Products Approved in FY 2014: 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	Mar. 10, 2015 Total review time: 126 days Regulatory review time: 80 days	– No clinical study results	1	Hoya CTR (Hoya Corporation)	Change	Medical products 4 Ophthalmic intracapsular ring	An intracapsular ring inserted into a lens capsule is used when surgical difficulty can be expected in a cataract surgery because of the risks associated with completion of the surgery due to a weakness or rupture of Zinn's Zonule. An application for partial changes of approval application for medical device to mainly add the insertion method using an injector in the usage instructions. (A partial change during the reexamination period)
3-1	Apr. 7, 2014 Total review time: 255 days Regulatory review time: 110 days	Nov. 21, 2013 Global clinical trial and foreign clinical study results	2	Promus Premier Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent coated with everolimus to inhibit neointimal proliferation and a delivery catheter. The delivery catheter was improved by adding a link at the proximal end of a stent to produce axial strength to be superior to the original product. Clinical studies were conducted to confirm the efficacy and safety of this product in the treatment of symptomatic ischemic diseases.
3-1	May 20, 2014 Total review time: 110 days Regulatory review time: 76 days	Dec. 21, 2012 Domestic clinical study results	3	XIENCE Xpedition Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-3.75 mm and a delivery catheter used to implant a stent to the coronary stenosis site. This application for partial changes of approval application for medical device to add a stent size of 2.25mm diameter and change a drug release profile determination method. The added stent is identical to the company's approved product "XIENCE PRIME SV Drug-Eluting Stent (22500BZX00070000, hereinafter referred to as XIENCE PRIME SV). The stent delivery system is identical to that of the product of 2.5 mm diameter except for the balloon size. Results from clinical studies on "XIENCE PRIME SV" were submitted to confirm the efficacy and safety of this product in the treatment of symptomatic ischemic diseases.
3-1	Jun. 12, 2014 Total review time: 43 days Regulatory review time: 41 days	- No clinical study results	4	XIENCE PRIME SV Drug-Eluting Stent System (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent used for the treatment of patients with symptomatic ischemic heart disease who have a new coronary lesion (a lesion length of 22 mm or less) with a reference vessel diameter of 2.25-2.5 mm. This application for a partial change of approval application for medical device to modify inconsistent information provided in the raw material or component field. (A partial change during the reexamination period)
3-1	Jul. 25, 2014 Total review time: 91 days Regulatory review time: 48 days	- No clinical study results	5	Zilver Flex Vascular Stent for SFA (Cook Japan Inc.)	Change	Instrument & apparatus 7 Stent for blood vessel	A vascular stent to be used in patients with symptomatic vascular diseases of the above-the-knee femoropopliteal artery with reference vessel diameter of 4-7 mm. This product is used for the treatment for acute or impending occlusion caused by failure of intervention therapy or for dissection, etc. after the maximum number of "Zilver PTX Drug-Eluting Peripheral Stent" implantations. This application for a partial change of approval application for medical device to add a manufacturing site. (A partial change during the reexamination period)
3-1	Sep. 25, 2014 Total review time: 360 days Regulatory review time: 218 days	Nov. 7, 2012 Domestic clinical study results	6	SMART CONTROL Stent (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for iliac artery	A self-expanding nickel-titanium alloy stent inserted into the site of lesion in the iliac artery and/or the superficial femoral artery to expand/maintain a vascular lumen. This application for a partial change to add an elective therapy for symptomatic vascular diseases to indications for the superficial femoral artery. A clinical study was conducted to evaluate the safety and efficacy of this product in elective patients. (A partial change during the reexamination period)

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3-1	Sep. 25, 2014 Total review time: 360 days Regulatory review time: 218 days	Nov. 7, 2012 Domestic clinical study results	7	SMART Stent (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for blood vessel	A self-expanding nickel-titanium alloy stent inserted into the site of lesion in the superficial femoral artery to expand/maintain a vascular lumen. This application to add an indication of elective therapy for symptomatic vascular diseases. A clinical study was conducted to evaluate the safety and efficacy of this product in elective patients. (A partial change during the reexamination period)
3-1	Jan. 14, 2015 Total review time: 404 days Regulatory review time: 178 days	May 22, 2015 Domestic and global clinical study results	8	Misago (Terumo Corporation)	Change	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nickel-titanium alloy stent and a delivery system to deliver the stent to the site of lesion, used for the treatment of symptomatic artery disease by dilatation of artery and maintenance of the lumen with target vessel diameter of 4-7 mm and target lesion of 40-150 mm in the superficial femoral artery region, and for the treatment of acute or impending occlusion associated with unsuccessful intervention treatment in the lesion. An application for a partial change to add palliative treatment for symptomatic vascular disease to the indications of this product. Clinical studies were conducted to evaluate efficacy and safety of this product for palliative cases.
3-2	May 29, 2014 Total review time: 358 days Regulatory review time: 172 days	Jun. 12, 2012 Foreign clinical study results	9	AMPLATZER Vascular Plug 4 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	This device is used to occlude blood vessels, and reduce, block, or modify blood flow, by transdermally inserting and placing it in arteries/veins, except blood vessels within the heart and the skull. It was changed to a form with two conical blocks, and improved its components to reduce the profile of the whole plug (the diameter in its closed state) so that the device can be advanced through an imaging catheter, maintaining the same barrier area to blood flow as that of the approved product “AMPLATZER Vascular Plug (approval No.: 22400BZX00361000) (hereinafter referred to as AVP). Results from domestic clinical studies using AVP were submitted as clinical data of this product because several non-clinical studies including design verification and animal studies had shown that the same efficiency of this product is secured as that of AVP.
3-2	Nov. 7, 2014 Total review time: 728 days Regulatory review time: 281 days	- Foreign clinical study results	10	COOK Zenith Dissection Endovascular System (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft system used for the treatment of acute complicated Stanford type B aortic dissection, consisting of a stent graft that is placed to close the primary entry tear, a bare stent that enlarges compressed or narrowed intravascular lumen due to aortic dissection, and a delivery system that delivers/places them in the lesions. Results from clinical studies were submitted to evaluate efficacy and safety on this product for patients with acute complicated Stanford type B aortic dissection.
