Products Approved in FY 2012: 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
3-1	Apr. 6, 2012 Total review time: 282 days Regulatory review time: 244 days	Nov. 1, 2011 Foreign clinical study results	1	XIENCE PRIME Drug-eluting Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. The improvements from the company's predicate device are the different strut and the new stent lengths, 33 mm and 38 mm. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with symptomatic ischemic heart disease. (The original product is in a reexamination period)
3-1	Jul. 9, 2012 Total review time: 69 days Regulatory review time: 45 days	－ No clinical study results	2	Nobori (Terumo Corporation)	Change	Instrument & apparatus 7 Coronary stent	A coronary stent used for treatment of patients with symptomatic ischemic heart diseases who have a new coronary lesion (a lesion length of 30 mm or less) with a reference vessel diameter of 2.5-3.5 mm. An application for a partial change to alter the test specifications for the drug (biolimus). (A partial change during the reexamination period)
3-1	Jul. 27, 2012 Total review time: 854 days Regulatory review time: 327 days	Oct. 15, 2009 Foreign clinical study results	3	MOMA Ultra (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting with dilatation of 2 balloons to occlude the common carotid artery and external carotid artery. Clinical studies were conducted by using the pre-improvement product to confirm the efficacy and safety of this product for patients at a high surgical risk of complications of carotid artery endarterectomy.
3-1	Sep. 6, 2012 Total review time: 385 days Regulatory review time: 291 days	Jun. 1, 2012 Global clinical trial and domestic clinical study results	4	Promus Element Plus Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. The stent with a diameter of 2.25 mm included in this product is the first coronary stent in Japan which is used for elective cases in patients with symptomatic ischemic heart diseases due to de novo lesions in native coronary arteries with a reference vessel diameter of 2.25-2.50 mm. Clinical studies were conducted to confirm the efficacy and safety of this product for small vascular lesions.
3-1	Nov. 29, 2012 Total review time: 49 days Regulatory review time: 47 days	- No clinical study results	5	MOMA Ultra (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting with dilatation of 2 balloons to occlude the common carotid artery and external carotid artery. An application for a partial change to change the specifications, etc. of endotoxin test. (A partial change during the reexamination period)
3-1	Dec. 5, 2012 Total review time: 433 days Regulatory review time: 195 days	- Domestic clinical study results	6	Misago (Terumo Corporation)	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 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. A clinical study was conducted to evaluate the efficacy and safety in bail-out treatment for stenosis or occlusion of the superficial femoral artery. (The original product is in a reexamination period)
3-1	Mar. 7, 2013 Total review time: 463 days Regulatory review time: 390 days	Nov. 1, 2011 Domestic clinical study results	7	XIENCE PRIME SV Drug-eluting Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with everolimus to inhibit the neointimal proliferation and a delivery catheter. This product is used for elective cases in patients with symptomatic ischemic heart diseases due to *de novo* lesions in native coronary arteries with a reference vessel diameter of 2.25-2.50 mm. Clinical studies were conducted to evaluate the efficacy and safety of this product for small vascular lesions. (The original product is in a 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
3-2	Sep. 28, 2012 Total review time: 470 days Regulatory review time: 109 days	May. 27, 2010 Domestic clinical study results	8	Neuroform Stent (Stryker Japan K.K.)	Approval	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. "Codman Enterprise VRD (Approval No. 22200BZX00078000)", an already-approved similar medical device, has a stent with a closed cell structure, but this product is characterized by a stent with an open cell structure. Clinical studies were conducted to evaluate the efficacy and safety of this product for patients with wide-necked cerebral aneurysm. (The original product is in a reexamination period)
3-2	Sep. 28, 2012 Total review time: 458 days Regulatory review time: 317 days	Sep. 9, 2003 Domestic clinical study results	9	AMPLATZER Vascular Plug (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material to promote vascular embolization which is used to occlude blood vessels and reduce, block, or alter blood flow by inserting and placing it transdermally in arteries/veins, except blood vessels in the heart and the skull. Clinical studies were conducted to confirm the efficacy and safety of this product for occlusion of vascular lesions, alteration of blood flow, and hemostasis for hemorrhagic lesions.
3-2	Nov. 21, 2012 Total review time: 100 days Regulatory review time: 38 days	- No clinical study results	10	Penumbra System (Medico's Hirata Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A catheter for removal of emboli in the central circulation system to be used to restore the blood flow by aspirating thrombi in patients in acute phase of cerebral infarction who fail intravenous infusion of a tissue plasminogen activator (t-PA). An application for a partial change to prolong the expiration period. (A partial change during the reexamination period)
3-2	Dec. 27, 2012 Total review time: 505 days Regulatory review time: 348 days	- Domestic clinical study results	11	Kawasumi Najuta Thoracic Stent Graft System (Kawasumi Laboratories, Incorporated)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of thoracic aortic aneurysm. For the product, 64 kinds of stent skeletons are set up as basic shapes by making differences in stent length, curvature, and torsion angle in order for it to fit the site and shape of the aorta where the product is placed. A straight-type or a tapered-type graft is sutured and fixed in accordance with the diastolic diameter of this stent skeleton, and fenestration is present or absent in a graft; and therefore there are 952 patterns of stent grafts depending on the combination. A clinical study was conducted to evaluate the efficacy and safety in the treatment of thoracic aortic aneurysm.
3-2	Mar. 22, 2013 Total review time: 493 days Regulatory review time: 199 days	- Clinical evaluation report	12	Serescue (Astellas Pharma Inc.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A porous gelatin sponge plate was developed as a vascular embolization material. Users cut this plate to an appropriate size using the sterilized medical knife, medical scissors, etc. with consideration of the vascular diameter of the site to be applied, suspend it with an appropriate amount of a contrast medium, and deliver it to the site in the blood vessel via a catheter to block the blood flow or to support forming an embolus. In this way, the hemostatic effect is expected for bleeding to which direct pressure cannot be applied from the body surface. A clinical evaluation report summarizing the results of literature searches on the efficacy and safety of transcatheter hemostasis using a gelatin sponge equivalent to this product was submitted.
