Products Approved in FY 2011: New Medical Devices

Review category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Generic Name	Notes
1	Aug. 31, 2011 Total review time: 518 days Regulatory review time: 209 days	Feb. 11, 1991 Clinical evaluation report	1	Baerveldt Glaucoma Implant (AMO Japan K.K..)	New	Medical products 4 Intraocular drain	An artificial aqueous drainage device implanted to decrease intraocular pressure in patients with refractory glaucoma who have not responded to conventional therapy. It drains aqueous humor from the anterior or posterior chamber to the episclera to decrease intraocular pressure. It consists of a silicone plate and a tube and has holes for suturing the device to the sclera. It is available in straight tube type and pars plana insertion type. A clinical evaluation report summarizing the results of literature search on overseas clinical studies and experiences of this product was submitted to evaluate its safety and efficacy in decreasing intraocular pressure. [Priority review]
1	Nov. 24, 2011 Total review time: 594 days Regulatory review time: 191 days	– Foreign clinical study results	2	ICL (STAAR Japan Inc.)	Change	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	A phakic posterior chamber intraocular lens. The existing product is a myopia correction model which is intended for vision correction of myopia. Application for a partial change to add "vision correction for eyes with refractive error (myopic astigmatism)" as an intended use by addition of the astigmatism correction model. In the astigmatism correction model, the placement position of the lens and the postoperative rotation of the lens affect the efficacy, and therefore a clinical study was conducted to evaluate the efficacy and safety by using the astigmatism correction model. (A partial change in the reexamination period)
1	Dec. 20, 2011 Total review time: 418 days Regulatory review time: 238 days	Mar. 13, 2003 Clinical evaluation report	3	Alcon Ex-PRESS Glaucoma Filtration Device (Alcon Japan Ltd.)	New	Medical products 4 Intraocular drain	A stainless-steel glaucoma filtration device intended to create an aqueous humor outflow pathway between the anterior chamber and extraocular segment and to lower the intraocular pressure by puncture and placement from the limbus into the anterior chamber under the scleral flap. A clinical evaluation report summarizing the results of literature search on the foreign clinical studies for subconjunctival placement and the survey results of literature regarding the experience of this product was submitted to evaluate the safety and efficacy for intraocular pressure lowering.
1	Mar. 19, 2012 Total review time: 537 days Regulatory review time: 270 days	– Domestic clinical study results	4	Breath-O Correct (Universal View Co., Ltd.)	New	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens with a special shape added to the inner lens surface that is intended to reshape the corneal surface by wearing it during sleep and to correct and maintain the unaided vision during daytime after removal of the lens. A clinical study was conducted to evaluate the efficacy of the correction precision, etc. and the safety for corneal disorder, etc. (The original product is in a reexamination period)
1	Mar. 29, 2012 Total review time: 66 days Regulatory review time: 30 days	– No clinical study results	5	ICL (STAAR Japan Inc.)	Change	Instrument & apparatus 72 Phakic posterior chamber intraocular lens	An intraocular lens to be implanted in the posterior chamber of the phakic eye (in front of the human crystalline lens) to correct refractive errors in the eye (myopia or myopic astigmatism). Addition of a manufacturing site. (A partial change in the reexamination period)
3-1	Jun. 3, 2011 Total review time: 49 days Regulatory review time: 14 days	Jul. 2, 2008 No clinical study results	6	PROMUS Drug-Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. Changes of manufacturing site. (A partial change in the reexamination period)
3-1	Jun. 3, 2011 Total review time: 49 days Regulatory review time: 14 days	Jul. 2, 2008 No clinical study results	7	XIENCE V Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with everolimus coating used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. Changes of manufacturing site. (A partial change in the reexamination period)
3-1	Jan. 24, 2012 Total review time: 543 days Regulatory review time: 133 days	– Global clinical trial results	8	Zilver PTX Drug-Eluting Peripheral Stent (Cook Japan Inc.)	New	Instrument & apparatus 7 Drug-eluting stent for femoral artery	A stent system consisting of a self-expanding nitinol stent to be inserted and placed at the site of a lesion to maintain the inner cavity of a stenosis site of the femoropopliteal artery and a delivery system to deliver the stent to the site of the lesion. The outer surface of the stent tube is coated directly with paclitaxel to prevent restenosis of the treated site due to neointimal proliferation. A clinical study was conducted to evaluate the efficacy and safety of this product in the treatment of symptomatic vascular diseases in the above-knee femoropopliteal artery.

3-1	Jan. 24, 2012 Total review time: 375 days Regulatory review time: 129 days	– Global clinical trial results	9	Zilver Flex Vascular Stent for SFA (Cook Japan Inc.)	New	Instrument & apparatus 7 Stent for blood vessel	A stent system consisting of a self-expanding nitinol stent to be inserted and placed at the site of a lesion to maintain the inner cavity of a stenosis site of the femoropopliteal artery and a delivery system to deliver the stent to the site of the lesion. A clinical study was conducted to evaluate the efficacy and safety of this product for bail-out use at the time of failure in intervention therapy for the treatment of symptomatic vascular diseases in the above-knee femoropopliteal artery.
3-1	Feb. 8, 2012 Total review time: 103 days Regulatory review time: 88 days	Sep. 30, 2011 No clinical study results	10	Endeavor Sprint Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with zotarolimus coating used for dilating and maintaining the stenotic site of the coronary artery in symptomatic ischemic heart diseases. An application for a partial change to alter specifications of zotarolimus drug substance, shelf life, etc. (A partial change in the reexamination period)
3-1	Feb. 8, 2012 Total review time: 330 days Regulatory review time: 252 days	Nov. 22, 2011 Global clinical trial results	11	Promus Element Stent System (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Coronary stent	A product consisting of a drug-eluting stent coated with everolimus used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Platinum chromium alloy is used as a raw material for the stent, and the stent strut design was changed from the original product. A clinical study was conducted to confirm the efficacy and safety for the treatment of coronary stenotic sites when using this product. (The original product is in a reexamination period)
3-2	May. 19, 2011 Total review time: 286 days Regulatory review time: 142 days	Aug. 11, 2004 No clinical study results	12	Merci Retriever (Century Medical, Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A wire device with helical loops at the distal end used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for treatment. Application for a partial change to add V2.0 Soft and V3.0 Soft of Merci Retriever and an insertion tool for V2.0 Soft. (A partial change in the reexamination period)
3-2	Jun. 9, 2011 Total review time: 479 days Regulatory review time: 150 days	Dec. 28, 2007 (Types 1 - 3) Sep. 21, 2009 (Type 4) Foreign clinical study results	13	Penumbra System (Medico's Hirata Inc.)	New	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A device used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for treatment. It is a product to aspirate the thrombus by connecting a reperfusion catheter and an aspiration pump (Penumbra aspiration pump) via an aspiration tubing. A clinical study was conducted to evaluate its efficacy and safety in thrombectomy for cerebral infarction.