3-2	Nov. 14, 2014 Total review time: 135 days Regulatory review time: 81 days	- No clinical study results	11	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 protrusion and/or dropout of embolic coils into/from the parent artery during coil embolization. An application for partial changes to add VRD that improves conformability and visibility of the vascular wall, and a delivery system that improves the operability. This product is an orphan medical device. (A partial change during the reexamination period)
3-2	Dec. 24, 2014 Total review time: 398 days Regulatory review time: 146 days	Oct. 26, 2001 Clinical evaluation report	12	BIOPATCH Protective Disk with CHG (Johnson & Johnson K.K.)	Approval	Medical products 4 Protective patch for puncture site	A sterilized disk pad with a slit, which consists of a layer of polyurethane foam impregnated with chlorhexidine gluconate antimicrobial constituent and a covering layer of foam. This product protects the insertion site of various percutaneous devices by covering the site and absorbing the fluids like wound exudate. In patients who are inserted with central venous or arterial catheters, this product also reduces the incidence of catheter-related bloodstream infections and local infections. Clinical evaluation report summarizing the clinical results on this product was submitted to evaluate the reduction of catheter-related bloodstream infections and safety of this product.

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3-2	Mar. 24, 2015 Total review time: 361 days Regulatory review time: 240 days	Jun. 16, 2014 Domestic and foreign clinical study results	13	Sapien XT (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic heart valve system is used for transcatheter valve implantation for patients with symptomatic severe aortic valve stenosis and for whom surgical aortic valve replacement cannot be performed due to the risks of complications. An application for a partial change of approval application to add the 20 mm- and 29 mm-diameter valves as the variation in size. A clinical study was conducted to confirm the equivalence in efficacy and safety between the new sizes and approved existing sizes. (A partial change during the reexamination period)
3-2	Mar. 25, 2015 Total review time: 357 days Regulatory review time: 198 days	Jan. 17, 2014 Domestic and foreign clinical study results	14	CoreValve (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Transcatheter porcine pericardial valve	A self-expanding biological percutaneous aortic valve (porcine pericardial valve) system is used for transcatheter valve implantation in the native aortic valve for patients with symptomatic severe aortic stenosis attributed to sclerosis and degeneration of the cusp of the native aortic valve, for whom surgery cannot be performed. A clinical study was conducted to evaluate the efficacy and safety of this product and to confirm the compatibility to the domestic medical environment.
4	May 30, 2014 Total review time: 287 days Regulatory review time: 144 days	- Clinical evaluation report	15	Entovis MRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. 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	May 30, 2014 Total review time: 287 days Regulatory review time: 144 days	- Clinical evaluation report	16	Safio S (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. 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	Jun. 5, 2014 Total review time: 108 days Regulatory review time: 106 days	- Clinical evaluation report	17	Etrinsa 8-T ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. 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	Jun. 5, 2014 Total review time: 108 days Regulatory review time: 106 days	- Clinical evaluation report	18	Etrinsa 6 ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. 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	Jun. 30, 2014 Total review time: 271 days Regulatory review time: 95 days	- No clinical study results	19	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 the need for cardiac transplantation is indicated, showing continuous decompensation in spite of drug therapy or circulation assist techniques such as an external ventricular assist system, and for whom it is considered difficult to survive without a heart transplant. An application for a partial change to alter the alarm setting when the automatic restart function of a blood pump (automatic return mechanism) works. (A partial change during the reexamination period) [Orphan device]

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4	Jul. 31, 2014 Total review time: 265 days Regulatory review time: 177 days	- No clinical study results	20	Solia JT (Biotronik Japan, Inc.)	Change	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. An application for a partial change to add a new lead size of 45 cm in length. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 89 days Regulatory review time: 73 days	- Clinical evaluation report	21	Iforia 7 ICD ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator connected with electrodes placed within the heart. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	22	Linox Smart Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	23	Linox Smart Pro SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Aug. 5, 2014 Total review time: 60 days Regulatory review time: 51 days	- Clinical evaluation report	24	Linox Smart Pro S DX (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A catheter electrode connected with an implantable defibrillator. The patients implanted with the device can conditionally undergo an MRI scan. This application for a partial change of approval application to change conditions of MRI compatibility. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Sep. 9, 2014 Total review time: 187 days Regulatory review time: 126 days	- Clinical evaluation report	25	Sentus ProMRI OTW BP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A pacemaker lead connected with an implantable pulse generator and implanted in the coronary vein. The patients implanted with the device can conditionally undergo an MRI scan. A clinical evaluation report summarizing clinical data on this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Sep. 9, 2014 Total review time: 102 days Regulatory review time: 31 days	Jul. 26, 2013 No clinical study results	26	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A flexible over-the-wire balloon catheter inserted into a blood vessel using a conventional minimally invasive procedure. It is used in cryoablation of cardiac tissue. This application for partial changes of approval application to remove a leak detection wire traveling in an outer lumen, and to add a manufacturing site. (A partial change during the reexamination period)
4	Sep. 17, 2014 Total review time: 265 days Regulatory review time: 158 days	Apr. 27, 2010 Foreign clinical study results	27	Alair Bronchial Thermoplasty System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Bronchial thermoplasty catheter system	A catheter system used to apply high frequency energization to the bronchial wall to reduce asthmatic symptoms in patients aged 18 or older with severe asthma whose asthmatic symptoms are not well controlled with high-dose inhaled steroids and long-acting beta2-agonists. Foreign clinical studies were conducted to demonstrate its relieving effect on asthmatic symptoms.