3-2	Mar. 29, 2013 Total review time: 499 days Regulatory review time: 194 days	Jun. 18, 2007 Domestic clinical study results	13	AMPLATZER Vascular Plug II (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels consisted of a self-expandable plug with a nitinol mesh wire of a cylindrical form, a push wire to send the plug to a target site, and a loader that stores the plug in the expanded state. It blocks a blood vessel by being percutaneously inserted and placed in the arteries and veins except blood vessels in the heart and the skull, and reduces, blocks or alters the blood flow. A major difference from the approved "AMPLATZER Vascular Plug" (Approval No. 22400BZX00361000) is a change in the plug shape from a simple cylindrical shape to a shape composed of three cylindrical blocks. The change intends to shorten the time for vascular occlusion by creating many barriers against the blood flow and adding size variations. Results from Japanese clinical studies using the approved product were submitted to evaluate the efficacy and safety of this product in patients with occlusion of vascular lesions, patients indicated for alternation of blood flow, and patients indicated for hemostasis of hemorrhagic lesions. (The original product is in a 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
3-2	Jan. 28, 2013 Total review time: 374 days Regulatory review time: 247 days	- Domestic clinical study results	14	Bronchial Blocker EWS (Harada Corporation)	Approval	Instrument & apparatus 7 Bronchial blocker	A silicone resin bronchial blocker that is used to fill the bronchi and close fistula in patients who have refractory and inoperable, secondary pneumothorax, prolonged airleak following pneumectomy or other fistula. Clinical studies were conducted to evaluate the efficacy and safety of this product for the target diseases. [Orphan device]
4	May. 31, 2012 Total review time: 168 days Regulatory review time: 85 days	Dec. 19, 2008 (Approval of application corresponding to the present partial change) No clinical study results	15	Vagus Nerve Stimulation Device VNS System (Nihon Kohden Corporation)	Change	Instrument & apparatus 12 Vagus nerve stimulation device with anti-seizure effects	An electrical stimulation device to stimulate vagus nerve as an adjuvant therapy to reduce the frequency of seizures for patients with drug-resistant epilepsy who have refractory epileptic seizures. An application for a partial change to add a lead which is intended to improve fatigue durability. (A partial change during the reexamination period)
4	Jun. 25, 2012 Total review time: 1666 days Regulatory review time: 446 days	Aug.1, 2003 Foreign clinical study results	16	Thermogard System (ZOLL Circulation, Inc.)	Approval	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 body temperature management. The product consists of a main device to deliver the perfusion fluid whose temperature is adjusted in the thermostatic chamber of the product and a central venous catheter with a perfusion-type balloon. Clinical studies were conducted to evaluate the performance and adverse events of this product when used in the human body.
4	Sep. 7, 2012 Total review time: 263 days Regulatory review time: 161 days	- No clinical study results	17	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. This application for a partial change was filed to alter the alarm and to add a small, light controller, etc. (A partial change during the reexamination period) [Orphan device]
4	Nov. 7, 2012 Total review time: 57 days Regulatory review time: 40 days	- No clinical study results	18	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 heart transplant is indicated, show continuous decompensation in spite of drug therapy or circulation assist techniques, such as the use of an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. An application for a partial change in order that the power connector will not easily come off, in accordance with the Instruction 1 given at the time of approval: "Continuously examine measures for reducing power disruption risk, and consider revising the specifications of the product." (A partial change during the reexamination period) [Orphan device]
4	Nov. 29, 2012 Total review time: 513 days Regulatory review time: 131 days	Apr. 21, 2008 Domestic and foreign clinical study results	19	Implantable ventricular assist device HeartMate II (Thoratec Corporation)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	The first axial-flow implantable ventricular assist device system in Japan 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 the use of an external ventricular assist system, and for whom it is considered difficult to survive without heart transplant. A clinical study was conducted in the US 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 US.
4	Nov. 29, 2012 Total review time: 139 days Regulatory review time: 91 days	- Foreign clinical study results	20	CapSure Sense MRI Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Endocardial implantable pacemaker leads	An endocardial implantable pacemaker lead used by connecting them to an implantable cardiac pacemaker. The patients implanted the device can conditionally undergo an MRI scan. Efficacy and safety evaluations of this product were performed based on the results of overseas clinical studies of the original product "CapSure FIX MRI Lead (approval No.: 22400BZX00132000)." (The original product is in a reexamination period)
4	Nov. 29, 2012 Total review time: 139 days Regulatory review time: 99 days	- No clinical study results	21	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker to be used by connecting it to electrodes placed within the heart. An application for a partial change to add the pacemaker lead "CapSure Sense MRI Lead," which is newly available for connection, as a compatible medical device. (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	Dec. 26, 2012 Total review time: 159 days Regulatory review time: 49 days	Aug. 23, 2007 No clinical study results	22	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 changes including modification of the compressor in the main device and partial deletion of options for flow rate settings. (A partial change during the reexamination period)
4	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 295 days	Jan. 4, 2008 Domestic clinical study results	23	NaviStar RMT ThermoCool (Johnson & Johnson K.K.)	Approval	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 by other ways. This device is manipulated with "Magnetic Navigation System Niobe" (Approval No. 22500BZX00103000). It also has an irrigation system that flows with saline from an irrigation hole at the tip electrode. The clinical study was conducted to evaluate the efficacy and safety of manipulating it by the Magnetic Navigation System Niobe.
4	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 295 days	Jan. 26, 2006 Domestic clinical study results	24	NaviStar RMT (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter for the radiofrequency catheter ablation and for the electrophysiological study; it is used to treat supraventricular tachycardia. This device is manipulated with "Magnetic Navigation System Niobe" (Approval No. 22500BZX00103000). The clinical study was conducted to evaluate the efficacy and safety of manipulating it by the Magnetic Navigation System Niobe.