3-2	Jun. 13, 2011 Total review time: 138 days Regulatory review time: 92 days	Jul. 21, 2005 No clinical study results	14	ONYX Liquid Embolic System LD (Ev3 K.K.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthesis for embolization in vessels of the central circulation system to be used as an embolic material in cases where preoperative embolization is necessary in surgical resection of cerebral arteriovenous malformation that cannot be managed by treatment with other means than surgery. This product consists of a vial containing Onyx solution, a vial containing dimethyl sulfoxide (DMSO), and syringes. Application for a partial change to modify descriptions concerning the stopper thickness of vials containing Onyx solution and DMSO. (A partial change in the reexamination period)
3-2	Dec. 20, 2011 Total review time: 554 days Regulatory review time: 338 days	- Domestic clinical study results	15	Matsudaito (Sanyo Chemical Industries, Ltd.)	New	Medical products 4 Non-absorbable topical hemostatic material for central circulatory system	A non-absorbable topical hemostatic material consisting of a viscous liquid made of polyether-based fluorine-containing urethane prepolymer filled in syringe and accessory sheets and spatula. It is used for auxiliary hemostasis at the site of artificial anastomosis associated with thoracic aorta replacement or branching artery arch replacement in which hemostasis cannot be achieved by usual surgical procedures including ligation. Clinical studies were conducted to evaluate the efficacy and safety of the hemostatic effect of this product at sites of vascular anastomosis in thoracic aorta replacement.
3-2	Mar. 29, 2012 Total review time: 262 days Regulatory review time: 196 days	Aug. 11, 2004 No clinical study results	16	Merci Retriever (Century Medical, Inc.)	Change	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A wire device with helical loops at the distal end used for thrombectomy. Patients in acute phase of cerebral infarction who are ineligible for intravenous infusion of tissue plasminogen activator (t-PA) or who fail intravenous infusion of t-PA to restore blood flow are candidates for this treatment. An application for a partial change to add an insertion tool improved for easily pushing out the main body of this device from the insertion tool. (A partial change in the reexamination period)

4	Nov. 24, 2011 Total review time: 79 days Regulatory review time: 40 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. An application for a partial change to alter the shape of the battery connector part. (A partial change in the reexamination period)
4	Feb. 8, 2012 Total review time: 65 days Regulatory review time: 25 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 used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. Change of manufacturing site. (A partial change in the reexamination period)
4	Feb. 14, 2012 Total review time: 54 days Regulatory review time: 39 days	– No clinical study results	19	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for a partial change to add an emergency controller which can cancel the alarm during a magnetic levitation error due to cable disconnection or another cause. (A partial change in the reexamination period)
4	Feb. 29, 2012 Total review time: 176 days Regulatory review time: 136 days	– No clinical study results	20	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	An implantable ventricular assist device used to improve circulation until heart transplantation in patients with severe heart failure for whom heart transplantation is indicated. An application for a partial change to add a type in which the inside of the artificial blood vessel of the outflow graft is coated with the same material as the inflow cannula for reducing the amount of fluid drained from the thoracic cavity drain. (A partial change in the reexamination period)
4	Mar. 29, 2012 Total review time: 538 days Regulatory review time: 341 days	– Foreign clinical study results	21	Medtronic Advisa MRI (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable cardiac pacemaker	An implantable cardiac pacemaker used to treat bradycardia. The design concept allows MRI examination to patients implanted with the device; it is the first MRI-compatible pacemaker in Japan. The device has the identical pacing function with the approved product "Medtronic Advisa DR." It is used in combination with "CapSure FIX MRI leads" as implantable pacemaker leads. A clinical study using the previous product was conducted to confirm the safety of MRI examination to patients implanted with the device.
4	Mar. 29, 2012 Total review time: 538 days Regulatory review time: 341 days	Feb. 8, 2011 Foreign clinical study results	22	CapSureFix MRI Lead (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Endocardial implantable pacemaker leads	Implantable pacemaker leads used by connecting them to an implantable cardiac pacemaker. The design concept allows MRI examination to patients implanted with the device when used in combination with "Medtronic Advisa MRI." A clinical study was conducted to confirm the safety of MRI examinations to patients implanted with the device.
5	Aug. 31, 2011 Total review time: 257 days Regulatory review time: 154 days	Jul. 26, 2007 Domestic and foreign clinical study results	23	CryoSeal Disposable kit (Asahi Kasei Kuraray Medical Co., Ltd.)	New	Instrument & Blood component separation kit	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. This product is to be used with "CryoSeal CS-1." Biological tissue adhesives prepared with this product are used in the adhesion and closure of tissues (in the case of leakage of blood, body fluid, or internal gas from sutured or bonded tissues). Clinical studies were conducted to evaluate efficacy and safety concerning the adhesion and closure of tissues by biological tissue adhesives prepared using this product.