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4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 154 days	- Foreign clinical study results	28	Evera MRI ICD Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator intended for the treatment of ventricular tachycardia, etc. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company's own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 142 days	- Foreign clinical study results	29	Sprint Quattro MRI Screw-In Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable catheter electrode connected with an implantable defibrillator and a defibrillator with biventricular pacing. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company' s own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 209 days Regulatory review time: 142 days	- Foreign clinical study results	30	Sprint Quattro MRI Screw-In Lead S (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An implantable catheter electrode connected with an implantable defibrillator and a defibrillator with biventricular pacing. The patients implanted with the device can conditionally undergo an MRI scan. This is a new application for the product with which an MRI scan can be conditionally conducted, based on the company' s own approved products. In order to evaluate the safety of this product in MRI scans, results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Sep. 25, 2014 Total review time: 87 days Regulatory review time: 44 days	Dec. 10, 2010 No clinical study results	31	Medtronic CryoConsole (Medtronic Japan Co., Ltd.)	Change	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 cryoablation catheters. This application for a partial change of approval application for medical device to add a manufacturing site. The application falls under "expedited review of changes of manufacturing site" stated in "Acceleration of the Procedure for Changing or Adding Manufacturing Site of Medical Devices and In-vitro Diagnostics" (PFSB/ELD Notification No. 0330004, PFSB/CND Notification No. 0330012 dated on March 30, 2007). (A partial change during the reexamination period)
4	Oct. 9, 2014 Total review time: 164 days Regulatory review time: 95 days	Oct. 13, 2014 Foreign clinical study results	32	CapSureFIX Novus Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an implantable pacing lead used by connecting it to an implantable cardiac pacemaker or defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for requirements for imaging. The application is for a partial change to conditionally allow MRI scan with this device. Data on foreign clinical study results related to this product were submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	2014/10/20 Total review time: 343 days Regulatory review time: 86 days	Oct. 13, 2014 Foreign clinical study results	33	CapSureFIX Novus MRI Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to pulse generators including an implantable cardiac pacemaker or defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. Data on foreign clinical study results related to this product 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	Nov. 14, 2014 Total review time: 162 days Regulatory review time: 95 days	- Foreign clinical study results	34	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add a single-chamber type which conditionally allows MRI scan to the existing dual-chamber type. Data on foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 130 days Regulatory review time: 83 days	- Clinical evaluation report	35	Iperia 7 ICD DF-1 ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an implantable cardiac defibrillator used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. This product was developed based on the approved product "Ilesto 7 ICD Pro" (Approval No.: 22500BZX00292000). The major improvements from the approved product include the addition of conditions for the strength of static magnetic field used in MRI and an additional function for detecting ventricular tachycardia. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 105 days Regulatory review time: 80 days	- Clinical evaluation report	36	Itrevia 7 CRT-D ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with defibrillator function used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. This product was developed based on the approved product "Ilesto 7 CRT-D Pro" (Approval No.: 22500BZX00293000). The major improvement from the approved product is an additional function of ventricular tachycardia detection. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	37	Linox Smart Pro S (Biotronik Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	38	Linox Smart Pro SD (Biotronik Japan, Inc)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)
4	Nov. 17, 2014 Total review time: 41 days Regulatory review time: 40 days	- Clinical evaluation report	39	Linox Smart Pro S DX (Biotronik Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used by connecting it to an implantable defibrillator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to add the condition for the strength of static magnetic field used in MRI scans. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (A partial change during the reexamination period)

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4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- No clinical study results	40	Nuance MRI RF (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. Patients implanted with the device can undergo an MRI scan under specific conditions. The application is for a partial change to add concomitant medical devices to perform MRI scan. (A partial change during the reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- No clinical study results	41	Accent MRI RF (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term. Patients implanted with the device can undergo an MRI scan under specific conditions. The application is for a partial change to add concomitant medical devices to perform MRI scan. (A partial change during the reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- Clinical evaluation report	42	IsoFlex Optim J (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead. The patient implanted with the device except for the 46 cm straight lead can undergo an MRI scan under specific conditions. The application is for a partial change to conditionally allow MRI scan with this device. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Nov. 20, 2014 Total review time: 168 days Regulatory review time: 105 days	- Clinical evaluation report	43	IsoFlex Optim (St. Jude Medical Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead. The patient implanted with the device except for the 46 cm straight lead can undergo an MRI scan under specific conditions. The application is for a partial change to conditionally allow MRI scan with this device. A clinical evaluation report summarizing foreign clinical study results related to this product was submitted to evaluate the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Dec. 22, 2014 Total review time: 115 days Regulatory review time: 59 days	- No clinical study results	44	Ingenio MRI (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker to regulate the heart rhythm by cardiac stimulation for a long term in order to perform the treatment of bradycardia. The application is for a partial change to change the materials of the header part. (A partial change during the reexamination period)
4	Jan. 19, 2015 Total review time: 109 days Regulatory review time: 62 days	- No clinical study results	45	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an axial-flow implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who is are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survival without heart transplant. The application is for partial changes to mainly change the battery cell incorporated into the portable battery. (A partial change during the reexamination period)
4	Jan. 21, 2015 Total review time: 125 days Regulatory review time: 55 days	Jun. 29, 2012 No clinical study results	46	LifeVest Wearable Cardioverter Defibrillator (ZOLL Lifecor Corporation)	Change	Instrument & apparatus 12 Wearable defibrillator	The device is a wearable cardioverter defibrillator intended for the following patients: Patients for whom indication for an implantable cardiac defibrillator (ICD) is unconfirmed despite having a high risk of sudden cardiac death due to ventricular tachycardia or ventricular fibrillation; Patients in whom an ICD cannot be implanted immediately due to their medical conditions although ICD is indicated. This wearable cardioverter defibrillator is used in the period until the propriety of indication of ICD is determined or the implantation is performed. The application is for a partial change to add an attaching method of velocro to electrocardiogram electrodes without an adhesive to the existing direct adhesive method. (A partial change during the reexamination period)