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	25	Evia T Series Pro (Biotronik Japan, Inc.)	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 an MRI scan. This device was newly applied as an implantable cardiac pacemaker 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)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	26	Evia Series Pro (Biotronik Japan, Inc.)	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 an MRI scan. This device was newly applied as an implantable cardiac pacemaker 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)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	27	Solia S (Biotronik Japan, Inc.)	Approval	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. 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)
4	Feb. 19, 2013 Total review time: 419 days Regulatory review time: 163 days	- Clinical evaluation report	28	Solia T (Biotronik Japan, Inc.)	Approval	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. 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)
4	Mar. 29, 2013 Total review time: 210 days Regulatory review time: 60 days	Aug. 23, 2007 No clinical study results	29	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 add a catheter introducer kit to components. (A partial change during the reexamination period)

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6-2	Jun. 25, 2012 Total review time: 278 days Regulatory review time: 216 days	- (No application filed for pustular psoriasis in US) Domestic clinical study results	30	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Purifier for blood cell removal	A extracorporeal column for improving pathological conditions by adsorption/apheresis of white blood cells, mainly granulocytes in the peripheral blood, and suppressing inflammatory reactions. An application for a partial change to add the improvement of clinical symptoms of pustular psoriasis to the indications. A clinical study was conducted to evaluate the efficacy and safety of this product in patients with moderate or severe pustular psoriasis. [Orphan medical device]
6-2	Jul. 31, 2012 Total review time: 319 days Regulatory review time: 230 days	Feb. 25, 2009 Domestic clinical study results	31	RENASYS Wound Therapy System (Smith & Nephew Wound Management K.K.)	Approval	Medical products 4 Negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by maintaining a local negative-pressure environment, protecting wounds, and removing exudative fluid, infectious material, etc. for patients with refractory wounds who have not responded to existing treatments or are considered to not be responding. Clinical studies were conducted to evaluate the efficacy and safety of this product for acute, subacute, and chronic refractory wounds. (The original product is in a reexamination period)
6-2	Sep. 12, 2012 Total review time: 104 days Regulatory review time: 95 days	- No clinical study results	32	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. An application for a partial change to add a new size of a component of the single-use vertebral body restoration device and manufacturing sites. (A partial change during the reexamination period)
6-2	Sep. 28, 2012 Total review time: 2080 days Regulatory review time: 436 days	Nov. 17, 2006 Foreign clinical study results	33	Natrelle Breast Implant (Allergan Japan K. K.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled breast in which silicone gel is filled in a shell made of silicone elastomer which repairs or forms the shape of a breast after insertion into the application site. It is used for breast reconstruction surgery or augmentation mammaplasty. Clinical studies were conducted to evaluate the efficacy and safety of this product when used for breast reconstruction surgery, augmentation mammaplasty, and revision surgery.
6-2	Sep. 28, 2012 Total review time: 309 days Regulatory review time: 147 days	- No clinical study results	34	V.A.C.ATS Therapy System (KCI K.K.)	Change	Medical products 4 Negative pressure wound therapy system	A negative-pressure wound therapy system to promote wound healing by maintaining the local negative-pressure environment, protect wounds, and remove exudative fluid, infectious material, etc. for patients with refractory wounds who have not responded to existing treatments or are considered to not be responding. An application for partial changes for addition of manufacturing sites and updating of approved matters regarding sizes, raw materials, etc. (A partial change during the reexamination period)
6-2	Oct. 22, 2012 Total review time: 39 days Regulatory review time: 28 days	- No clinical study results	35	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. Addition of a manufacturing site. (A partial change during the reexamination period)
6-2	Nov. 12, 2012 Total review time: 60 days Regulatory review time: 28 days	- No clinical study results	36	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	A therapeutic spinal bone cement used in percutaneous kyphosis correction in acute spinal compression fracture performed for restoration of the height of fractured vertebrae, fixation of the vertebral body, and pain relief. This product is used with KYPHON BKP System. Addition of a manufacturing site. (A partial change during the reexamination period)
6-2	Dec. 18, 2012 Total review time: 280 days Regulatory review time: 102 days	Dec. 7, 2007 No clinical study results	37	VertaPlex Bone Cement (Stryker Japan K.K.)	Change	Medical products 4 Orthopedic bone cement	The product is used in percutaneous vertebroplasty to mitigate pain in patients with malignant spinal tumor such as painful metastatic bone tumor and myeloma who have not responded to conventional therapy. An application for a partial change to change the setting time (hardening time). (A partial change during the reexamination period)
6-2	Mar. 22, 2013 Total review time: 387 days Regulatory review time: 143 days	- Domestic clinical study results	38	Nerve Regeneration Guidance Conduit Nerbridge (Toyobo Co., Ltd.)	Approval	Medical products 4 Collagen-containing absorbable nerve regeneration inducing material	A polyglycolic acid conduit filled with sponge-like collagen which is inserted into defects of the peripheral nerves that have been ruptured or broken because of injuries, etc. in order to induce regeneration of the nerve and reconstruct the function by bridging both ends of nerve. A prospective clinical study was conducted to evaluate the efficacy and safety of this product in patients with peripheral nerve defect on the distal wrist.

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8	Oct. 18, 2012 Total review time: 385 days Regulatory review time: 235 days	Feb. 18, 2009 Foreign clinical study results	39	da Vinci Si Surgical System (Intuitive Surgical Inc.)	Approval	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist the surgeon's manipulation of endoscopic surgical devices when endoscopic surgery is performed in areas of general digestive surgery, thoracic surgery (except cardiac surgery), urology, and gynecology. Improvement from the original product "da Vinci Surgical System (approval No.: 22100BZX01049000)" includes downsizing of the surgeon consoles and enabling setting of the position of movement according to the needs of the surgeon. In addition, as a secondary function, two surgeons can manipulate the device, when two surgeon consoles are connected. Results of clinical studies using the original product were submitted to explain the extrapolability to efficacy and safety evaluation of this product. (The original product is in a reexamination period)
8	Mar. 22, 2013 Total review time: 451 days Regulatory review time: 327 days	Jan. 15, 2003 Domestic clinical study results	40	Magnetic Navigation System Niobe (Siemens Japan K.K.)	Approval	Instrument & apparatus 51 Cardiac Mapping System Workstation	A guiding system that navigates "NaviStar RMT ThermoCool" (Approval No. 22500BZX00104000) or "NaviStar RMT" (Approval No. 22500BZX00107000), both of which are exclusive catheters to this system, to a target region in intervention procedures. Clinical studies were conducted to evaluate the efficacy and safety of manipulating these exclusive catheters with this device.