5	Aug. 31, 2011 Total review time: 257 days Regulatory review time: 154 days	Jul. 26, 2007 Domestic and foreign clinical study results	24	CryoSeal CS-1 (Asahi Kasei Kuraray Medical Co., Ltd.)	New	Instrument & apparatus 7 Apparatus for blood component separation	A device to be used to prepare a biological tissue adhesive of autologous plasma origin in a sterilized closed circuit for patients whose blood was donated for preserved blood type autotransfusion. This product is to be used with "CryoSeal Disposable Kit." Biological tissue adhesives prepared with this product are used in the adhesion and closure of tissues (in the case of leakage of blood, body fluid, or internal gas from sutured or bonded tissues). Clinical studies were conducted to evaluate efficacy and safety concerning the adhesion and closure of tissues by biological tissue adhesives prepared using this product.
5	Dec. 20, 2011 Total review time: 390 days Regulatory review time: 164 days	- Clinical evaluation report	25	Fetal Shunt (Hakko Co., Ltd.)	New	Instrument & apparatus 51 Shunt for fetal pleural effusion	A shunt tube to be placed in the fetal pleural cavity under ultrasonic guidance and a delivery system for the purpose of continuously draining fetal pleural effusion into the maternal amniotic cavity. A clinical evaluation report summarizing the results of literature research on the efficacy and safety of fetal thoraco-amniotic shunt and results of clinical research in Japan was submitted. [Orphan device]

6-2	May. 19, 2011 Total review time: 90 days Regulatory review time: 65 days	Oct. 10, 2003 No clinical study results	26	V.A.C.ATS Therapy System (KCI K.K.)	Change	Medical products 4 Negative pressure wound therapy system	A therapy system used for protection of wounds, maintaining a healing environment, and promoting and shortening the time of wound healing in patients with intractable traumatic wounds or dehisced wounds, post-operative open wounds or skin defective wounds, and post-operative wounds after dismemberment of extremities due to diabetes, etc. Application for a partial change to add manufacturing and sterilization facilities. (A partial change in the reexamination period)
6-2	Jun. 3, 2011 Total review time: 308 days Regulatory review time: 190 days	Jul. 7, 2004 Foreign clinical study results	27	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 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. This application for a partial change is to add an indication for painful spinal compression fracture of up to three levels due to multiple myeloma or metastatic bone tumor to an already approved indication for acute compression fracture of one vertebral body due to primary osteoporosis. A clinical study was conducted to evaluate the efficacy and safety of this product for the additional indication. (A partial change in the reexamination period)
6-2	Jun. 3, 2011 Total review time: 308 days Regulatory review time: 190 days	Jul. 9, 2004 Foreign clinical study	28	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 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 Bone Cement HV-R. This application for a partial change is to add an indication for painful spinal compression fracture of up to three levels due to multiple myeloma or metastatic bone tumor to an already approved indication for acute compression fracture of one vertebral body due to primary osteoporosis. A clinical study was conducted to evaluate the efficacy and safety of this product for the additional indication. (A partial change in the reexamination period)
6-2	Jul. 21, 2011 Total review time: 659 days Regulatory review time: 309 days	Dec. 7, 2007 Clinical evaluation report	29	VertaPlex Bone Cement (Stryker Japan K.K.)	New	Medical products 4 Orthopedic bone cement	An orthopedic bone cement to mitigate pain that is used in percutaneous vertebroplasty in patients with malignant spinal tumor such as painful metastatic bone tumor and myeloma who have not responded to conventional therapy. This product was developed with the aim of attaining a working time longer than that of the original product "Stryker Bone Cement for Exclusive Use in the Spine" (22100BZX01112000) by containing a homopolymer component without the styrene group and decreasing a catalyst. A clinical evaluation report summarizing a literature search on the results of domestic general clinical studies including previous products and the clinical results of bone cement that is used in percutaneous vertebroplasty in Japan and overseas was submitted to evaluate its efficacy and safety.
6-2	Jul. 21, 2011 Total review time: 13 days Regulatory review time: 13 days	Aug. 8, 2006 No clinical study results	30	X-STOP PEEK Implant (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Single-use interspinous implant device	An implant to be placed between target spinous processes in order to hold the lumbar spine in flexion and prevent it from going into extension for relief of lower back pain and leg pain in patients with lumbar spinal stenosis. Application for a partial change to correct the column for operation methods. (A partial change during the reexamination period)
8	Aug. 26, 2011 Total review time: 169 days Regulatory review time: 141 days	Apr. 29, 2005 No clinical study results	31	da Vinci Surgical System (Johnson & Johnson K.K.)	Change	Instrument & apparatus 12 Surgical robot, operation unit	A device to assist a surgeon in controlling endoscopic instruments attached to three arms of the patient cart with master-slave control in order to cut, coagulate and suture the tissue by manipulating the master controller on the surgeon console. Addition of a manufacturing site. (A partial change during the reexamination period)
8	Dec. 27, 2011 Total review time: 292 days Regulatory review time: 208 days	Apr. 29, 2005 No clinical study results	32	EndoWrist Instrument (Johnson & Johnson K.K.)	Change	Instrument & apparatus 25 Reusable active endotherapy device	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping, suturing, ligation etc. under endoscopic visualization. Addition of a manufacturing site. (A partial change in the reexamination period)
8	Dec. 27, 2011 Total review time: 111 days Regulatory review time: 86 days	Apr. 29, 2005 No clinical study results	33	EndoWrist Bipolar Instrument (Johnson & Johnson K.K.)	Change	Instrument & apparatus 25 Reusable active endotherapy device using radio frequency	An endoscopic instrument to be connected to "da Vinci Surgical System" to follow the movement of surgeon's hands and wrists by manipulating the master controller intended to work mechanically including grasping, suturing etc. and to cut and coagulate the tissue by using radiofrequency electrosurgery current under endoscopic visualization. Addition of a manufacturing site. (A partial change in the reexamination period)

Products Approved in FY 2011: 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	Jul. 13, 2011 Total review time: 351 days Regulatory review time: 134 days	May 3, 2011 Foreign clinical study results	1	Alcon AcrySof IQ Toric Single-Piece (Alcon Japan Ltd.)	Change	Instrument & apparatus 72 Posterior chamber lens	A posterior chamber lens to be inserted into an aphakic eye after cataract surgery, with corneal astigmatism-correcting function. This product is the only approved posterior chamber lens for astigmatism correction. The existing product is models with cylinder power of 1.50D, 2.25D, and 3.00D. This application is an application for a partial change to add the models with cylinder power of 3.75D, 4.50D, 5.25D, and 6.00D to deal with severe astigmatic eyes. A clinical study was conducted to confirm the efficacy and safety for correction of severe astigmatism.