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4	Feb. 3, 2015 Total review time: 418 days Regulatory review time: 174 days	- Clinical evaluation report	47	Beflex lead (Sorin CRM SAS)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to an implantable cardiac pacemaker. The application is for a partial change to allow MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Feb. 3, 2015 Total review time: 417 days Regulatory review time: 173 days	- Clinical evaluation report	48	Kora 100 (Sorin CRM SAS)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	The device is an implantable cardiac pacemaker used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 4, 2015 Total review time: 132 days Regulatory review time: 87 days	- Clinical evaluation report	49	Itrevia 7 CRT-D QP ProMRI (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function implanted in the chest or abdomen for the treatment of ventricular tachycardia, etc. by ventricular sensing, pacing and defibrillation. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 4, 2015 Total review time: 132 days Regulatory review time: 87 days	- Clinical evaluation report	50	Sentus ProMRI OTW QP (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is a pacemaker lead with four electrodes at its tip used by placing it in the coronary vein and connecting it to an implantable pulse generator. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. A clinical evaluation report was submitted to confirm the safety of this device in MRI scans. (The original product is in a reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical evaluation report	51	Linox Smart Pro DF4 SD (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used for conducting ventricular sensing and pacing, antitachycardia pacing, and defibrillation by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (A partial change during the reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical evaluation report	52	Protego Pro S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable defibrillator/pacemaker lead used for conducting ventricular sensing and pacing, antitachycardia pacing, and defibrillation by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (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	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical study results	53	Iforia 7 ICD ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	The device is an implantable defibrillator used by connecting it to electrodes placed in the heart. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change of approval application to add a model having a different header. (A partial change during the reexamination period)
4	Mar. 23, 2015 Total review time: 101 days Regulatory review time: 84 days	- No clinical study results	54	Solia S (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Endocardial implantable pacemaker leads	The device is an endocardial implantable pacemaker lead used by connecting it to an implantable defibrillator, etc. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change of approval application to change the condition allowed an MRI scan when the device is connected to a specific implantable defibrillator. (A partial change during the reexamination period)
4	Mar. 26, 2015 Total review time: 125 days Regulatory review time: 97 days	- Foreign clinical study results	55	Sprint Quattro Screw-In Lead S (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable catheter electrode used by connecting it to an implantable defibrillator and a defibrillator with biventricular pacing. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change for some components with which an MRI scan can be conditionally conducted. In order to evaluate the safety of this product in MRI scans, the results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
4	Mar. 26, 2015 Total review time: 125 days Regulatory review time: 97 days	- Foreign clinical study results	56	Sprint Quattro Screw-In Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	The device is an implantable catheter electrode used by connecting it to an implantable defibrillator and a defibrillator with biventricular pacing. Patients implanted with the device can conditionally undergo an MRI scan only when the patient's condition is suitable for the requirements for imaging. The application is for a partial change for some components with which an MRI scan can be conditionally conducted. In order to evaluate the safety of this product in MRI scans, the results of clinical studies using the original product were submitted, in which the extrapolability in the evaluation was explained. (The original product is in a reexamination period)
5	Sep. 30, 2014 Total review time: 305 days Regulatory review time: 202 days	Apr. 18, 2014 No clinical study results	57	InterStim II Neurostimulator for Sacral Neuromodulation (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Implantable stimulator for bladder and bowel control	An implantable nerve stimulation system consisting of an electric stimulator and leads to be used in sacral nerve stimulation therapy for fecal incontinence. This application for a partial change of approval application to change a testing stimulator to a new type. A testing stimulator control is changed from a constant voltage control to a constant current control, while an implantable electric stimulator remains to be controlled by a constant voltage. (A partial change during the reexamination period)
6-1	Jun. 5, 2014 Total review time: 160 days Regulatory review time: 40 days	Jul. 20, 2006 Clinical evaluation report	58	Aequalis Reversed Shoulder Prosthesis (Tornier S.A.S.)	Change	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system used in patients with shoulder rotator cuff dysfunction. This application for partial changes to add new components (eccentric or other type of inserts and glenoid sphere, small-diameter and HA-coated base plate, conversion adaptor for anatomical type) and to add usage (fixation of glenoid component with specific bone graft: BIO-RSA). A clinical evaluation report was submitted to demonstrate that this device is equivalent to the approved product and that there is no new unacceptable risk while option for the product is extended by the added components and the usage.

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
6-1	Sep. 25, 2014 Total review time: 118 days Regulatory review time: 79 days	Oct. 11, 2012 No clinical study results	59	Trabecular Metal Reverse Shoulder System (Zimmer K.K.)	Change	Medical products 4 Total shoulder prosthesis	A reversed shoulder prosthesis system used in patients with shoulder rotator cuff dysfunction including arthropathy with tendon rupture and massive rotator cuff tears. This application for a partial change of approval application to add a new component with a changed base plate (extended post length and off-set model), which is intended to improve suitability to patients' bone shapes. Based on the results of non-clinical studies, it was judged that new additional clinical evaluation is not required, because it is difficult to assume that a new clinical risk is actualized by the difference from the approved product. (A partial change during the reexamination period)
6-1	Oct. 9, 2014 Total review time: 197 days Regulatory review time: 90 days	Aug. 18, 2011 Clinical evaluation report	60	Lima Reverse Shoulder System (Lima Japan K.K.)	Approval	Medical products 4 Total shoulder prosthesis	A shoulder prosthesis having the concept of a reversed shoulder prosthesis system in which the anatomical structure is reversed. It is used for cases of rotator cuff dysfunction such as a massive rotator cuff tears or rotator cuff tear arthropathy. When it is difficult to be combined with a reversed shape, it can be combined with an anatomical shape in humerus or total shoulder joint replacement. A clinical evaluation report was submitted to confirm that the efficacy and safety of this device are equivalent to the existing approved devices based on overseas usage histories and publications of this device and similar devices.
8	Jul. 3, 2014 Total review time: 415 days Regulatory review time: 200 days	- Domestic and foreign clinical study results	61	Radioactive Pharmaceutical Synthesizer NEPTIS Plug-01 (Eli Lilly Japan K.K.)	Approval	Instrument & apparatus 10 Radiopharmaceutical synthesizer	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound, florbetapir (18F) injection by remote control system indicated for the visualization of beta-amyloid plaque in the brain in patients with cognitive impairment who are suspected of having Alzheimer's disease. Results from non-clinical studies, and domestic and foreign clinical studies were submitted as evaluation data on the efficacy and safety of this product and florbetapir (18F) injection.