Biologics-2	Jul. 27, 2012 Total review time: 1068 days Regulatory review time: 200 days	- Domestic clinical study results	41	Jacc (Japan Tissue Engineering Co., Ltd.)	Approval	Instrument & apparatus 7 Human autologous cells and tissue	An autologous cultured cartilage to alleviate clinical symptoms by implanting it in the affected site of traumatic cartilage deficiency and osteochondritis dissecans (excluding knee osteoarthritis) in knee joints with a cartilage defective area of 4 cm2 or more for which there are no other treatment options. Chondrocytes isolated from the non-load-bearing site of a knee joint of patients by taking a small amount of cartilage tissue are three-dimensionally cultured in atelocollagen gel to obtain this product. Clinical studies were conducted to evaluate the efficacy and safety of this product for patients with traumatic cartilage deficiency, osteochondritis dissecans, and knee osteoarthritis.
Biologics-2	Sep. 28, 2012 Total review time: 1652 days Regulatory review time: 357 days	Nov. 21, 2003 Foreign clinical study results	42	Contegra Pulmonary Valved Conduit (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Artificial blood vessel with a bovine-derived valve	A conduit with a pulmonary valve made of bovine jugular veins which is used to repair/reconstruct the right ventricular outflow tract leading to the pulmonary arteries from the heart. A clinical study was conducted to evaluate the efficacy and safety of this product in children (aged under 18 years) with abnormality of the right ventricular outflow tract or functional failure of an already-implanted homograft, etc.
Cellular and tissue-based products	Dec. 27, 2012 Total review time: 59 days Regulatory review time: 37 days	- No clinical study results	43	Jacc (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	This autologous cultured cartilage uses atelocollagen as a scaffolding material for culture. It is necessary to perform an allergy test for atelocollagen before applying this product. An application for partial changes, including addition of a syringe for intradermal tests of the atelocollagen as a component of this product, and change in biological ingredients in the raw materials. (A partial change during the reexamination period)
Cellular and tissue-based products	Mar. 29, 2013 Total review time: 205 days Regulatory review time: 102 days	- No clinical study results	44	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autologous cells and tissue	An autologous-cultured epidermis manufactured with epidermal cells derived from patients with severe burn injury and multiple biological materials. An application for partial changes, including change in the biological raw materials and addition of component(s). (A partial change during the reexamination period)
Specified Partial Change	Apr. 19, 2012 Total review time: 56 days Regulatory review time: 34 days	- No clinical study results	45	Zilver PTX Drug-eluting Peripheral Stent (Cook Japan Inc.)	Change	Instrument & apparatus 7 Drug-eluting femoral artery stent	A nitinol self-expanding stent to be inserted and placed at the site of a lesion to maintain the lumen of a femoropopliteal stenotic site and a delivery system used to deliver the stent to the site of the lesion. An application for a partial change to change the specification of paclitaxel, etc. (A partial change during the reexamination period)
Specified Partial Change	Sep. 28, 2012 Total review time: 73 days Regulatory review time: 51 days	- No clinical study results	46	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. The raw material of spike needles was changed. (A partial change during the reexamination period)

Products Approved in FY 2012: 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	May 15, 2012 Total review time: 407 days Regulatory review time: 115 days	- Foreign clinical study results	1	Tecnis 1-Piece VB (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	A monofocal posterior chamber lens to be implanted in the posterior chamber of the eye as a substitute for the crystalline lens to correct the vision of the aphakic eye. As the raw materials, an ultraviolet absorbing agent and a violet light absorbing agent, both of which are new covalent materials, were added to acrylic-methacrylic cross-linked copolymer, a base material of the approved "Tecnis 1-Piece". A clinical study was conducted to evaluate the optical efficacy and safety of the new raw materials.
1	Oct. 30, 2012 Total review time: 246 days Regulatory review time: 140 days	Mar. 30, 2012 Domestic clinical study results	2	Dailies Total 1 (Ciba Vision Corporation)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	Single-use tinted contact lenses for correcting visual acuity. The silicone hydrogel lens is indicated for daily wear. The product has high oxygen transmissibility and uses a new material called Delefilcon A to improve the quality. The raw material has novelty, and a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Dec. 26, 2012 Total review time: 512 days Regulatory review time: 118 days	- Domestic clinical study results	3	Four Seasons (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored contact lenses for correcting visual acuity. The lens is indicated for daily wear and replaced in three-month intervals. A silicon-containing material which has oxygen transmissibility equivalent to or greater than the approved "Menicon Tinu" (Approval No. 21800BZZ10125000) is used for this product. The combination of major component monomers in the raw material has novelty, and a clinical study was conducted to evaluate the efficacy and safety of wearing this product for correction of visual acuity.
1	Dec. 26, 2012 Total review time: 348 days Regulatory review time: 236 days	- Domestic clinical study results	4	HOYA Vivinex iSert (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	A posterior chamber lens with an injector, for which single focus posterior chamber lens that is inserted into the aphakic eye after cataract surgery is preloaded in an injector. With the haptics and the optics made of the same raw material, it has a casting one-piece structure. A major difference from the approved "HOYA iSert Micro (Approval No. 22200BZX00615000) is a change in the raw material of the posterior chamber lens to reduce the risk of capsule opacification. The raw material has novelty, and a clinical study was conducted to evaluate the optical efficacy and safety of this product in clinical use.
2	Feb. 14, 2013 Total review time: 637 days Regulatory review time: 116 days	Jun. 11, 1997 (Initial approval) Nov. 15, 2004 (Addition of GTR method) Aug. 9, 2005 (Change in manufacturing process) Domestic clinical study results	5	Geistlich Bio-Gide (Geistlich Pharma AG)	Approval	Medical products 4 Absorbent periodontal tissue regeneration material	An absorbent material using collagen derived from porcine membrane (originated in Switzerland) as a raw material. It is used in combination with autologous bone or bone substitute in guided (periodontal) tissue regeneration (GTR) for a defective part of the alveolar bone as a protective membrane against epithelial migration to new bone. A clinical study was conducted to evaluate the efficacy and safety of the combined use of this product with a dental bone substitute.
3-1	May 18, 2012 Total review time: 1569 days Regulatory review time: 374 days	Feb. 16, 2006 Foreign clinical study results	6	Spider Protection Device (At the time of approval, ev3 K.K.; currently (post-approval transfer of approval), Covidien Japan Inc.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli, which is used for capture and removal of obstructing materials such as thrombi during percutaneous carotid artery stenting. It is transdermally inserted into blood vessels and temporarily placed in the distal side of a lesion. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with angiostenosis in the carotid artery with the rate of stenosis of at least 70% (for asymptomatic patients) and at least 50% (for symptomatic patients).

