta) for improvement of its brittleness and abrasion property. It was developed to obtain a hip joint bearing with excellent abrasion characteristics and fracture strength by delta on delta in combination with a delta ceramic head made of the same material. A clinical evaluation report was submitted to confirm the performance of the bearing surface with the new material.
6-1	Feb. 13, 2014 Total review time: 539 days Regulatory review time: 159 days	- Domestic clinical study results	47	Zimmer Delta Ceramic Liner (Zimmer K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for total hip replacement. It is made of zirconia-toughened alumina (BIOLOX delta) for improvement of its brittleness and abrasion property. It was developed to obtain a hip joint bearing with excellent abrasion characteristics and fracture strength by delta on delta in combination with the company's artificial caput made of the same material. Domestic clinical study results were submitted to demonstrate that this device with the newly adopted material is not inferior to the approved prosthetic hip joint in the efficacy and safety.
6-2	Aug. 9, 2013 Total review time: 591 days Regulatory review time: 220 days	Mar. 31, 2004 Domestic clinical study results	48	CranioFix Absorbable (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Absorbable cranial fixation clamp	An implantable cranial fixation device composed of two absorbable discs, of which are made of polyester [Poly (L-lactide-co-D, L-lactide) 70:30], and a non-absorbable suture to fix them. It is used to fix a free bone flap during closing of the cranium in a craniotomy. This device has the following points as differences from the approved devices: (1) The device offers a more simple operation of cranial fixation in a shorter time because operation to heat and shape a plate and exclusive tools became unnecessary; (2) It also has no artifact in postoperative MRI or CT images; (3) The absorbable material causes no problems of impeding growth of bones in children or its moving and it is not necessary to be removed at the time of repeat surgery. Clinical studies were conducted to confirm the efficacy and safety of this product with the newly adopted absorbable material.

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	Sep. 6, 2013 Total review time: 220 days Regulatory review time: 138 days	Mar. 11, 2009 Domestic clinical study results	49	GRYPHON BR Anchor (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	A suture anchor used to fix soft tissues such as ligaments in a shoulder, foot/ankle, elbow, hip to a bone. The product consists of an absorbable anchor, partially absorbable sutures, and an inserter. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate which is unprecedented in Japan, is adopted as a raw material of the anchor. A clinical study was conducted to confirm the efficacy and safety of this product with the newly adopted absorbable material.
6-2	Sep. 6, 2013 Total review time: 220 days Regulatory review time: 140 days	Feb. 29, 2012 Domestic clinical study results	50	HEALIX ADVANCE BR Anchor (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	A suture anchor to fix a rotator cuff to a bone. The product consists of an absorbable anchor, partially absorbable sutures, and an inserter. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate of which a remaining period is shorter than that of a poly-L-lactic acid anchor, is adopted as a raw material. Clinical study results using anchors of the same raw material as that of this product were submitted to confirm that failure caused by the material does not occur.
6-2	Sep. 6, 2013 Total review time: 190 days Regulatory review time: 103 days	Mar. 31, 2004 Domestic clinical study results	51	MILAGRO Interference Screw (Johnson & Johnson K.K.)	Approval	Medical products 4 Absorbable ligament anchor	An interference screw used to fix soft tissue to a bone. The point of improvement is that a complex of glycolic acid-lactic acid polyester and β-tricalcium phosphate of which a remaining period is shorter than that of a poly-L-lactic acid anchor, is adopted as a raw material. Clinical study results using anchors of the same raw material as that of this product were submitted to confirm that failure caused by the material does not occur.
6-2	Sep. 17, 2013 Total review time: 1040 days Regulatory review time: 529 days	Apr. 3, 2009 Foreign clinical study results	52	Hydrosite Gentle Ag (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	An antibacterial wound dressing and protecting material containing sulfadiazine silver as an antibacterial ingredient added to the absorption pad layer of the approved product “Hydrosite AD Gentle (Approval No. 22100BZX00942000).” It is used for wounds with exudate fluid which have a high possibility of infection. Foreign clinical study results on a similar product which has a different adhesive agent on a wound contact layer were submitted to confirm if the antibacterial ingredient causes no problems such as protracted wound healing.