8	Nov. 7, 2014 Total review time: 322 days Regulatory review time: 180 days	Oct. 18, 2012 Foreign clinical study results	62	MR-Guided Focused Ultrasound Surgery System ExAblate 2000 (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 12 Ultrasound hyperthermia system	The device is a focused ultrosonic surgery system intended for heating and necrotizing target tissues by focusing ultrasound generated using an external transducer on internal targets. The application is for partial changes to (1) add a new indication, "relief of pain due to painful metastatic bone cancer" and (2) make an improvement intended to enhance operability in a previously approved indication, "improvement of symptoms of symptomatic uterine myoma." For (1), results of clinical study conducted to evaluate the efficacy and safety of this device in the new additional indication were submitted. For (2), results of non-clinical study conducted to evaluate efficiency of the additional capability, etc. in previously approved indication were submitted.
8	Dec. 12, 2014 Total review time: 73 days Regulatory review time: 19 days	Jan. 21, 2010 No clinical study results	63	Magnetic Navigation System Niobe (Medix Japan, Inc.)	Change	Instrument & apparatus 51 Cardiac Mapping System Workstation	The device is a guiding system that navigates an exclusive catheter for this system to a target region in the diagnosis of arrhythmia and intervention procedures. This device is used in combination with cardiovascular fluoroscopic X-ray diagnosing apparatus, and consists of a magnetic positioner, a control cabinet, a user interface, a ceiling-suspended monitor and a catheter advancement system. The application is for partial changes to add an image control support device, and to change the monitor size and emergency switch. (A partial change during the reexamination period)
8	Mar. 25, 2015 Total review time: 266 days Regulatory review time: 174 days	Apr. 8, 2011 Foreign clinical study results	64	NovoTTF-100A System (NovoCure Ltd.)	Approval	Instrument & apparatus 12 Alternating electric field tumor treatment system	The medical device is a non-invasive device that delivers alternating electric fields -referred to as Tumor Treating Fields (TTfield) - that inhibit cancer cell replication and cause cancer cell death. TTFields are delivered to the tumor in the brain through insulated transducer arrays (INE transducer array) that are placed on the scalp. A clinical trial was conducted to compare the efficacy and safety of the device to chemotherapy in patients with recurrent glioblastoma multiforme after receiving all possible surgery and radiation therapy options. [Priority review]

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
Specified partial change	May 1, 2014 Total review time: 76 days Regulatory review time: 32 days	- No clinical study results	65	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Change	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft used for the treatment of thoracic aortic aneurysm. This application for a partial change of approval application for medical device to add a PFOA-free raw material to a raw material of graft “polytetrafluoroethylene.” The application was submitted as a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008).
Specified partial change	Jul. 25, 2014 Total review time: 121 days Regulatory review time: 36 days	Jan. 4, 2008 No clinical study results	66	NaviStar RMT ThermoCool (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter for the radiofrequency catheter ablation and for the electrophysiological study; it is used to treat symptomatic drug refractory paroxysmal and persistent atrial fibrillation, atrial flutter and ventricular tachycardia which is not treated effectively in other ways. This device is manipulated with a magnetic navigation system. It also has an irrigation system that flows with saline from an irrigation hole at the tip of the electrode. This application for a partial change of approval application for medical device to change a raw material of the hub (polycarbonate). The application was submitted as a "specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A partial change during the reexamination period)
Specified partial change	Aug. 29, 2014 Total review time: 80 days Regulatory review time: 80 days	- No clinical study results	67	Matsudaito (Sanyo Chemical Industries, Ltd.)	Change	Medical products 4 Non-absorbable local hemostatic material for central circulation system	A non-absorbable local hemostatic material consisting of sealant liquid (main body) filled in a syringe and accessory sheets and spatula. This application for a partial change of approval application for medical device to add a manufacturer of a raw material of sealant liquid, fluorine-containing diisocyanate. The application was submitted as a "specified partial change" based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A partial change during the reexamination period)

Products Approved in FY2014: 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. 3, 2014 Total review time: 83 days Regulatory review time: 58 days	- Domestic clinical study results	1	Alcon Acrysof IQ Restor +2.5D Single-Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens to correct near and/or far vision in patients with aphakia. The raw materials, basic form and principle of the multifocal mechanism are identical to those of the company's approved product, "Alcon Acrysof IQ Restor Single-Piece" (Approval No.: 22000BZX00970000). However, the diameter of apodized diffraction region, diffraction region number and central refractive region are different from the existing approved product. Domestic clinical study results were submitted to evaluate the efficacy and safety of the multifocal mechanism.
1	Jun. 30, 2014 Total review time: 349 days Regulatory review time: 178 days	Mar. 8, 2012 Clinical evaluation report	2	Advanced Femtosecond Laser (AMO Japan K.K.)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An ophthalmic laser corneal surgical instrument to create lamellar cut/resection of the cornea by irradiating a focused ultrashort pulsed laser beam (wavelength 1053 nm, few hundred femtosecond) on corneal tissue. It is used for creation of a corneal flap in LASIK (laser in-situ keratomileusis) and for corneal resection in keratoplasty. An application for partial changes to mainly add arcuate incisions in the cornea (penetrating incision or intrastromal incision) in ophthalmic surgery to the intended use. A clinical evaluation report was submitted to confirm the safety of intrastromal incision in actual clinical practice because an intrastromal incision cannot be performed with a diamond knife.
1	Aug. 25, 2014 Total review time: 299 days Regulatory review time: 66 days	Oct. 18, 2010 Foreign clinical study results	3	LenSx Laser System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 31 Ophthalmic pulsed laser surgical instrument	An ophthalmic pulsed laser surgical instrument used for incision of anterior lens capsule, split of crystalline lens and corneal incision in cataract surgery. It consists of main body of the laser oscillator and patient interface that sucks and fixes the affected patient's eye. Although in conventional cataract surgery, incision of the anterior lens capsule, split of crystalline lens and corneal incision are performed using a cystotome, ultrasonic shock wave generated by cataract surgery instrument and ophthalmic knife, respectively, this device enables these procedures to be performed consecutively or in arbitrary combinations of each function using a femtosecond laser having a maximum energy of 15 microjoules. A foreign clinical study was conducted to confirm that this product has no particular problems by comparing this method to existing methods in cataract surgery.