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	May 18, 2012 Total review time: 1449 days Regulatory review time: 356 days	Jan. 24, 2007 Foreign clinical study results	7	PROTEGE Carotid Stent Set (At the time of approval, ev3 K.K.; currently [post-approval transfer of approval], Covidien Japan Inc.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	A stent which is used to expand the carotid artery (common carotid artery, internal carotid artery) or maintain the lumen in patients who are at high risk for adverse events by surgical treatment (carotid endarterectomy), and a delivery catheter that transdermally delivers the stent to the site of stenosis in the carotid artery. Clinical studies were conducted to evaluate the efficacy and safety of this product in patients with angiostenosis in the carotid artery with the rate of stenosis of at least 70% (for asymptomatic patients) and at least 50% (for symptomatic patients).
3-1	May 18, 2012 Total review time: 364 days Regulatory review time: 242 days	Feb. 17, 2012 Domestic and foreign clinical study results	8	Resolute Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with zotarolimus to inhibit the neointimal proliferation and a delivery catheter. The improvemjent from the approved "Endeavor Coronary Stent System" is the prolonged drug-eluting duration as a result of modification of the drug coating base material. A clinical study was conducted to evaluate the efficacy and safety of this product including such improvement in patients with symptomatic ischemic heart disease.
3-1	Jun. 25, 2012 Total review time: 620 days Regulatory review time: 280 days	- Clinical evaluation report	9	Expansor Balloon Catheter (Fuji Systems Corporation)	Approval	Instrument & apparatus 51 Balloon catheter for neuroendoscopy	A balloon catheter which is inserted through a working channel of the endoscopy to expand a puncture hole created by an endoscopic clamp, etc. during surgery for hydrocephalus using neuroendoscopy (ventriculostomy, laparoscopic fenestration of cyst, etc.). Because there is no balloon catheter indicated for this treatment, a clinical evaluation report summarizing the results of literature searches on the efficacy and safety of this treatment using the balloon catheter was submitted.
3-1	Sep. 28, 2012 Total review time: 277 days Regulatory review time: 235 days	- Foreign clinical study results	10	Kaname (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A cobalt-chromium alloy coronary stent which is used for the treatment of patients with symptomatic ischemic disease (including the treatment of acute or threatened coronary artery closure as a result of unsuccessful intervention) whose reference vessel diameter is in the range of 3.0 mm to 4.0 mm and who have new or restenosis coronary lesion (length of lesion up to 25 mm). Clinical studies were conducted to confirm the efficacy and safety of this product for the treatment of symptomatic ischemic disease.
3-1	Dec. 27, 2012 Total review time: 302 days Regulatory review time: 77 days	Apr. 13, 2012 Foreign clinical study results	11	Epic Vascular Stent (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for iliac artery	This product consists of a self-expandable stent made of nickel-titanium alloy and its delivery system. The stent is transdermally inserted and placed in a blood vessel to maintain or expand the vascular lumen for the treatment of symptomatic vascular disease in the iliac artery such as stenotic lesion. The stent has a tandem structure, including closed cells at both ends and an open cell at the center in order to reduce a position gap when it is expanded. Clinical studies were conducted to confirm the efficacy and safety of this product for the treatment of symptomatic vascular disease in the iliac artery.
3-2	Jun. 27, 2012 Total review time: 565 days Regulatory review time: 139 days	Mar. 23, 2010 (Approval of application corresponding to the present partial change) Foreign clinical study results	12	Gore TAG Thoracic Endoprosthesis (W.L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of thoracic aortic aneurysm. Application for a partial change to add a 45 mm-diameter stent graft, etc. A clinical study was conducted to evaluate the equivalence of the efficacy and safety between the existing stent graft and the added 45 mm-diameter stent graft.
3-2	Sep. 28, 2012 Total review time: 826 days Regulatory review time: 127 days	Mar. 5, 2009 Foreign clinical study results	13	Gore Excluder AAA Endoprosthesis (W.L. Gore & Associates, Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of abdominal aortic aneurysm. Application for a partial change to add a 31 mm-diameter Trunk-Ipsilateral Leg, 32 mm-diameter Aortic Extender, etc. A clinical study was conducted to evaluate the equivalence of the efficacy and safety between the existing stent graft and the stent graft with the added diameter.

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	Nov. 27, 2012 Total review time: 1246 days Regulatory review time: 269 days	Oct. 23, 2007 Foreign clinical study results	14	Mitroflow (Sorin Biomedica Cardio S.r.l.)	Approval	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve used to replace the aortic valve which has become dysfunctional due to disease, etc. Unlike the existing product, this product has a valve leaflet outside the stent frame. A clinical study was conducted to confirm that the efficacy and safety of this product in target patients are within the assumed range.
3-2	Mar. 29, 2013 Total review time: 407 days Regulatory review time: 237 days	Sep. 21, 2012 Foreign clinical study results	15	Relay Plus Thoracic Stent Graft System (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of descending thoracic aortic aneurysm. The two covered stent rings at the proximal end of the stent graft are free from a spiral support wire, which allows independent bending at the proximal end. The placement position of the stent graft can be adjusted by keeping a bare stent on the proximal end with a holder at the tip in the delivery system. A clinical study was conducted to evaluate the efficacy and safety of this product for the treatment of descending thoracic aortic aneurysm in comparison with a control group treated with surgical procedures.
4	Apr. 24, 2012 Total review time: 407 days Regulatory review time: 237 days	- Foreign clinical study results	16	Thermocool Smarttouch (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation system used for radiofrequency catheter ablation and electrophysiological study. The contact force-sensing function is loaded at the tip of electrode; it is used to calculate and to display the degree of contact between the tip and the tissue. A clinical study was conducted to evaluate the behavior of contact force level in clinical use.
