Table 2. Products Approved in FY 2009: New Medical Devices

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 28, 2009 Total review time: 876 days Regulatory review time: 621 days	- Domestic clinical study results	1	Ortho-K (Alpha Corporation Inc.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	The first orthokeratology contact lens in Japan for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct unaided vision after removal of the lens.
1	May 22, 2009 Total review time: 1669 days Regulatory review time: 615 days	Oct. 17, 2003 Overseas clinical study results	2	Allegretto Wave (Wavelight Laser Technologie AG)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Jul. 1, 2009 Total review time: 96 days Regulatory review time: 91 days	May 23, 2003 No clinical study results	3	VISX Excimer Laser System (AMO Japan K.K.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism and remove corneal opacities by laser ablation of corneal tissue. (Application for change from a foreign exceptional approval to a regular marketing approval in the reexamination period)
1	Jul. 3, 2009 Total review time: 51 days Regulatory review time: 50 days	- No clinical study results	4	Ortho-K (Alpha Corporation Inc.)	Change	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and to correct unaided vision after removal. The addition of a manufacturing site. (A partial change in the reexamination period)
1	Jul. 24, 2009 Total review time: 186 days Regulatory review time: 131 days	Nov. 8, 2006 Overseas clinical study results	5	Excimer Laser Corneal Surgery System EC-5000CXIII (Nidek Co., Ltd.)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia, hyperopia or astigmatism, remove corneal surface opacities, or smooth corneal irregularities by laser ablation of corneal tissue. A partial change for the objectives including the addition of correction of hyperopia to the indications. (A partial change in the reexamination period)
1	Aug. 13, 2009 Total review time: 394 days Regulatory review time: 142 days	Oct. 1, 2001 No clinical study results	6	O_2 Optics (Ciba Vision K.K.)	Change	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A silicone hydrogel contact lens indicated for daily or up to 1 month extended wear. Addition of a supplementary fluid and a manufacturing site. (A partial change in the reexamination period)
1	Dec. 17, 2009 Total review time: 28 days Regulatory review time: 20 days	- No clinical study results	7	α Ortho-K (Alpha Corporation Inc.)	Approval	Instrument & apparatus 72 Orthokeratology contact lens	An orthokeratology contact lens for patients with myopia and myopic astigmatism to reshape the corneal anterior surface by wearing it during sleep and correct the unaided vision after removal. (Addition of a brand name to Ortho-K in the reexamination period) (The original product is in a reexamination period)
1	Feb. 2, 2010 Total review time: 1771 days Regulatory review time: 524 days	Dec. 22, 2005 Domestic clinical study results	8	ICL (STAAR Japan Inc.)	Approval	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).
3-1	April 27, 2009 Total review time: 55 days Regulatory review time: 48 days	Sep. 22, 2006 No clinical study results	9	Angioguard XP (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	The first device in Japan to prevent distal emboli with a polyurethane filter to capture and remove embolic substances including thrombi released while a stent is placed in the carotid artery. Application for a partial change to alter the materials. (A partial change in the reexamination period)
3-1	Aug. 25, 2009 Total review time: 265 days Regulatory review time: 251 days	Jul. 12, 2007 No clinical study results	10	Precise for Carotid Artery (Johnson & Johnson K.K.)	Change	Instrument & apparatus 7 Stent for the carotid artery	The first stent for the carotid artery in Japan to dilate carotid stenosis and prevent restenosis. Change for addition of RX type. (A partial change in the reexamination period)
3-1	Jan. 8, 2010 Total review time: 589 days Regulatory review time: 229 days	Jul. 2, 2008 Domestic and overseas clinical study results	11	XIENCE V Drug Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Approval	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.
3-1	Jan. 8, 2010 Total review time: 589 days Regulatory review time: 229 days	Jul. 2, 2008 Domestic and overseas clinical study results	12	PROMUS Drug-Eluting Stent (Abbott Vascular Japan Co., Ltd.)	Approval	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.