2	Jun. 11, 2014 Total review time: 168 days Regulatory review time: 76 days	Jun. 30, 2004 Domestic clinical study result and clinical evaluation report	4	Straumann Implant (SLActive) BL (Straumann Japan K.K.)	Approval	Medical products 4 Dental implant body	Pure titanium dental implant body having the roughened surface by sandblasting and acid etching. This product is a bone level type of the company's approved product "Straumann Implant (SLActive) TL" (Approval No.: 22600BZX00016000), which accelerates osteointegration and enables earlier loading by providing the product sealed into a vial filled with normal saline to keep the hydrophilic nature of titanium until just before use. 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.
2	Jan. 23, 2015 Total review time: 1488 days Regulatory review time: 319 days	Dec. 14, 2011 Clinical evaluation report	5	Tapered Screw-Vent X (Zimmer K.K.)	Approval	Medical products 4 Intraosseous dental implant	An implant fixture partially or wholly implanted in the jawbone, which supports for the upper structure. In order to confirm the bone fixation performance of the new structure with a porous structure on the surface, a clinical evaluation report created from clinical results in published literatures on this product was submitted to evaluate the clinical performance in addition to the normal performance evaluation test.

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	Jul. 25, 2014 Total review time: 512 days Regulatory review time: 183 days	- Domestic clinical study results	6	MOMO Coronary Stent System (Japan Stent Technology Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent consisting of a stent to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion in percutaneous coronary stent placement. This stent is made of a cobalt-chromium alloy and the surface is coated with a diamond-like carbon to reduce in-stent restenosis. A domestic clinical study was conducted to verify the efficacy and safety of this product in patients with symptomatic ischemic heart disease who have a new stenosis or restenosis of a coronary lesion (lesion length is 26 mm or less) with a reference vascular diameter ranging from 3.0 mm to 4.0 mm.
3-1	Aug. 29, 2014 Total review time: 336 days Regulatory review time: 118 days	Jan. 11, 2013 Clinical evaluation report	7	TransForm Occlusion Balloon Catheter (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	An intravascular catheter for embolization of the central circulation system used for temporary interruption of blood flow in percutaneous intravascular surgery or for prevention of a coil mass from protruding into and/or prolapsing into the parent artery as an adjunct of coil embolization for cerebral aneurysms. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-1	Oct. 30, 2014 Total review time: 269 days Regulatory review time: 195 days	Feb. 17, 2012 Foreign clinical study results	8	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 zotarolimus-eluting stent to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. An application for a partial change to add a 4.0-mm diameter stent. Foreign clinical study results were submitted to evaluate the efficacy and safety of a stent having a diameter of 4.0 mm.
3-1	Nov. 17, 2014 Total review time: 836 days Regulatory review time: 250 days	- Domestic clinical study results	9	Vival Coronary Stent (Goodman Co., LTD.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be placed at the narrowed or blocked segment of coronary artery to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion and dilate the stent. The raw materials were changed from those of the "Duraflex Coronary Stent" (Approval No.: 21500BZY00516000) to reduce the thickness of the stent, and the delivery catheter was also changed. A domestic clinical study was conducted to evaluate the efficacy and safety of this product in patients with symptomatic ischemic heart diseases who have a new stenosis or restenosis lesion in a coronary artery (a lesion length of 25 mm or less).
3-1	Nov. 28, 2014 Total review time: 246 days Regulatory review time: 164 days	Nov. 21, 2013 Global clinical trial and foreign clinical study results	10	Promus Premier LV Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a everolimus-eluting stent with diameter of 4.0 mm to be inserted and placed at the site of a lesion to maintain the patency of the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The product having a diameter of 2.25 - 3.5 mm was previously approved in Japan as "Promus Premier Stent System" (Approval No.: 22600BZX00181000). A clinical study was conducted to evaluate the efficacy and safety of the stent with a 4.0 mm diameter.
3-1	Jan. 19, 2015 Total review time: 528 days Regulatory review time: 220 days	Jan. 21, 2005 Clinical evaluation report	11	Outback Re-entry Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Vascular recanalization catheter	A catheter consisting of a cannula, an outer shaft, a lure assembly and a handle. It assists recanalization back into the true lumen with a guidewire advanced via the subintimal space during percutaneous angioplasty to treat chronic total occlusion in the region of the femoropopliteal artery. A clinical evaluation report has been created based on the reports that were collected from an adverse-event database with clinical results and published literatures. The clinical report was submitted to confirm the performance and safety of this product to be used for the lesions with chronic total occlusion.

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3-1	Feb. 12, 2015 Total review time: 240 days Regulatory review time: 116 days	Oct. 26, 2011 Foreign clinical study results	12	ASSURANT COBALT Stent (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac artery	A balloon expandable stent and the delivery system used to maintain the patency of the vessel lumen of de novo and restenotic symptomatic lesions in the common iliac artery and external iliac artery. A clinical study was conducted to evaluate the efficacy and safety of this product in clinical use.
3-2	May 19, 2014 Total review time: 220 days Regulatory review time: 92 days	Scepter C：Sep. 29, 2011, Scepter XC：Jan. 13, 2012 Clinical evaluation report	13	Scepter C (Terumo Corporation)	Change	Instrument & apparatus 51 Intravascular catheter for embolization of the central circulation system	A balloon catheter used for temporary interruption of blood flow in percutaneous intravascular surgery or for prevention of a coil clot protruding into and/or dropping out from the parent artery as an adjunct of coil embolization for cerebral aneurysms. A clinical evaluation report was submitted to confirm the efficacy and safety of balloon-assisted coil embolization using this device.
3-2	Aug. 1, 2014 Total review time: 458 days Regulatory review time: 265 days	Feb. 14, 2013 Foreign clinical study results	14	AORFIX AAA Stent Graft System (Medico's Hirata Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft system consisting of a stent graft and delivery system used for intravascular treatment of abdominal aortic aneurysms and aortic aneurysms extended from the abdominal aorta to the iliac artery. For the indication of infrarenal aortic aneurysm, although an existing approved stent graft for abdominal aortic aneurysms is limited to treat patients with an aortic neck angle not greater than 60 degrees, this product enable to treat patients with the angles of up to 90 degrees. A foreign clinical study was conducted to evaluate the efficacy and safety of this product in case groups where the aortic neck angles are ranging from 60 degrees to 90 degrees.