4	Jul. 26, 2012 Total review time: 848 days Regulatory review time: 314 days	- Clinical evaluation report	17	Linox Smart S DX (Biotronik Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A screw-type electrode lead that is used to conduct atrial sensing, ventricular sensing/pacing, anti-trancycardia pacing treatment and defibrillation with one lead. It consists of 1 defibrillation electrode, 3 ring electrodes and 1 screw electrode. A clinical evaluation report was submitted to evaluate that defibrillation is properly achieved when this product is used in clinical practice.
4	Aug. 24, 2012 Total review time: 534 days Regulatory review time: 344 days	Feb. 7, 2007 Clinical evaluation report	18	Servo Ventilator Series (Fukuda Denshi Co., Ltd.)	Change	Instrument & apparatus 6 Versatile artificial respirator	A versatile artificial ventilator that sends the mixed gas of oxygen and air to the lung through the oral or nasal cavity under the mechanical adjustment. In the application for a partial change, the assisted ventilation mode is added; the mode detects a patient's electrical activity of the diaphragm and drives a pressure support in line with respiratory timing. Furthermore, components needed for the mode are added. A clinical evaluation report of this device was submitted to evaluate that the support in line with respiratory timing is achieved in clinical use.
4	Oct. 30, 2012 Total review time: 193 days Regulatory review time: 141 days	May 28, 2008 Clinical evaluation report	19	NRG RF Transseptal Needle (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 47 Transseptal needle	A transseptal needle with an electrode to be used to create a puncture in interatrial septum in order to insert a catheter, etc. from the right atrium to the left atrium. The atrial septum is punctured by the tissue causarization with high-frequency energy generated from a dedicated high-frequency generator. In contrast to conventional transseptal needles, this device can puncture using high-frequency energy. A clinical evaluation report summarizing the clinical data of literature was submitted to evaluate the efficacy and safety of this product in comparison with conventional transseptal needles.
4	Oct. 30, 2012 Total review time: 181 days Regulatory review time: 99 days	Nov. 21, 2007 Clinical evaluation report	20	Medtronic Reveal XT (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 Implantable data recorder for electrocardiogram	An implantable electrocardiogram recorder, subcutaneously implanted to continuously monitor the electrocardiogram. This device detects, records and stores wave patterns of atrial fibrillation, and sends the information recorded in this product to a server through the approved "Medtronic CareLink Monitor" (Approval No. 21900BZX00664000); the functions are the major improvements from the approved device "Medtronic Reveal DX" (Approval No. 22000BZX01025000). A clinical evaluation report was submitted to evaluate that this product can detect atrial fibrillation.

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	Mar. 28, 2013 Total review time: 1554 days Regulatory review time: 577 days	Mar. 3, 2008 Foreign clinical study results	21	Niox Mino (Chest M.I., Inc.)	Approval	Instrument & apparatus 21 Nitric oxide analysis instrument	A measuring instrument used to measure the level of nitric oxide, used as a biomarker of eosinophic inflammation, in the expired air. In a clinical study, the measuring performance for the concentration of nitric oxide is evaluated on equivalence to predicate devices outside Japan, and the changes in the concentration of nitric oxide was compared before and after the treatment of inflammation.
4	Feb. 22, 2013 Total review time: 231 days Regulatory review time: 149 days	- Clinical evaluation report	22	FastView (Terumo Corporation)	Approval	Instrument & apparatus 51 Intravascular optical tomographic catheter	An intravascular optical coherence tomographic (OCT) catheter to conduct OCT of the coronary artery; it is connected to "Lunawave" (Approval No. 22500BZX00058000), an OCT image diagnosis equipment for exclusive use with this catheter. The broadband near-infrared light guided from the exclusive equipment is irradiated toward the circumferential direction from near the tip of the catheter. Then, the reflected from the vessel interferes with the reference light, and the interference signal is generated. This equipment obtains the cross-sectional images of blood vessels by Fourier-transforming the interference signal. A clinical evaluation report was submitted to evaluate the efficacy and safety of this equipment in clinical use.
5	May 25, 2012 Total review time: 1123 days Regulatory review time: 397 days	Nov. 19, 2002 Foreign clinical study results	23	Monarc Transobturator System (American Medical Systems, Inc.)	Approval	Instrument & apparatus 30 Urinary incontinence treatment tape	This product consists of a mesh to be placed suburethrally and its introducer, both of which are intended to improve stress urinary incontinence in women caused by urethral hypermobility or intrinsic sphincter deficiency of the urethra. While the approved product is placed retropubically, this product is placed in the obturator foramen. A clinical study was conducted to evaluate the objective efficacy (pad weight test, cough stress test, etc.), subjective efficacy (QOL improvement), and safety of this product for stress urinary incontinence.
5	May 31, 2012 Total review time: 330 days Regulatory review time: 86 days	- Domestic clinical study results	24	Nipro Polyether Sulfone Dialyzer (Nipro Corporation)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow-fiber dialyzer intended to remove fluid and uremic substances stored in the body due to uremia. It is indicated for patients whose renal function has markedly reduced due to chronic or acute renal failure, etc. Although this product uses the same membrane material as the approved products, because equivalence to the approved products was not demonstrated with regard to the performance profile, a clinical study was conducted to evaluate its performance profile.
5	Jul. 27, 2012 Total review time: 872 days Regulatory review time: 332 days	- Domestic clinical study results	25	Bipolar RFA System CelonPOWER (Olympus Medical Systems Corporation)	Approval	Instrument & apparatus 29 Radiofrequency ablation system	A device to be used to coagulate a malignant tumor of the liver with radiofrequency current. While the approved product is a monopolar system, this product is a bipolar system with two electrodes for one applicator. It also has a mode to energize up to 6 electrodes (15 pairs) sequentially by simultaneous puncture of up to 3 applicators. A clinical study was conducted to evaluate the necrogenic effect and safety of this product for hepatic malignancy.
5	Sep. 7, 2012 Total review time: 1036 days Regulatory review time: 427 days	Apr. 17, 2002 Clinical evaluation report	26	Cook Postpartum Balloon (Cook Japan Inc.)	Approval	Instrument & apparatus 51 Uterine balloon	A balloon used to relieve or stop uterine bleeding after delivery. There is no product that specializes in such intended use in Japan. Considering the fact that pressure hemostasis using a balloon such as this product is common in and out of Japan, a clinical evaluation report was submitted to evaluate the efficacy and safety of this product.