3-1	Jan. 8, 2010 Total review time: 283 days Regulatory review time: 236 days	Oct. 2, 2008 Overseas clinical study results	13	Endeavor Sprint Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	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, with a different delivery catheter from the original product. (The original product is in a reexamination period)
3-1	Jan. 25, 2010 Total review time: 285 days Regulatory review time: 73 days	Oct. 10, 2008 No clinical study results	14	TAXUS Liberté Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Application for a partial change to alter the test method for raw materials. (A partial change in the reexamination period)

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-1	Jan. 25, 2010 Total review time: 285 days Regulatory review time: 73 days	Mar. 4, 2004 No clinical study results	15	TAXUS Express2 Stent (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating used for dilating and holding a stenotic site of the coronary artery in ischemic heart disease. Application for a partial change to alter the test method for raw materials. (A partial change in the reexamination period)
3-1	Feb. 15, 2010 Total review time: 374 days Regulatory review time: 155 days	Oct. 23, 2008 Overseas clinical study results	16	Carotid Wallstent Monorail (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	A stent made of cobalt-chromium alloy used for dilating and holding a stenotic site of the cartoid artery in cartoid stenosis. (The original product is in a reexamination period)
3-1	Feb. 15, 2010 Total review time: 374 days Regulatory review time: 155 days	Dec. 14, 2006 Overseas clinical study results	17	FilterWire EZ (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli with a polyurethane filter to capture and remove embolic substances including thrombi released while a stent is placed in the carotid artery. (The original product is in a reexamination period)
3-2	Apr. 9, 2009 Total review time: 714 days Regulatory review time: 243 days	Jun. 5, 2008 Overseas clinical study results	18	TALENT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysms used to prevent blood flow into the aneurysm and aneurysm rupture. (The original product is in a reexamination period)
3-2	May 1, 2009 Total review time: 56 days Regulatory review time: 52 days	- No clinical study results	19	Triplex (Terumo Corporation)	Change	Instrument & apparatus 7 Artificial blood vessel for the central circulation system	An artificial blood vessel consisting of a triple layer structure containing a non-porous layer held between 2 polyester stockinette layers; together these layers form a tubular body. This does not require sealing with biological materials. Application for a partial change to alter the materials. (A partial change in the reexamination period)
3-2	May 27, 2009 Total review time: 187 days Regulatory review time: 181 days	Jul. 21, 2005 No clinical study results	20	ONYX Liquid Embolic System LD (ev3 Inc.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	The first liquid embolic material in Japan used to occlude the flow of blood as pretreatment for surgical resection of arteriovenous malformations (bAVM's). A change of adding description concerning compatible catheters. (A partial change in the reexamination period)
3-2	Nov. 25, 2009 Total review time: 215 days Regulatory review time: 139 days	Nov. 7, 2008 No clinical study results	21	GORE TAG Thoracic Aortic Stent Graft System (Japan Gore-Tex Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysm used to prevent blood flow into the aneurysm and its rupture. Application for a partial change to add a delivery system. (A partial change in the reexamination period)
3-2	Jan. 8, 2010 Total review time: 302 days Regulatory review time: 179 days	May 8, 2007 Domestic and overseas clinical study results	22	Codman Enterprise VRD (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A cylindrical, mesh-like vascular reconstruction device to be deployed in the parent artery in order to prevent the embolic coils from protrude and/or dropout into the parent artery during coil embolization of wide-neck intracranial aneurysms, which are difficult to treat with surgery. [Orphan device]