3-2	Nov. 20, 2014 Total review time: 262 days Regulatory review time: 181 days	- Domestic clinical study results	15	Steering Microcatheter (Akita Sumitomo Bakelite Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system Microcatheter	An intravascular microcatheter for the central circulation system (except for the cardiac and cerebral [intracranial] vessels) used for selective angiography, drug infusion and embolization. The direction of the catheter tip can be controlled by rotating a dial and thereby the catheter can be inserted selectively into the bent vessels without a guidewire. The results of a domestic clinical study was submitted to confirm the efficacy and safety of this product that enables directional operation of the catheter tip by the dial.
3-2	Jan. 23, 2015 Total review time: 490 days Regulatory review time: 100 days	Apr. 9, 2013 Foreign clinical study results	16	Gore Acuseal Vascular Graft (W.L. GORE & Associates, Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel using heparin of the non-central circulation system	An artificial triple-layered blood vessel used for vascular access. The lumen is coated with heparin. A clinical study was conducted to evaluate the efficacy and safety of this product in patients requiring hemodialysis.
4	Aug. 8, 2014 Total review time: 294 days Regulatory review time: 197 days	Oct. 28, 2010 Foreign clinical study results	17	ccNexfin Hemodynamic Monitor (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 21 Monitor of arterial blood pressure and cardiac output	The device is an apparatus for continuously monitoring hemodynamic parameters including systolic/diastolic blood pressures (BP), heart rate (HR), stroke volume (SV), cardiac output (CO) and systemic vascular resistance (SVR). The hemodynamic parameters are calculated from arterial blood pressure waveform at the fingertips measured non-invasively and continuously by using the volume-clamp method. Non-clinical study and foreign clinical study results were submitted as the evaluation data on the efficacy and safety of this 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
4	Aug. 19, 2014 Total review time: 560 days Regulatory review time: 252 days	Jun. 30, 2010 Foreign clinical study results	18	TVC Imaging System (Nipro Corporation)	Approval	Instrument & apparatus 12 Cardiovascular ultrasonic diagnostic imaging instrument	The device is a device to visualize the form and characteristics of the vascular lumen and wall in the central circulation system and to provide the image data for diagnosis. This device has a function to detect a lipid core plaque using near-infrared light and to provide image data combined with an ultrasonogram. However, the image detected by this function is not intended to diagnose. A clinical study was conducted to evaluate that the device can detect a lipid core plaque using near-infrared light.
4	Aug. 19, 2014 Total review time: 512 days Regulatory review time: 159 days	Jun. 30, 2010 Foreign clinical study results	19	TVC Insight Catheter (Nipro Corporation)	Approval	Instrument & apparatus 51 Central circulation system intravascular ultrasound catheter	The device is a catheter equipped with a transducer for sending and receiving ultrasound on the tip to visualize the form and characteristics of the vascular lumen and wall in the central circulation system. This device is also equipped with an optical mirror and an optical fiber that irradiate and collect near-infrared light to detect a lipid core plaque and to provide image data combined with an ultrasonogram. However, the image detected by near-infrared light is not intended to diagnose. A clinical study was conducted to evaluate that the device can detect a lipid core plaque using near-infrared light.
4	Nov. 26, 2014 Total review time: 299 days Regulatory review time: 115 days	- Foreign clinical study results and clinical evaluation report	20	Vercise DBS System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 12 Electrical brain stimulation device for tremor	The device is an electrical brain stimulation device used to reduce tremors that do not sufficiently respond to drug therapy and symptoms of movement disorder associated with Parkinson's disease by providing an electrical stimulus unilaterally or bilaterally to the deep brain (thalamus, subthalamic nucleus or internal globus pallidus). This device consists of an implantable pulse generator and lead, an external trial stimulator to evaluate presence or absence of effect by test stimulation, and a remote controller to control stimulation parameter. Foreign clinical study results to evaluate the efficacy and safety in patients with Parkinson's disease and a clinical evaluation report summarizing foreign clinical studies and published papers to evaluate the efficacy and safety in patients with tremors were submitted.
4	Dec. 22, 2014 Total review time: 361 days Regulatory review time: 268 days	Jan. 30, 2014 Foreign clinical study results	21	Navvus Catheter (ACIST Medical Systems, Inc.)	Approval	Instrument & apparatus 51 Central circulation system transducer-tipped catheter	The device is a catheter with a pressure sensor at the distal tip. It is used for invasive measuring of intravascular pressure in the central and non-central circulation systems excluding the cerebral blood vessel and carotid artery, and also used for evaluation of hemodynamics. The catheter type was adopted to enhance the operability by comparing with a conventional wire type of a similar medical device. The data on results of clinical study to compare the measurement accuracy with that of a previously approved product "SJM PressureWire Certus" (Approval No.: 22300BZX00247000) was submitted.
5	Jul. 9, 2014 Total review time: 575 days Regulatory review time: 159 days	Jan. 28, 1993 Clinical evaluation report	22	EHL Autolith (AMCO Inc.)	Approval	Instrument & apparatus 12 Intracorporeal electrohydraulic shock wave lithotriptor	An intracorporeal electrohydraulic shock wave lithotriptor used to crush calculuses in the kidney and bladder (urinary calculus) and bileduct stone using an electrohydraulic shock wave. A clinical evaluation report was submitted to evaluate the efficacy and safety of this product in patients with bile duct stone.
5	Sep. 10, 2014 Total review time: 376 days Regulatory review time: 84 days	Mar. 29, 2011 Clinical evaluation report	23	Cook Evolution Duodenal Stent System (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Gastroduodenal stent	A stent system to place a stent by endoscopically inserting a delivery system to maintain patency in gastroduodenal obstruction and duodenal stenosis associated with malignant tumors in patients for whom alleviative gastrectomy is considered difficult to be performed or other treatments is unlikely to have an effect. A clinical evaluation report was submitted to confirm the efficacy and safety of treatment using this stent in patients with malignant gastric outlet obstruction.