6-2	Sep. 17, 2013 Total review time: 1040 days Regulatory review time: 529 days	Apr. 3, 2009 Foreign clinical study results	53	Hydrosite Ag (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	An antibacterial wound dressing and protecting material containing sulfadiazine silver as an antibacterial ingredient added to the absorption pad layer of the approved product “Hydrosite Plus (Approval No. 22100BZX01097000).” In addition, soft gel is applied to the wound contact surface of the approved product to improve the operability. It is used for wounds with exudate fluid which have a high possibility of infection. Foreign clinical study results on a similar product which has a different adhesive agent on a wound contact layer were submitted to confirm if the antibacterial ingredient causes no problems such as protracted wound healing.
6-2	Sep. 24, 2013 Total review time: 501 days Regulatory review time: 197 days	Aug. 1, 2011 Domestic clinical study results	54	Versajet II (Smith & Nephew Wound Management KK)	Approval	Instrument & apparatus 12 Hydraulic knife	A device to be used for wound debridement (acute wounds, chronic wounds and burn wounds), soft tissue debridement and operative wound cleaning with waterjet. Improvement in connectivity between the hand piece and the console and water resistance of the console was provided to enhance the operability of the approved product “Versajet S (Approval No. 22400BZX00233000)”. A non-clinical study demonstrated the performance equality between both products. A clinical study was conducted to confirm the efficacy and safety of debridement.

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6-2	Sep. 27, 2013 Total review time: 1646 days Regulatory review time: 346 days	Jan. 25, 2007 Clinical evaluation report	55	Mepilex Ag (Mölnlycke Health Care K.K.)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	A wound dressing and protecting material used to "protect wound" reaching subcutaneous adipose tissue (except for third degree burns), "maintain a moist environment," "promote healing," and "relieve pain." It is used for wounds with exudate fluid which have a high possibility of infection. The product consists of a silicone gel-coated hydrophilic polyurethane foam containing silver and a vapor-permeable polyurethane film. A clinical evaluation report based on foreign use-results and published literature of this product and similar products was submitted to confirm if silver contained in the product causes no problem such as protracted wound healing.
6-2	Dec. 12, 2013 Total review time: 1081 days Regulatory review time: 256 days	- Clinical evaluation report	56	Laminoplasty Basket Plate Set (Ammtec Inc.)	Approval	Medical products 4 Internal fixation plate	An internal fixation plate used for fixing severed bone parts after spinal decompression for spinal cord compression. It is fixed to the space of vertebral lamina removed in laminoplasty by a screw. In addition, an implanted bone is able to be filled into the basket portion. A clinical evaluation report based on literature research on usual laminoplasty and use results of the approved product used in the surgery was submitted to demonstrate that the fixation performance and safety of this product are equivalent to the approved product.
6-2	Dec. 25, 2013 Total review time: 288 days Regulatory review time: 75 days	- Clinical evaluation report	57	SonicWeld Rx System (Nippon Martin K.K.)	Approval	Medical products 4 Absorbable plate for internal fixation	A device consisting of a plate and a pin used in a bone junction or reconstruction of cranio-maxillo-facial bone or bone fragment fixation in bone transplantation to cranio-maxillo-facial bone, and an ultrasonic fixator to fix them. The pin and the plate are made of polylactic acid which is absorbed into the body. This product has a characteristic that its ultrasonic fixator generates vibrating energy, which melts and hardens the pin in the bone hole to fix the plate. A clinical evaluation report was submitted to evaluate that the fixation performance and safety with this absorbable material are equivalent to those of similar products.