1	Aug. 26, 2011 Total review time: 227 days Regulatory review time: 140 days	Jan. 4, 2008 Domestic clinical study results	2	Avaira (CooperVision Japan, Inc.)	New	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	Reusable colored contact lenses for correcting visual acuity. The silicone hydrogel lens is indicated for daily wear and replaced in two-week intervals. There is no novelty in the lens design, but the use of cross-linking agent and ultraviolet absorbing agent and the blend ratio of monomer among raw materials have novelty, and therefore a clinical study was conducted to confirm the efficacy and safety for wearing the lens for vision correction.
1	Nov. 14, 2011 Total review time: 1102 days Regulatory review time: 176 days	– Domestic clinical study results	3	HOYA iSii (HOYA Corporation)	New	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery, with multifocal function consisting of three zones for distant, near, and distant visions in a concentric pattern on the optic surface. A clinical study was conducted to evaluate the efficacy and safety of the intraocular lens, focusing on the efficacy of the multifocal mechanism.
1	Nov. 14, 2011 Total review time: 1095 days Regulatory review time: 169 days	– Domestic clinical study results	4	AF-1 iSii (HOYA Corporation)	New	Instrument & apparatus 72 Posterior chamber lens with an injector	A posterior chamber lens with an injector, for which "HOYA iSii" is preloaded in an injector. A clinical study was conducted to evaluate the efficacy and safety of the intraocular lens, focusing on the efficacy of the multifocal mechanism.
1	Nov. 18, 2011 Total review time: 326 days Regulatory review time: 207 days	Mar. 19, 2003 Clinical evaluation report	5	O_2 Optix (Ciba Vision Corporation)	Change	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A silicon hydrogel contact lens that can be worn continuously for up to 1 month. An application for a partial change to add the intended use "for treatment accompanied with vision correction capability for eyes with corneal diseases" to the conventional use "for visual acuity." A clinical evaluation report summarizing the results of a literature research on use-results of this product and other contact lenses used for treatment in Japan and overseas was submitted to evaluate the efficacy and safety in therapeutic use.
1	Feb. 23, 2012 Total review time: 1704 days Regulatory review time: 383 days	Oct. 12, 2000 Domestic clinical study results	6	Mechanical Microkeratome M2 (Moria Japan K.K.)	New	Instrument & apparatus 34 Mechanical keratome	A medical blade (mechanical keratome) for lamellar resection of the cornea in LASIK (laser in situ keratomileusis). A flap is made by putting negative pressure around the sclera to stabilize the cornea and resecting the corneal surface layer with the self-propelled blade. A clinical study was conducted to evaluate the efficacy in terms of the precision, quality, etc. of the flap, and the safety for the cornea, etc.
1	Feb. 28, 2012 Total review time: 1169 days Regulatory review time: 497 days	Apr. 11, 2006 (hardware) Aug. 17, 2006 (software) Foreign clinical study results	7	HiRes Auria Sound Processor (Nihon Bionics Co., Ltd.)	Change	Medical products 4 Cochlear implant	A cochlear implant for recovering sound perception by electrical stimulation in patients with bilateral severe hearing loss who have not responded sufficiently to wearing hearing aids. This application is an application for a partial change to add a sound processor and the HiRes 120 sound processing strategy. A clinical study was conducted to evaluate the efficacy and safety of HiRes 120.
1	Mar. 19, 2012 Total review time: 493 days Regulatory review time: 220 days	– Domestic clinical study results	8	Avansee 1P (Kowa Company, Ltd.)	New	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. A one-piece lens for which the optic and haptic are made from the same material. As the raw material has novelty, a clinical study was conducted to evaluate the efficacy for vision correction and the safety for the eye.

2	Dec. 6, 2011 Total review time: 832 days Regulatory review time: 222 days	Jan. 15, 2004 Domestic clinical study results	9	Geistlich Bio-Oss (Geistlich Pharma AG)	New	Medical products 4 Nonabsorbable material for bone regeneration	A nonabsorbable bone substitute that uses bovine bones originating from Australia as raw material and is prepared in the form of granules by heating and drying. It is used with a membrane for filling up bone defects when Guided Tissue Regeneration (GTR) is performed for vertical bone defects and defects in bones with class II root bifurcation lesions that are destroyed by periodontal disease. A clinical study was conducted to evaluate the efficacy and safety with the objective of bone improvement by conducting combination therapy of this product which is a bone substitute for bone regeneration and a dental collagen membrane for vertical bone defects and root bifurcation lesions caused by periodontitis.
2	Jan. 13, 2012 Total review time: 840 days Regulatory review time: 341 days	Jul. 22, 2005 Clinical evaluation report	10	Cerasorb M (Hakuho Corporation)	New	Medical products 4 Absorbable dental bone reconstruction implant material	An absorbable dental bone reconstruction implant material made from beta tricalcium phosphate (β-TCP) with a phase purity of higher than 99% in compliance with ASTM F 1088 and a granular product to be used as a substitute for bone for alveolar bone defects as a dental bone substitute (excluding indications on the assumption of placement of an implant). A clinical evaluation report was submitted to evaluate the clinical efficacy and safety of the product as a dental bone substitute.
3-1	May 23, 2011 Total review time: 879 days Regulatory review time: 457 days	May 5, 2005 (change of the time limit for removal) Nov. 18, 2007 (addition of a type) Foreign clinical study results	11	Inferior Vena Cava Filter Set (Cook Japan Inc.)	Change	Instrument & apparatus 51 Inferior vena cava filter	A permanent thrombus-capturing filter to be placed in the inferior vena cava to capture thrombi occurring in veins in the lower limb or pelvis for the prevention of pulmonary artery embolism or the prevention of its recurrence. If removal of this product is required for some reason, the product can be removed by using the dedicated loop system for removal. An application for a partial change was filed to add a type of delivery system and change the time limit for removal from within 10 days to an indefinite period. A clinical study was conducted to confirm the feasibility of removal after long-term placement.