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	May 7, 2014 Total review time: 303 days Regulatory review time: 116 days	May 31, 2007 Clinical evaluation report	24	VEPTR II System (Johnson & Johnson K.K.)	Approval	Medical products 4 Internal fixation system	An internal fixation system made of titanium alloy and titanium which corrects thoracic deformity while allowing further growth of thorax by implanting an expandable-metallic rod which is extendable along body axial direction in the thorax of the patients with thoracic insufficiency syndrome. Based on the approved product "VEPTR system (Approved No.: 22000BZX01655000)", and major difference from the approved product is that the usability and compatibility of this device with the patient's thorax were enhanced by adding variations on the components or improving the components. A clinical evaluation was conducted with the literatures on this product and the approved product, overseas safety information and clinical evaluation report based on a use-results survey of the approved product to confirm that efficacy and safety of this device equivalent to or greater than that of the approved product were also maintained by the differences.
6-2	May 26, 2014 Total review time: 124 days Regulatory review time: 91 days	Apr. 11, 2013 Domestic clinical study results	25	HEALICOIL RG Suture Anchor (Smith & Nephew Endoscopy KK)	Approval	Medical products 4 Absorbable ligament fixation	A suture anchor used to fix soft tissues of the tendons and ligaments to the bones of the shoulder, elbow, groin (gluteal tendons), knee and foot/ankle. It consists of an absorbable anchor that adopts the hollow coil configuration of the approved product "HEALICOIL Suture Anchor" (Approval No.: 22500BZX00193000), sutures and an inserter. The point of improvement is that a glycolic acid/L-lactic copolymer and a mixture of calcium sulfate and beta-tricalcium phosphate which are new bioabsorbable materials, were adopted as raw materials. The results of a domestic clinical study on arthroscopic labrum repair in shoulder for traumatic shoulder instability using "Osteoraptor OS Anchor" (Approval No.: 22600BZX00228000) made of the same raw materials as this product were submitted to confirm the efficacy and safety of the new bioabsorbable materials.
6-2	May 26, 2014 Total review time: 180 days Regulatory review time: 119 days	May 18, 2012 Domestic clinical study results	26	PICO Wound Therapy System (Smith & Nephew Wound Management KK)	Approval	Medical products 4 Single-use negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by providing a locally managed negative-pressure for patients with a refractory wound who have not responded to or are considered to be unlikely to respond to existing treatment. This device consists of a negative pressure maintenance unit, dressing and a tube to connect the unit and the dressing. Exudate is retained in the dressing applied to wound area and transpired through the backing film. The point of improvement from the approved product "RENASYS Wound Therapy System" (Approval No: 22400BZX00276000) is a downsizing and weight lightening of the main body of the device which allows the device to be used for outpatient. A clinical study on inpatients and outpatients was conducted to evaluate if the performance of this device was equivalent to that of approved product, and to confirm any defects or adverse events specific to this product.
6-2	May 26, 2014 Total review time: 124 days Regulatory review time: 103 days	Jan. 27, 2011 Domestic clinical study results	27	Osteoraptor OS Anchor (Smith & Nephew Endoscopy KK)	Approval	Medical products 4 Absorbable ligament fixation	A suture anchor used to fix the soft tissues of tendons and ligaments to the bone in the shoulder, elbow, wrist/hand, groin, knee and foot/ankle. It consists of an absorbable anchor, sutures and an inserter. The point of improvement is that a glycolic acid/L-lactic acid copolymer and a mixture of calcium sulfate and beta-tricalcium phosphate which are new bioabsorbable materials, were adopted as raw materials for the anchor. The results of a domestic clinical study on arthroscopic labrum repair in shoulder for traumatic shoulder instability using this device were submitted to confirm the efficacy and safety of the new bioabsorbable materials.

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6-2	Jun. 23, 2014 Total review time: 1242 days Regulatory review time: 281 days	Apr. 30, 1998 Foreign clinical study results	28	OASIS Extracellular Matrix (Cook Japan Inc.)	Approval	Medical products 4 Collagen-based artificial skin	Collagen-based artificial skin for control and treatment of full and partial thickness wounds. Porcine small-intestinal submucosa is used as a raw material. Viral clearance study results were submitted to evaluate the virus safety of this product. In addition, foreign post-marketing clinical study results were submitted to evaluate the efficacy and safety in clinical use for patients with venous ulceration and pressure ulcers (decubitus ulcers).
6-2	Dec. 3, 2014 Total review time: 244 days Regulatory review time: 85 days	Mar. 18, 1998 Clinical evaluation report	29	Orthofix HA Coating Pin (Orthofix S. r. l.)	Approval	Medical products 4 Internal fixation pin	A stainless steel pin used with external fixators. No products such as pins coated with hydroxyapatite to enhance the fixation have been approved in Japan. Therefore, in addition to the results of a tensile strength test, a clinical evaluation report summarizing overseas published papers was submitted to evaluate the efficacy and safety of fixation with this product.
6-2	Feb. 6, 2015 Total review time: 267 days Regulatory review time: 196 days	- Foreign clinical study results	30	Duolith SD1 (Storz Medical AG)	Approval	Instrument & apparatus 12 Extracorporeal shock wave pain therapy system	An extracorporeal shock wave pain therapy system designed to enable adjustment of output by the conventional electromagnetic induction-type extracorporeal shock wave lithotripter to the low power output. It is used for pain relief in patients with refractory plantar aponeurositis. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with refractory plantar aponeurositis.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	31	Leksell Gamma Knife C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	32	Leksell Gamma Knife 4C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	33	Leksell Gamma Knife Model-C (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.

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8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	May. 24, 2012 Clinical evaluation report	34	Leksell Gamma Knife Perfexion (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment in trigeminal neuralgia with difficult pain control by drug therapy.
8	Mar. 26, 2015 Total review time: 209 days Regulatory review time: 150 days	- Clinical evaluation report	35	Leksell Gamma Knife (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	The device is a gamma knife used for non-incisional surgery by gamma ray irradiation in patients with brain diseases including cerebral vascular disorder or brain tumor, and brain functional disorder. The application is for a partial change to add the indication for trigeminal neuralgia for which pain control is difficult by drug therapy. A clinical evaluation report summarizing domestic and overseas published papers was submitted to evaluate the efficacy and safety of gamma knife treatment for trigeminal neuralgia with difficult pain control by drug therapy.