6-2	Jan. 28, 2014 Total review time: 1065 days Regulatory review time: 123 days	May 6, 2003 Clinical evaluation report	58	Simplex P with Tobramycin (Stryker Japan K.K.)	Approval	Medical products 4 Orthopedic bone cement	The acrylic orthopedic bone cement used to fix a substitution material (artificial bone head, hip joint or knee joint) to an in vivo bone. One gram of tobramycin is sterilely added to the approved product “Surgical Simplex.” It is used in the second stage of a two-stage revision prosthetic joint replacement associated with postoperative infection in a prosthetic joint replacement. A clinical evaluation report was submitted to demonstrate that the added antibacterial agent does not affect the efficacy and safety of the orthopedic bone cement.
6-2	Feb. 28, 2014 Total review time: 273 days Regulatory review time: 94 days	Aug. 3, 2005 Clinical evaluation report	59	Cobalt G-HV Bone Cement (At the time of approval, Biomet Japan, Inc.; currently, Biomet Japan, LLC)	Approval	Medical products 4 Orthopedic bone cement	A device that gentamicin sulfate is added to the company’s approved orthopedic bone cement “Cobalt HV Bone Cement” as an antibacterial agent. It is used in the second stage of a two-stage revision prosthetic joint replacement associated with postoperative infection in a prosthetic joint replacement. A clinical evaluation report was submitted to demonstrate that the added antibacterial agent does not affect the efficacy and safety of the orthopedic bone cement.
6-2	Mar. 19, 2014 Total review time: 2211 days Regulatory review time: 484 days	Jun. 2, 2006 Foreign clinical study results	60	Juvederm Vista Ultra (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. It is injected into the dermis to correct facial wrinkles and folds. Crosslinked and non-crosslinked hyaluronic acid, non-animal derived, obtained by fermentation of bacteria are mixed and filled into a syringe. Compared to the conventional injectable material using animal-derived collagen, the risk of allergy and infection was reduced. This product has different degrees of gel crosslinking from “Juvederm Vista Ultra Plus,” an application of which was submitted at the same time. This product is a softer injectable material. Foreign clinical study results were submitted to demonstrate its non-inferiority and safety compared to a control injectable material using collagen and safety.

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6-2	Mar. 19, 2014 Total review time: 2211 days Regulatory review time: 484 days	Jun. 2, 2006 Foreign clinical study results	61	Juvederm Vista Ultra Plus (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. It is injected into the dermis to correct facial wrinkles and folds. Crosslinked and non-crosslinked hyaluronic acid, non-animal derived, obtained by fermentation of bacteria are mixed and filled into a syringe. Compared to the conventional injectable material using animal-derived collagen, the risk of allergy and infection was reduced. This product has different degrees of gel crosslinking from “Juvederm Vista Ultra,” an application of which was submitted at the same time. This product is a harder injectable material. Foreign clinical study results were submitted to demonstrate its non-inferiority and safety compared to a control injectable material using collagen and safety.
8	Dec. 6, 2013 Total review time: 525 days Regulatory review time: 118 days	- Domestic clinical study results	62	Visceral Fat Meter EW-FA90 (Panasonic Corporation)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A body component analyzer consisting of an apparatus body, a measuring belt for abdomen, and pads. The cross section area of visceral fat estimated by a unique calculating formula based on abdominal impedance and the measured value of abdominal circumference is displayed on the apparatus body. A clinical study was conducted to evaluate the correlation between the cross section area of visceral fat by CT tomogram of the abdomen and an estimated value by this product and its screening performance (sensitivity and specificity).
8	Jan. 16, 2014 Total review time: 294 days Regulatory review time: 100 days	- Clinical evaluation report	63	Elmammo, Dedicated PET Scanner for Breast Imaging (Shimadzu Corporation)	Approval	Instrument & apparatus 10 Positron emission tomography device for nuclear medicine diagnosis	A dedicated PET scanner for breast imaging to provide image information of distribution of a positron radioactive drug administered to patients within breasts by detecting exogenously with a gamma radiation detector. A clinical evaluation report was submitted to evaluate the effectiveness of images provided by this product in comparison to those by whole-body PET, contract-enhanced MRI and mammography.