4	May 27, 2009 Total review time: 106 days Regulatory review time: 94 days	Dec. 9, 1997 (12Fr) Sep. 4, 1998 (14Fr/16Fr) Jan. 25, 2002 (16Fr SLSII) May 2, 2002 (12/14FrSLSII) No clinical study results	23	Excimer Laser Cardiac Lead Removal System (DVx Inc.)	Change	Instrument & apparatus 7 Pacemaker/defibrillator lead removal kit	The first extraction laser sheath in Japan used at removal of chronically implanted pacing or defibrillator leads to ablate binding tissue around the circumference of leads using the laser energy delivered from a dedicated excimer laser system. Addition of a manufacturing site. (A partial change in the reexamination period)
4	Nov. 18, 2009 Total review time: 2091 days Regulatory review time: 200 days	May 31, 2001 Domestic and overseas clinical study results	24	Implantable Ventricular Assist Device HeartMate XVE LVAS (Nipro Corporation)	Approval	Instrument & apparatus 7 Implantable ventricular assist device	An implantable diaphram left ventricular assist device intended for use to improve the circulation in patients with end-stage heart failure who are difficult to survive despite the conventional short-term, mechanically-assisted circulation and maximum medical management, and are considered to be difficult to be rescued without heart transplantation. The efficacy and safety of this product for the target patients were evaluated in the clinical studies using the previous model. [Orphan device]
4	Jan. 8, 2010 Total review time: 423 days Regulatory review time: 192 days	Jun. 16, 1997 Overseas clinical study results	25	Vagus Nerve Stimulation (VNS) System (Nihon Kohden Corporation)	Approval	Instrument & apparatus 12 Vagus nerve stimulation device with anti-seizure effects	An electrical stimulation device to stimulate vagus nerve as an adjuvant therapy for patients with drug-resistant epilepsy who have refractory epileptic seizures. Clinical studies were conducted to confirm the efficacy and safety of this product in the target patients. [Priority review]
5	Aug. 6, 2009 Total review time: 427 days Regulatory review time: 188 days	Jan. 15, 2002 No clinical study results	26	Dornier Epos Ultra (Dornier MedTech Japan Co. Ltd.)	Change	Instrument & apparatus 12 Extracorporeal shock wave pain therapy system	A low-energy extracorporeal shock wave therapy system for orthopedic use with reduced output of the conventional electromagnetic induction-type extracorporeal shock wave lithotripter applied for pain relief therapy. Application for a partial change for the objectives including for addition of the ultrasonic imaging device used to position the affected area. (A partial change in the reexamination period)
5	Sep. 1, 2009 Total review time: 679 days Regulatory review time: 413 days	Oct. 22, 2004 Overseas clinical study results	27	MR-Guided Focused Ultrasound Surgery System ExAblate 2000 (GE Healthcare Japan Corporation)	Approval	Instrument & apparatus 12 Ultrasound hyperthermia system	A focused ultrosonic surgery system used for treatment of symptomatic uterine fibroid while monitoring the tissue temperature with MR in order to improve the symptoms.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Jan. 8, 2010 Total review time: 283 days Regulatory review time: 84 days	May 6, 2005 Domestic clinical study results	28	Cryosurgical Unit CryoHit (Hitachi Medical Corporation)	Approval	Instrument & apparatus 31 Versatile cryosurgical unit	A cryosurgical system used to kill renal tumor cells of small diameter by utilizing Joule-Thompson effect of high-pressure argon gas to cool the tip end of probe or needle (-100°C or lower) under Magnetic Resonance (MR) Image guidance.
5	Jan. 15, 2010 Total review time: 703 days Regulatory review time: 254 days	Sep. 24, 2001 Domestic clinical study results	29	Deflux (Q-Med AB)	Approval	Medical products 4 Filling material for the treatment of vesicoureteral reflux	A device with injectable material consisting of dextranomer microspheres which is a bulge forming material and solution of stabilized hyaluronate sodium in phosphate buffered saline filled in a disposable syringe equipped with a tip cap, used for treatment of patients with vesicoureteral reflux grade II - IV.