5	Feb. 19, 2013 Total review time: 358 days Regulatory review time: 80 days	- Domestic clinical study results	27	Double-balloon Endoscopy System (Fujifilm Corporation)	Approval	Instrument & apparatus 25 Balloon-guided small-intestine endoscopy system	A system that inserts an endoscope deep inside of the small intestine by using the technique to fold the intestinal tract with the combination of the endoscope, an over-tube with a balloon, a balloon to be attached to the endoscope and a balloon controller. A clinical study was conducted to verify the capability of this system to reach deep inside of the small intestine with the technique to fold the small intestine and to ensure the safety of the system.

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
6-1	Jul. 10, 2012 Total review time: 1489 days Regulatory review time: 444 days	Apr. 29, 2009 Clinical evaluation report	28	Biolox Option Head (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Hemi hip prosthesis	A stem head made of a zirconia-toughened high-purity aluminum matrix composite (BIOLOX® Delta) and used in combination with the company's approved system and "Ceramic Hip System Delta". The raw material of this system is innovative as an artificial hip prosthesis in Japan. The equivalence of the shape between the approved products and this product was explained, and a clinical evaluation report was submitted to provide clinical evaluation of differences in the raw materials.
6-1	Jul. 10, 2012 Total review time: 1404 days Regulatory review time: 565 days	Nov. 20, 2008 (Delta head) Clinical evaluation report	29	Ceramic Hip System Delta (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 4 Total hip prosthesis	This product consists of a stem head made of a zirconia-toughened high-purity aluminum matrix composite (BIOLOX® Delta) and a liner for shelf operation. It is used in combination with the company's approved system. Although the raw material of this system is innovative as an artificial hip prosthesis in Japan, a clinical evaluation report was submitted to explain the equivalence of the shape between the approved products and this product and the clinical evaluation of differences in the raw materials.
6-1	Sep. 28, 2012 Total review time: 161 days Regulatory review time: 96 days	Oct. 18, 2007 Clinical evaluation report	30	Restoration ADM (Stryker Japan K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	This product consists of an acetabular cup and an acetabular insert used for hip replacement. The inner side of the acetabular insert is located on the femoral stem head, while the external side forms a bearing surface with the acetabular cup. This product was developed to increase the range of motion for the artificial hip prosthesis by the two bearing surfaces (dual-mobility) of the acetabular insert and to enhance the stability of the prosthesis because dislocation of the hip requires severer displacement of the femoral head in the vertical direction. A clinical evaluation report was submitted to evaluate the treatment outcome of the artificial hip prosthesis with the dual-mobility structure.
6-1	Nov. 21, 2012 Total review time: 601 days Regulatory review time: 400 days	Jan. 14, 2011 Clinical evaluation report	31	Active Articulation E1 (Biomet Japan, Inc.)	Approval	Medical products 4 Artificial hip joint, acetabular component	An acetabular liner used for hip replacement. It is used in combination with an acetabular cup and a femoral stem head. It is a dual-mobility system that has bearing surfaces both inside and outside the product. This double-mobility system enables increase of the range of motion and enhances the implant stability. It is made of ultra high molecular weight polyethylene which was given cross-linking treatment to enhance the resistance to abrasion, and was immersed in vitamin E to enhance the resistance to oxygen. A clinical evaluation report was submitted to evaluate the efficacy and safety of the dual-mobility structure.
6-1	Jan. 28, 2013 Total review time: 581 days Regulatory review time: 73 days	- Clinical evaluation report	32	Adler Hip Prosthesis System (Robert Reid Inc.)	Approval	Medical products 4 Total hip prosthesis	This product consists of a press-fit fixed stem, modular neck and head which are used on the femoral side and a cup and liner which are used on the acetabular side to replace the hip function in total hip replacement. Aluminum oxide (alumina) is adopted for the liner and head to improve the resistance to abrasion and toughness of the bearing surface, while the acetabular cup surface has a porous structure by layering technique to improve the synostosis. Since there have been concerns about a risk of breakage caused by a new raw material of alumina, a clinical evaluation report that evaluated the incidence of repeat replacement when this product was used for total hip replacement was submitted.
6-1	Jan. 28, 2013 Total review time: 356 days Regulatory review time: 109 days	- Clinical evaluation report	33	BIOLOX Delta Ceramic Head (Robert Reid Inc.)	Approval	Medical products 4 Hemi hip prosthesis	An artificial head prosthesis used to replace the hip function on the femoral side in total hip replacement. The raw material, shape and structure of this product are equivalent to those of the approved product "BIOLOX Delta Ceramic Femoral Head" (Approval No. 22300BZX00018000). A major difference is the acetabular liner, which is used in combination with this product, made of aluminum oxide (alumina). A clinical evaluation report that evaluated the incidence of repeat replacement, incidence of defects, etc. when this product and the alumina-made acetabular liner were used together was submitted.

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
6-1	Mar. 29, 2013 Total review time: 273 days Regulatory review time: 131 days	Dec. 23, 2010 (inner diameter 28 mm) Apr. 2, 2013 (inner diameter 36 mm) (inner diameter 32 mm: has not been applied in the US) Foreign clinical study results	34	Pinnacle Ceramic Liner (CERAMAX) (Johnson & Johnson K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	A liner that costitutes an acetabular component used in total hip replacement. The major improvement is its raw material, an Alumina-Zirconia ceramic matrix composites (BIOLOX delta) that has better intensity than the conventional ceramic material. Used in combination with the company's artificial femoral head made by the same raw material, this product composes a ceramic-on-ceramic system. A clinical study was conducted to evaluate the usability and safety of this product in clinical use.
6-1	Mar. 29, 2013 Total review time: 273 days Regulatory review time: 154 days	Jul. 1, 2003 (excluding some sizes) Apr. 8, 2004 (some sizes) Nov. 30, 2006 (same as above) (36 mm 9/10 taper has not been applied in the US) Foreign clinical study results	35	BIOLOX Delta Ceramic Head (CERAMAX) (Johnson & Johnson K.K.)	Change	Medical products 4 Hemi hip prosthesis	An application for partial change to add "Pinnacle Ceramic Liner (CERAMAX)" (Approval No. 22500BZX00165000) as a liner to be combined with this product and add a head component with the bearing surface of 36 mm in diameter. A clinical study was conducted to evaluate the usability and safety of this product in combination with the aforementioned liner.