3-1	Jul. 7, 2011 Total review time: 251 days Regulatory review time: 216 days	– Clinical evaluation report	12	Kaneka PTCA Catheter CO-R5 (Kaneka Corporation)	New	Instrument & apparatus 51 Balloon-dilating coronary perfusion catheter for angioplasty	A balloon catheter to be used for dilating stenotic sites in percutaneous transluminal coronary angioplasty (PTCA) or temporary sealing of blood vessel perforations caused during PTCA. With multiple holes made on the proximal and distal sides of the balloon, it enables perfusion from the proximal to distal side during expansion of the balloon. A clinical evaluation report was submitted to confirm the efficacy and safety of the use of the catheter for sealing of blood vessel perforations.
3-1	Aug. 2, 2011 Total review time: 368 days Regulatory review time: 209 days	Sep. 14, 2010 Clinical evaluation report	13	Integrity Coronary Stent System (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Coronary stent	A stent set for percutaneous coronary stent placement to be inserted and placed at the site of a lesion to maintain the vascular lumen. The approved product is formed by lining up the rings with crowns, whereas this product is formed by wrapping a wire that has crowns. A clinical evaluation report was submitted to confirm that this product can be used similarly to the approved product.
3-1	Sep. 5, 2011 Total review time: 418 days Regulatory review time: 243 days	Apr. 22, 2011 Foreign clinical study results	14	Taxus Element Stent System (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Coronary stent	A product consisting of a drug-eluting stent coated with paclitaxel and a delivery catheter to inhibit neointimal proliferation. The stent strut design of this product is changed and platinum chromium is used as a raw material for the stent to enhance the deliverability. The use of semisynthetic paclitaxel was also added. A clinical study was conducted to confirm the efficacy and safety for the treatment of coronary stenotic sites by using this product.
3-1	Feb. 21, 2012 Total review time: 424 days Regulatory review time: 118 days	May 19, 2011 Foreign clinical study results	15	ExoSeal (Johnson & Johnson K.K.)	New	Medical products 4 Absorbable topical hemostatic material	An absorbable topical hemostatic material to be used for hemostasis at the femoral artery puncture site in patients who have undergone percutaneous catheterization. The product consists of a polyglycolic acid plug which is a bioabsorbable material and a delivery system to place the plug. This product is intended for hemostasis by placement of the plug on the side of the vascular wall tissue. A clinical study was conducted to confirm the efficacy and safety of this product for hemostasis at the femoral artery puncture site.

3-2	Sep. 16, 2011 Total review time: 421 days Regulatory review time: 215 days	Dec. 16, 2010 Foreign clinical study results	16	ENDURANT Stent Graft System (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Aortic stent graft	The product consists of a stent graft and a delivery system used for endovascular treatment of lower abdominal aortic aneurysm of the renal artery. Compared to the approved product "TALENT Abdominal Stent Graft System," a tip-capture system was introduced and also the low profile delivery system was adapted in order to enhance the control capability for positioning the stent graft. A clinical study was conducted to confirm the efficacy and safety of this product for the treatment of aortic aneurysm.
3-2	Mar. 29, 2012 Total review time: 359 days Regulatory review time: 117 days	Apr. 1, 2011 Foreign clinical study results	17	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	New	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. Compared to the approved product "TALENT Thoracic Stent Graft System" (Approval No. 22100BZX00355000), improvements such as improvement of the stent graft design and introduction of a tip-capture system to the distal side of the delivery system (enhancement of the control capability for positioning the stent graft) were performed. A clinical study was conducted to evaluate the efficacy and safety of this product in the treatment of descending thoracic aortic aneurysm.
4	Apr. 13, 2011 Total review time: 285 days Regulatory review time: 164 days	– Foreign clinical study results	18	Fortify ST Pre (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 12 Automatic implantable defibrillator	An implantable defibrillator with the function of bradycardia pacing. The four variations of conectors are as follows: single-chamber types (VR) (IS-1/DF-1 or DF4 connector) and dual-chamber types (DR) (IS-1/DF-1 or IS-1/DF4 connector). Improvements compared with approved defibrillators are as follows: (1) downsizing, (2) addition of thoracic impedance measurement function, (3) addition of ATP treatment in the VF zone, (4) addition of pacing rate alert, (5) addition of low-frequency attenuation filter and (6) setting of the maximum defibrillation energy to be 40J. The device automatically adjusts pulse amplitude, when the patient's ventricular and atrial thresholds change. The efficacy and safety of the function was evaluated by the results of clinical studies for the different defibrillator, because another device with the identical function was under review at the time to compile this application.
4	Apr. 13, 2011 Total review time: 285 days Regulatory review time: 164 days	– Foreign clinical study results	19	Unify (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function. The two variations of connector are as follows: IS-1/DF4 connectors. Improvements from approved defibrillators are as follows: (1) downsizing, (2) addition of thoracic impedance measurement function, (3) addition of ATP treatment in the VF zone, (4) addition of pacing rate alert, (5) addition of low-frequency attenuation filter, and (6) setting of the maximum defibrillation energy to be 40J. The device automatically adjusts pulse amplitude, when the patient's ventricular and atrial thresholds change. The efficacy and safety of the function was evaluated by the results of clinical studies for the different defibrillator, because another device with the identical function was under review at the time to compile this application.
4	Jul. 5, 2011 Total review time: 333 days Regulatory review time: 137 days	May 3, 2010 Foreign clinical study results	20	SJM FD-OCT Imaging System (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 12 OCT diagnostic imaging instrument	The OCT diagnostic imaging instrument is intended for intravascular tomographic imaging. The device is for exclusive use with the catheter "SJM OCT Imaging Catheter". A clinical study was conducted to evaluate the observation capability and the intrinsic safety for target patients.