6	Nov. 2, 2009 Total review time: 584 days Regulatory review time: 273 days	Oct. 10, 2003 Domestic clinical study results	30	V.A.C. ATS Therapy System (KCI KK)	Approval	Medical products 4 Negative Pressure Wound Therapy System	A therapy system used for protection of the 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 defect wounds, post-operative wounds after dismemberment of extremities due to diabetics, etc. The novelty of this product is the capability of the system to control the treatment mechanically while the conventional simple suction therapy was performed by individual physicians using a prepared set of tools. A clinical study was conducted in Japan to evaluate its clinical efficacy and safety.
6	Dec. 24, 2009 Total review time: 462 days Regulatory review time: 142 days	May 25, 2004 Clinical evaluation report	31	Stryker SpinePlex Bone Cement (Stryker Japan K.K.)	Approval	Medical products 4 Orthopedic bone cement	An acrylic bone cement used for pain relief in percutaneous vertebroplasty for painful vertebral body fracture caused by malignant spine tumor such as metastatic bone tumor and myeloma which are not responsive to conventional therapies. A clinical evaluation report summarizing the Japanese clinical study results and the literature research data on the use results of this and similar products in foreign countries was submitted to verify the safety and efficacy. [Priority review]
6	Feb. 5, 2010 Total review time: 651 days Regulatory review time: 368 days	Jul. 2, 1998 Domestic and overseas clinical study results	32	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Approval	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system to be used in percutaneous kyphosis correction performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief in spinal compression fracture. The novelty of this product is the capability to fill the bone cement safely after restoration of the physical vertebral height by forming a cavity in the fractured vertebral body in comparison with the conventional vertebroplasty. A clinical study was conducted in Japan to evaluate its efficacy and safety. In addition, results from overseas clinical studies were submitted.
6	Feb. 5, 2010 Total review time: 651 days Regulatory review time: 347 days	Apr. 1, 2004 Domestic and overseas clinical study results	33	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Orthopedic bone cement	A therapeutic spine bone cement used in percutaneous kyphosis correction in spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. The novelty of this product is the capability to fill the bone cement safely after restoration of the physical vertebral height by forming a cavity in the fractured vertebral body in comparison with the conventional vertebroplasty. A clinical study was conducted in Japan to evaluate its efficacy and safety.In addition, results from overseas clinical studies were submitted.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 205 days	Apr. 29, 2005 Overseas clinical study results	34	da Vinci Surgical System (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 12 Surgical robot, operational 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 perform cutting, coagulating and suturing the tissue by manipulating the master controller on the surgeon console.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 232 days	Apr. 29, 2005 Overseas clinical study results	35	EndoWrist Bipolar Instrument (Johnson & Johnson K.K.)	Approval	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.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 232 days	Apr. 29, 2005 Overseas clinical study results	36	EndoWrist Monopolar Instrument (Johnson & Johnson K.K.)	Approval	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 etc. and to cut and coagulate the tissue by using radiofrequency electrosurgery current under endoscopic visualization.
8	Nov. 18, 2009 Total review time: 331 days Regulatory review time: 235 days	Apr. 29, 2005 Overseas clinical study results	37	EndoWrist Instrument (Johnson & Johnson K.K.)	Approval	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.

Note: Products submitted for application in 2003 and before are included.

Table 3. Products Approved in FY 2009: Improved Medical Devices (with Clinical Data)

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Jul. 24, 2009 Total review time: 401 days Regulatory review time: 161 days	Apr. 5, 2005 Clinical evaluation report	1	Relieva Sinus Balloon Catheter Set (Medico's Hirata Inc.)	Approval	Instrument & apparatus 51 Endoscopic dilatation catheter	A catheter set used to drain the pus by dilating narrowed natural openings of the frontal sinus, sphenoid sinus, and maxillary sinus with balloons for the treatment of sinusitis. A clinical evaluation report based on the overseas post-marketing clinical research was submitted to evaluate its efficacy and safety.