6-2	Jun. 26, 2012 Total review time: 358 days Regulatory review time: 167 days	- Domestic clinical study results	36	Refit (Hoya Corporation)	Approval	Medical products 4 Artificial bone using collagen	An artificial bone implant made of sponge-like low-crystalline calcium phosphate and swine collagen. It is intended to enhance the porosity and improve the elasticity and bioabsorption. Since this product is a new raw material, a clinical study was conducted to confirm the effect of this product to promote bone regeneration for bone defects is equivalent to or greater than the existing products.
6-2	Jul. 3, 2012 Total review time: 627 days Regulatory review time: 242 days	Mar. 31, 2000 Domestic clinical study results	37	Versajet S (Smith & Nephew Wound Management K.K.)	Approval	Instrument & apparatus 12 Hydraulic knife	A device to be used for wound debridement (acute wound, chronic wound and thermal burn), soft tissue debridement and cleaning of surgical wound site. With the high-pressure water flow and its Venturi effect, it enables debridement and cleaning of surgical wound site. While it has the same mechanism of tissue ablation as the approved product, a major difference is that this product was developed as a device for debridement. A clinical study was conducted to evaluate the efficacy and safety of this product in wound debridement.
6-2	Sep. 19, 2012 Total review time: 1267 days Regulatory review time: 775 days	- Clinical evaluation report	38	Nerve Regeneration Guidance Conduit Nerbridge (Toyobo Co., Ltd.)	Approval	Medical products 4 Collagen-containing absorbable nerve regeneration inducing material	A femoral component of artificial hip prosthesis used for reconstruction of joint function in patients with femur head necrosis and coxarthrosis. While the shape and structure of this product are the same as those of the approved product, this product uses different raw materials for the compression bolt and cortical crew. A clinical evaluation report was submitted to confirm the efficacy and safety of hip replacement and bipolar hip arthroplasty using this product.
6-2	Sep. 28, 2012 Total review time: 1642 days Regulatory review time: 87 days	Jul. 23, 1986 Clinical evaluation report	39	Natrelle 133 Tissue Expander (Allergan Japan K.K.)	Approval	Medical products 4 Skin tissue expander	A device to be temporary implanted under the breast subcutaneous tissue or the pectoralis major muscle to facilitate placement of artificial breast in which purpose is to expand/extend the skin and tissues surrounding the breast prior to breast reconstruction surgery. A clinical evaluation report was submitted to confirm that the insertion of a round-type breast implant is possible after skin/tissue expansion using this product in breast reconstruction surgery.
6-2	Dec. 5, 2012 Total review time: 344 days Regulatory review time: 138 days	Aug. 7, 2009 Foreign clinical study results	40	SNaP Negative Pressure Wound Therapy System (Century Medical, Inc.)	Approval	Medical products 4 Single-use negative pressure wound therapy system	A negative pressure wound therapy system to promote wound healing by adding the controlled negative-pressure, protecting wounds, promoting granulation of the wound, and removing exudative fluid and infectious waste materials for patients with refractory wounds who have not responded to existing treatments or are considered not to be responding. This product is a portable device for single use and can be used for outpatients. Thus, a clinical study was conducted to evaluate the efficacy and safety of this product in outpatients.

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6-2	Dec. 20, 2012 Total review time: 869 days Regulatory review time: 307 days	Jun. 6, 2005 Clinical evaluation report	41	CENTERPIECE OD Plate System (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Fixation device placed in the spine	A fixation device placed in the spine. This product is used for laminectomy to maintain the location of the vertebral arch which is dilated from the lower cervical spine to the upper thoracic spine (C3 to Th3). It is used for the treatment of cervical spine diseases such as spondylitic myelopathy and ossification of posterior longitudinal ligament, spinal cord tumor, etc. It consists of a cervical spine plate and a cervical spine screw. While one-side open laminectomy is performed for the existing therapy using a titanium plate in the same way with this product, the form structure has been improved for this product to optimize the surgical technique. Since there is no other product with the similar form and structure, a clinical evaluation report was submitted to confirm the efficacy and safety of the surgical technique with this product.
6-2	Dec. 21, 2012 Total review time: 360 days Regulatory review time: 282days	Nov. 3, 2008 Domestic clinical study results	42	Osteoraptor HA Anchor (Smith & Nephew Endoscopy K.K.)	Approval	Medical products 4 Absorbable ligament anchor	This product consists of absorbable anchors made of poly-L-lactic acid and hydroxyapatite, suture and inserter. Multiple anchors are implanted in the bone to secure them to the bone by surgically suturing damaged, ruptured or exfoliated soft tissues such as tendons, ligaments or muscles. The point of improvement is that hydroxyapatite was mixed to poly-L-lactic acid, which is an absorbable material of the existing product. A clinical study was conducted to confirm the efficacy and safety of the aforementioned purpose and usage of this new absorbable material.
8	Jul. 24, 2012 Total review time: 589 days Regulatory review time: 346 days	Mar. 31, 2009 Clinical evaluation report	43	PEM Flex Solo II PET Scanner (Sceti K.K.)	Approval	Instrument & apparatus 10 Positron emission tomography device for nuclear medicine diagnosis	A positron CT device for nuclear medicine diagnosis; it images distribution of the pre-dosed radioactive agent that releases positive electrons in the breast. The breast is sandwiched by a tray with built-in gamma-ray scanner and the distribution of a radioactive agent is imaged. A clinical evaluation report was submitted to evaluate the images obtained when this product was applied to the breast.
8	Mar. 22, 2013 Total review time: 276 days Regulatory review time: 229 days	Sep. 22, 2009 Clinical evaluation report	44	Leksell Gamma Knife Perfexion (Elekta K.K.)	Change	Instrument & apparatus 10 Radionuclide system for stereotactic radiotherapy	A radioactive nuclide system for stereotactic radiotherapy; it is used for non-incisional surgery by gamma ray irradiation for the treatment of cerebral vascular disorder and brain tumor. In an application for partial change, a component that fixes and positions the patient head in a non-invasive manner is added. A clinical evaluation report was submitted to evaluate the positioning and re-positioning accuracy of the mouth piece which is prepared with respect to each patient.