4	Jul. 5, 2011 Total review time: 333 days Regulatory review time: 137 days	May 3, 2010 Foreign clinical study results	21	SJM OCT Imaging Catheter (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 51 Intravascular optical tomographic catheter	The catheter is intended for intravascular tomographic imaging. The device is for exclusive use with "SJM FD-OCT Imaging System." A clinical study was conducted to evaluate the observation capability and the intrinsic safety for target patients.

4	Aug. 19, 2011 Total review time: 479 days Regulatory review time: 187 days	Nov. 26, 2010 Foreign clinical study results	22	Evia DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. In the application for a partial change, the following functions are added: a capture control function for the right atrium, a ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and ventricular pacing suppression function.
4	Aug. 19, 2011 Total review time: 280 days Regulatory review time: 204 days	Nov. 26, 2010 Foreign clinical study results	23	Evia DR (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker. In the application for a partial change, the following functions are added: a capture control function for the right atrium, a ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and the ventricular pacing suppression function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	24	Evia DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	25	Evia SR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A single-chamber implantable cardiac pacemaker with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	26	Lumax 540 HF-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	A CRT-D with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device are provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	27	Lumax 540 DR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	A dual-chamber pacing ICD with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device is provided to healthcare professionals via the component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to verify the usefulness of the home monitoring function.
4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	May 12, 2009 Foreign clinical study results	28	Lumax 540 VR-T (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	A single-chamber pacing ICD with the remote monitoring function. By using the home monitoring function of the device, the information collected by the device are provided to healthcare professionals via a component "Cardio Messenger." In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.

4	Sep. 12, 2011 Total review time: 346 days Regulatory review time: 177 days	Apr. 16, 2009 Foreign clinical study results	29	Cardio Messenger (Biotronik Japan, Inc.)	Change	Instrument & apparatus 21 Telemetry data transmitter	A device to receive information of patients from implanted pacemaker, ICD, etc, with the remote monitoring function and to transmit them to healthcare professionals by wireless communication. In the application for a partial change, the usefulness of the home monitoring function is professed in the "intended use; indication." A clinical study was conducted to evaluate the usefulness of the home monitoring function.
4	Sep. 22, 2011 Total review time: 328 days Regulatory review time: 94 days	Nov. 26, 2010 Foreign clinical study results	30	Entovis DR-T (Nihon Kohden Corporation)	Change	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker with the remote monitoring function. In the application for a partial change, the following functions are added: a capture control function for the right atrium, ventricular pacing suppression function and a rate stabilization function. The setting range of parameters is also expanded. A clinical study was conducted to evaluate the efficacy and safety of the capture control function for the right atrium and the ventricular pacing suppression function.
4	Oct. 5, 2011 Total review time: 559 days Regulatory review time: 224 days	Aug. 11, 2006 Foreign clinical study results	31	NaviStar ThermoCool (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation function used for radiofrequency catheter ablation and electrophysiological study. In the application for a partial change, the use for atrial fibrillation and ventricular tachycardia were added to the indication. Clinical studies were conducted to evaluate the efficacy and safety of the use for atrial fibrillation and ventricular tachycardia.
4	Oct. 20, 2011 Total review time: 360 days Regulatory review time: 209 days	Mar. 27, 2009 Clinical evaluation report	32	Activa RC (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrical stimulation device to reduce tremors associated with Parkinson's disease, essential tremor, etc. that do not sufficiently respond to drug therapy. The device stimulates the deep brain unilaterally or bilaterally. It is designed based on the intrinsic concept of the approved product "Itrel II (Approval No. 21100BZY00563000)" with changing to a dual-channel type, adding an electrical charge function, multi-program function, and constant current mode stimulation function, increasing the maximum pulse rate, etc. The clinical efficacy and safety of the multi-program function, the increased maximum pulse rate and constant current mode are evaluated with a clinical evaluation report.
4	Oct. 20, 2011 Total review time: 360 days Regulatory review time: 212 days	Jan. 26, 2011 Clinical evaluation report	33	Activa SC (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 12 Electrical brain stimulation device for tremor	An electrical stimulation device to reduce tremors associated with Parkinson's disease, essential tremor, etc. that do not sufficiently respond to drug therapy. The device stimulates the deep brain unilaterally or bilaterally. It is designed based on the intrinsic concept of the approved product "Itrel II (Approval No. 21100BZY00563000)" with adding a multi-program function and constant current mode stimulation function, increasing the maximum pulse rate, etc. The clinical efficacy and safety of the multi-program function, the increased maximum pulse rate and constant current mode are evaluated with a clinical evaluation report.
4	Dec. 12, 2011 Total review time: 605 days Regulatory review time: 204 days	Dec. 21, 2011 Foreign clinical study results	34	NaviStar ThermoCool SF (Johnson & Johnson K.K.)	New	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter with the irrigation function used for radiofrequency catheter ablation and electrophysiological study. The device was developed based on the approved product "NaviStar ThermoCool (Approval No. 22000BZX01645000)", and the catheter tip electrode design and the irrigation flow rate were changed. Clinical studies were conducted to evaluate the efficacy and safety of the use for atrial fibrillation and ventricular tachycardia.
4	Jan. 17, 2012 Total review time: 823 days Regulatory review time: 365 days	Aug. 3, 2005 Foreign clinical study results	35	Select Secure Lead (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 7 Endocardial implantable pacemaker leads	A screw-in bipolar transvenous lead. The diameter of device is made smaller than usual leads by modifications such as removal of the lumen for stylet insertion; it aims to combine with "Medtronic Deflectable Catheter" that can be bent at the distal part of the catheter and to be located in cardiac chamber. A clinical study was conducted to evaluate the efficacy and the safety to place the device with "Medtronic Deflectable Catheter" through the comparison with lead placement using the conventional stylet.