1	Dec. 9, 2009 Total review time: 588 days Regulatory review time: 384 days	- Domestic clinical study results	2	Menicon 1day Flat Pack (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	A daily disposable soft contact lens for myopia and hyperopia. A copolymer of HEMA and GMA is used as lens materials. Clinical studies were conducted to evaluate the efficacy and safety.
1	Mar. 4, 2010 Total review time: 769 days Regulatory review time: 418 days	Mar. 3, 2008 Overseas clinical study results	3	1-Day Acuvue TruEye (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	A daily disposable soft contact lens for myopia, hyperopia, astigmatism, or presbyopia. A copolymer of HEMA, OH-mPDMS, and DMA is used as lens materials. Clinical studies were conducted to evaluate the efficacy and safety.
2	Jan. 15, 2010 Total review time: 697 days Regulatory review time: 447 days	- Domestic clinical study results	4	Neobone (Covalent Materials Corporation)	Change	Medical products 4 Artificial bone implant	An artificial bone implant material consisting of granular and shaped (e.g. rectangular cuboid) products to be used for filling bone defect and for supporting bone regeneration. Application for a partial change to add spherical granular product and to add granular products for use in dental field to the indication in addition to its use in the orthopedic field. Clinical studies were conducted to evaluate its efficacy as bone filler for dental use.
3-1	Apr. 20, 2009 Total review time: 641 days Regulatory review time: 427 days	- Overseas clinical study results	5	Palmaz Genesis for Renal Artery (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A stent used for dilating and holding a stenotic site in renal artery stenosis. Clinical studies were conducted to evaluate its clinical efficacy in renal artery stenosis.
3-1	Aug. 6, 2009 Total review time: 1989 days Regulatory review time: 859 days	Jul. 29, 2002 Clinical evaluation report	6	HydroCoil Embolic System (Terumo Corporation)	Approval	Instrument & apparatus 51 Sterilized tube and catheter for vascular treatment	A delivery pusher for platinum alloy coil intended to block the blood flow into brain aneurysm and for guiding the coil to the implanting site. The coil is coated with swellable hydrogel. Clinical evaluation data to evaluate its efficacy and safety were submitted.
3-1	Jan. 8, 2010 Total review time: 226 days Regulatory review time: 182 days	- Overseas clinical study results	7	Cypher Select+ Stent (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting stent coated with drugs to inhibit the neointimal proliferation and a delivery catheter. Clinical studies were conducted to evaluate its efficacy and safety.
3-2	Aug. 21, 2009 Total review time: 549 days Regulatory review time: 482 days	Apr. 7, 2005 Overseas clinical study results	8	DuraSeal Blue Spray (Tyco Healthcare Japan Inc.)	Approval	Medical products 4 Absorbable tissue reinforcement material	An absorbable prosthetic material for dura mater applied as an adjunct to suturing, on the dural gap, sutured site of dura mater, and the gap between the duraplasty material and dura mater. A clinical study was conducted to evaluate its efficacy and safety.
4	Apr. 16, 2009 Total review time: 533 days Regulatory review time: 195 days	May 7, 2007 Overseas clinical study results	9	Promote 36 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT (treatment method to improve cardiac failure symptoms, which synchronizes ventricular contraction by stimulating cardiac muscles of both ventricles electrically for a long time), with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Apr. 16, 2009 Total review time: 533 days Regulatory review time: 243 days	Sep. 11, 2007 Overseas clinical study results	10	Promote RF 36 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Apr. 24, 2009 Total review time: 238 days Regulatory review time: 137 days	Sep. 11, 2007 Overseas clinical study results	11	Promote RF 30 (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. The function to set the pacing timing was evaluated in the clinical study.
4	Jul. 7, 2009 Total review time: 439 days Regulatory review time: 335 days	Nov. 12, 2003 Overseas clinical study results	12	Endo-PAT2000 (CCI Corporation)	Approval	Instrument & apparatus 21 Regional body plethysmograph	A device to determine the vascular endothelium-mediated changes by measuring the volume pulse waves before and after 5-minute occlusion of the brachial artery with a cuff applied on the upper arm. Overseas clinical study results were used to evaluate the safety.