4	Jan. 17, 2012 Total review time: 823 days Regulatory review time: 365 days	Oct. 25, 2006 Foreign clinical study results	36	Medtronic Deflectable Catheter (Medtronic Japan Co., Ltd.)	New	Instrument & apparatus 51 Cardiac catheter introducer kit	A guiding catheter and accessories to be used to pass leads for implantable cardiac pacemakers through the atrium or ventricle. It is used together with "Select Secure Lead." A clinical study was conducted to evaluate the efficacy and the safety to place "Select Secure Lead" with the device through the comparison with lead placement using the conventional stylet.
4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 192 days	– Foreign clinical study results	37	Promote Quadra (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device conducts cardiac resynchronization therapy that synchronizes the ventricular contraction. The design concept is similar to that of the approved product "Promote Accel RF (Approval No.: 22200BZX00962000)", but the connector is changed from IS-1 (2 poles) to IS4 (4 poles) and the left ventricular pacing polarity is added. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead) .
4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 192 days	– Foreign clinical study results	38	Unify Quadra (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable biventricular pacing pulse generator with defibrillator function and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device conducts cardiac resynchronization therapy that synchronizes the ventricular contraction. The design concept is similar to that of the approved product "Unify (Approval No. 22300BZX00210000)", but the connector is changed from IS-1 (2 poles) to IS4 (4 poles) and the left ventricular pacing polarity is added. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead).
4	Feb. 2, 2012 Total review time: 349 days Regulatory review time: 182 days	Nov. 29, 2011 Foreign clinical study results	39	Quartet (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	A left ventricular lead and accessories to improve cardiac failure symptoms with regular and weak electrical stimulation to bilateral ventricular myocardium. The device is connected with a biventricular pacing pulse generator with defibrillator function when performing cardiac resynchronization therapy. The device has 4 poles and allows to select the more options for pacing polarity than the approved left ventricular leads, which have 2 poles. A clinical study was conducted to evaluate the efficacy and safety associated with an increase in pacing polarity (e.g. stability of 4-pole lead).
4	Feb. 13, 2012 Total review time: 770 days Regulatory review time: 310 days	– Domestic clinical study results	40	Intracardiac Defibrillation Multi-catheter (Japan Lifeline Co., Ltd.)	New	Instrument & apparatus 51 Cardiac catheter-type electrode	A cardiac catheter electrode used for cardiac electrophysiological examination. Moreover, the device is connected with "Intracardiac Defibrillator" and used for defibrillation when atrial fibrillation, atrial flutter, or atrial tachycardia occurs during percutaneous catheter ablation or cardiac electrophysiological examination. A clinical study was conducted to evaluate the efficacy and safety of the defibrillation using the device.
4	Feb. 13, 2012 Total review time: 770 days Regulatory review time: 276 days	– Domestic clinical study results	41	Intracardiac Defibrillator (Japan Lifeline Co., Ltd.)	New	Instrument & apparatus 12 Manual defibrillator	This is a generator for electric defibrillation connected with "Intracardiac Defibrillation Multi-catheter" when atrial fibrillation, atrial flutter, or atrial tachycardia occurs during percutaneous catheter ablation or cardiac electrophysiological examination. A clinical study was conducted to evaluate the efficacy and safety of the defibrillation using the device.
4	Feb. 23, 2012 Total review time: 423 days Regulatory review time: 234 days	Oct. 2, 2009 Foreign clinical study results	42	Blazer Prime XP Ablation Catheter (Boston Scientific Japan K.K.)	New	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter to apply radiofrequency current to the target site of arrhythmia identified electrophysiologically, in order to treat persistent or recurrent type I atrial flutter. The shaft part was improved in order to enhance the delivery capability. A clinical study was conducted to evaluate the efficacy and safety to use the device for persistent or recurrent type I atrial flutter.

5	Apr. 18, 2011 Total review time: 755 days Regulatory review time: 404 days	Dec. 1, 2006 Foreign clinical study results	43	AMS GreenLight HPS Console (American Medical Systems, Inc.)	New	Instrument & apparatus 31 Double-frequency neodymium-YAG laser	A surgical device for resection of the prostate gland with 532 nm double-frequency neodymium-YAG laser under cystoscopy for the treatment of benign prostate hypertrophy/hyperplasia. Improvements from the approved product are the use of the oscillation wavelength of 532 nm and change of the maximum output power to 120 W. A clinical study was conducted to confirm the efficacy and safety of this product for benign prostate hypertrophy/hyperplasia.
5	Apr. 18, 2011 Total review time: 755 days Regulatory review time: 404 days	Dec. 1, 2006 Foreign clinical study results	44	AMS GreenLight HPS Fiber (American Medical Systems, Inc.)	New	Instrument & apparatus 31 Single-use probe for laser guidance	A side-firing fiber to be used in combination with the surgical device "AMS GreenLight HPS Console" to resect the prostate gland with 532 nm double-frequency neodymium-YAG laser under cystoscopy for the treatment of benign prostate hypertrophy/hyperplasia. A clinical study was conducted to confirm the efficacy and safety of this product for benign prostate hypertrophy/hyperplasia.
5	Jul. 7, 2011 Total review time: 645 days Regulatory review time: 225 days	Sep. 30, 2004 Clinical evaluation report	45	WallFlex Colonic Stent (Boston Scientific Japan K.K.)	New	Instrument & apparatus 7 Colonic stent	A colonic stent to be used for colonic strictures produced by malignant neoplasm to relieve large bowel obstruction prior to operation, also to be used for the palliative treatment for patients who cannot be managed by palliative surgical treatment or are not expected to achieve improvement with other treatments. A clinical evaluation report was submitted to evaluate the efficacy and safety for the use of this product for preoperative relief of bowel obstruction or as palliative treatment.
5	Nov. 14, 2011 Total review time: 693 days Regulatory review time: 363 days	– Clinical evaluation report	46	Niti-S Gastroduodenal Stent (Century Medical, Inc.)	New	Instrument & apparatus 7 Gastroduodenal stent	A gastroduodenal stent to be used to maintain patency at stenotic sites in patients with unresectable malignant gastroduodenal stenosis who are not expected to achieve improvement with surgical treatment or other treatment methods. A clinical evaluation report summarizing the results of literature research on clinical data on gastroduodenal stent placement was submitted to evaluate the efficacy and safety.
5	Mar. 26, 2012 Total review time: 536 days Regulatory review time: 331 days	May 8, 2006 Clinical evaluation report	47	Given Patency Capsule Endoscope (Given Imaging K.K.)	New	Instrument & apparatus 25 Capsule electronic endoscope system	A product to take and provide images of the small-intestinal mucosa for diagnosis of small-intestinal diseases. The approved product "Given Capsule Endoscope (Approval No. 22100BZX00363000) has been improved with the addition of Agile J Patency Capsule (AJP), which is used to assess appropriateness of the patency of the digestive tract prior to the use of a capsule endoscope in patients who have or are suspected of having stenosis or narrowing of the digestive tract. A clinical evaluation report summarizing literature information, etc. on occurrence of retention of capsule endoscopes after assessment of patency by AJP was submitted to evaluate the accuracy of assessment of patency with AJP.
6-1	Apr. 28, 2011 Total review time: 388 days Regulatory review time: 195 days	– Domestic clinical study results	48	Aquala Liner (Japan Medical Materials Corporation)	New	Medical products 4 Artificial hip joint, acetabular component	An ultra-high-molecular-weight polyethylene liner for an artificial hip joint. This product is photoinduced graft-polymerized with 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer on the bearing surface in addition to cross-link processing, in order to improve the wear resistance of the bearing surface while inheriting the design of the approved products. A clinical study was conducted to confirm the efficacy and safety of the liner for which the bearing surface was modified with the novel raw material.
6-2	Jun. 14, 2011 Total review time: 1174 days Regulatory review time: 788 days	– Domestic clinical study results	49	Osmix (Kuraray Medical Inc.)	New	Medical products 4 Artificial bone implant	An artificial bone implant in paste form for which silane-coating hydroxyapatite particles and polymerizable monomers are mixed. This product is designed to start polymerization when discharged from the dedicated injector. It is injected into the affected site in paste form to compensate for bone defects after reconstruction of bone fracture of non-loaded region and for bone defects after removals of bone tumor/necrosis bone. A clinical study was conducted to confirm the efficacy and safety of the use of the novel raw material.

6-2	Jun. 14, 2011 Total review time: 287 days Regulatory review time: 172 days	Jun. 27, 2001 Aug. 8, 2003 Domestic clinical study results	50	TwinFix AB Anchor (Smith & Nephew Endoscopy KK)	New	Medical products 4 Absorbable ligament anchor	An absorbable suture anchor to be used to repair the binding of soft tissues such as ruptured tendons, ligament, and muscles to bones. The product is only indicated for repair of rotator cuff tear in the shoulder. The improvement from the approved nonabsorbable product is the use of absorbable poly-L-lactic acid as raw material for the anchor. A clinical study was conducted to evaluate the efficacy and safety of this product which is an absorbable screw-type anchor.
6-2	Dec. 1, 2011 Total review time: 975 days Regulatory review time: 674 days	Nov. 20, 2001 Clinical evaluation report	51	Lacto Screw Suture Anchor (Biomet Japan, Inc.)	New	Medical products 4 Absorbable ligament anchor	A resorbable screw-type suture anchor made of polylactic/polyglycolic acid copolymer used to attach ligaments or tendons to bones with a suture. The device is to be used in patients who require repair due to damage of soft tissues in regions adjacent to the shoulder joint such as the articular labrum, and soft tissues of the elbow and hand joints. A clinical evaluation report summarizing literatures on clinical data using this device and other screw-type anchor made from the same raw material, was submitted to evaluate the efficacy and safety.
6-2	Dec. 1, 2011 Total review time: 945 days Regulatory review time: 868 days	Jul. 19, 2006 Clinical evaluation report	52	AllThread Screw L15 (Biomet Japan, Inc.)	New	Medical products 4 Absorbable ligament anchor	A resorbable screw-type suture anchor made of polylactic/polyglycolic acid copolymer used to attach ligaments or tendons to bones with a suture. The device is to be used in patients who require repair due to damage of soft tissues in regions adjacent to the shoulder joint, and soft tissues of the elbow and hand joints. A clinical evaluation report summarizing literatures on clinical data using other screw-type anchor made from the same raw material as this device, was submitted to evaluate the efficacy and safety.
6-2	Feb. 17, 2012 Total review time: 1803 days Regulatory review time: 805 days	May 1, 2000 Domestic clinical study results	53	Arthrex Bio-FASTak Suture Anchor (Kobayashi Medical Co., Ltd.)	New	Medical products 4 Absorbable screw for internal fixation	An absorbable screw-type suture anchor made of poly DL-lactic acid to be used to fix soft tissues to bones in shoulder joints. A clinical study was conducted to evaluate the efficacy and safety for the treatment of shoulder joint instability in order to evaluate whether tissues such as ligaments in shoulder joints can be repaired.
Biologics	Apr. 8, 2011 Total review time: 952 days Regulatory review time: 315 days	Nov. 15, 2007 Foreign clinical study results	54	SJM Epic Stented Tissue Valve (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Porcine cardiac valve	A biological prosthetic cardiac valve with stent derived from pig aortic valve that is intended to substitute for the function of aortic valves or mitral valves with a disease, damage, or dysfunction. This product is treated for anticalcification and uses bovine pericardial membrane at the stent part for the protection of the valve leaflet. A clinical study was conducted to confirm the efficacy and safety of this product.
Biologics	Mar. 8, 2012 Total review time: 416 days Regulatory review time: 122 days	Apr. 20, 2011 Foreign clinical study results	55	SJM Trifecta Valve (St. Jude Medical Japan Co., Ltd.)	New	Instrument & apparatus 7 Bovine pericardial valve	A bovine pericardial valve to be used to substitute for the function of aortic valves with a disease, damage, or dysfunction. This product is to be implanted into the supra annular position. It is treated for anticalcification. Pig pericardial membrane is used at the outflow of the stent for the protection of the valve leaflet. A clinical study was conducted to confirm the clinical safety and efficacy of this product.