4	Aug. 5, 2009 Total review time: 383 days Regulatory review time: 299 days	Apr. 23, 2008 D970003/S096 Apr. 30, 2008 D970003/S097 Overseas clinical study results	13	Altrua 60DR (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. A clinical study was conducted to evaluate its Automatic Capture feature capability, which automatically adjusts the ventricular pacing output.
4	Aug. 5, 2009 Total review time: 352 days Regulatory review time: 268 days	Apr. 23, 2008 D970003/S096 Apr. 30, 2008 D970003/S097 Overseas clinical study results	14	Altrua 60SR (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. A clinical study was conducted to evaluate its Automatic Capture feature capability, which automatically adjusts the ventricular pacing output.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Aug. 10, 2009 Total review time: 510 days Regulatory review time: 290 days	Mar. 16, 2007 Overseas clinical study results	15	Cool Path Ablation System (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used for the electrophysiological study of the heart and for creating endocardial lesions to treat typical atrial flutter with radiofrequency current. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to avoid increasing tip electrode-tissue interface temperature.
4	Oct. 19, 2009 Total review time: 327 days Regulatory review time: 200 days	- Overseas clinical study results	16	Cool Path Duo Irrigation Catheter (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used for the electrophysiological study of the heart and for creating endocardial lesions to treat typical atrial flutter with radiofrequency current. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to avoid increasing tip electrode-tissue interface temperature.
4	Oct. 28, 2009 Total review time: 485 days Regulatory review time: 313 days	May 7, 2007 Overseas clinical study results	17	OptiSense S (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the pulse generator (PG).
4	Oct. 28, 2009 Total review time: 485 days Regulatory review time: 313 days	Oct. 1, 2009 Overseas clinical study results	18	OptiSense Optim (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the PG.
4	Oct. 28, 2009 Total review time: 467 days Regulatory review time: 309 days	Oct. 1, 2009 Overseas clinical study results	19	OptiSense Optim Lead (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A straight transvenous lead to be implanted in the right atrium, used for bradycardia pacing therapy (sensing and pacing). Clinical studies were conducted to evaluate the novel capability of this product to reduce far field sensing in order to inhibit inadequate actuation of the PG.
4	Nov. 12, 2009 Total review time: 332 days Regulatory review time: 204 days	Nov. 21, 2001 Overseas clinical study results	20	Genesis Single 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief to be applied to patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. Clinical studies were conducted to evaluate the constant current stimulation that is generally used for electrical tissue stimulation and used in this product, while the constant voltage stimulation is used in conventional approved products.
4	Dec. 2, 2009 Total review time: 278 days Regulatory review time: 202 days	Mar. 28, 2008 Overseas clinical study results	21	EON Mini Dual 8 Neurostimulator (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Implantable stimulator for pain relief	An implantable stimulator for pain relief to be applied to patients with chronic refractory pain in the trunk and extremities who are not sufficiently responsive to pain relief therapy with drugs or nerve block. It can be charged non-invasively from outside the body. Clinical studies were conducted to evaluate the constant current stimulation that is generally used for electrical tissue stimulation and applied in this product.
4	Mar. 26, 2010 Total review time: 847 days Regulatory review time: 410 days	Feb. 4, 2005 Overseas clinical study results	22	ZOLL AED Pro Semi-Automatic Defibrillator (ZOLL Medical Corporation)	Approval	Instrument & apparatus 12 Semi-automatic defibrillator	A semi-automatic external defibrillator using biphasic defibrillator waveform dedicated for use by healthcare professionals, equipped with a pad with an acceleration sensor to enable the display of the rate and depth of chest compression during cardiopulmonary resuscitation. A clinical study was conducted to confirm the efficacy and safety of defibrillator function using biphasic waveform.
5	Jun. 2, 2009 Total review time: 736 days Regulatory review time: 303 days	Jun. 29, 2001 Domestic clinical study results	23	Monosyn (B. Braun Aesculap Japan Co., Ltd.)	Approval	Medical products 2 Polyglyconate suture	An absorbable synthetic monofilament suture made of glycolide/trimethylene carbonate/ε-caprolactone. A clinical trial was conducted to evaluate the efficacy and safety because the combination and amount of the polymers are different from the precedented approved product's.
5	Jun. 8, 2009 Total review time: 619 days Regulatory review time: 383 days	- Domestic clinical study results	24	Fuji IR (Fuji Latex Co., Ltd.)	Approval	Hygienic products 2 Contraceptive condom for males	A condom made chiefly from polyisoprene rubber used to cover the penis for the purpose of contraception and as an adjunct in the prevention of sexually transmitted diseases. A clinical study was conducted to compare its efficacy and safety with those of commercially available condoms (condom made from natural rubber latex).
5	Nov. 10, 2009 Total review time: 375 days Regulatory review time: 297 days	Dec. 4, 2006 Overseas clinical study results	25	WallFlex Duodenal Stent (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Gastroduodental stent	The device consists of a metal stent intended for dilatation and to maintain the patency in gastroduodenal obstructions produced by malignant neoplasms, and a delivery system for endoscopic implantation of the stent. Clinical studies were conducted to evaluate its efficacy for improvement of QOL for a certain period and the safety.

Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Nov. 20, 2009 Total review time: 624 days Regulatory review time: 433 days	Jan. 8, 2002 Clinical evaluation report	26	Gynemesh (Johnson & Johnson K.K.)	Approval	Medical products 4 Nonabsorbable prosthetic material for hernia, chest wall, and abdominal wall	A mesh used for repair of pelvic organ prolapse, with limited intended use and shape and structure, while manufactured in the same way from the same materials as "Prolene Mesh (polypropylene)" (Approval No. 20400BZY00787000). A clinical evaluation report discussing the efficacy and safety through the defined algorithm for the literature survey was submitted.
5	Feb. 3, 2010 Total review time: 406 days Regulatory review time: 262 days	- Domestic clinical study results	27	Hemodialysis Monitoring Equipment TR-3000MA (Toray Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodialysis equipment	A hemodialysis monitoring equipment with additional functions to "TR-3000M (Approval No. 21500BZZ00045000),"of assisting priming, blood return, blood taking with diahysate, as well as rapid substitution and manual substitution. Clinical studies were performed in Japan to confirm its efficacy and safety.
6	May 8, 2009 Total review time: 2907 days Regulatory review time: 791 days	- Domestic clinical study results	28	Care Sheet "SS" (SSP Co., Ltd.)	Approval	Medical products 4 Hydrocolloid material	A wound dressing and protecting material using hydrogel in a form of poultice. A clinical study was conducted to evaluate its efficacy and safety.
6	Jun. 29, 2009 Total review time: 732 days Regulatory review time: 451 days	Aug. 5, 2004 Domestic clinical study results	29	OIC PEEK Interbody Cage (Stryker Japan K.K.)	Approval	Medical products 4 Spinal cage	A spinal cage made from a novel material polyetheretherketone (PEEK) resin. A pair of these products with bone graft packed inside are intervertebrally inserted and fixed by pressure using another intervertebral fixation system. Clinical studies were performed in Japan to confirm its efficacy and safety.
6	Aug. 6, 2009 Total review time: 934 days Regulatory review time: 487 days	- Domestic clinical study results	30	Blend-E (Nakashima Medical Co., Ltd.)	Approval	Medical products 4 Artificial knee joint, patellar and tibial component	A tibial insert and patellar component made from ultrahigh molecular weight polyethylene. The shape and structure are the same as the approved products of the company, but dl-α-Tocopherol, a kind of vitamin E, has been added to this product in order to give the antioxidative potential to the material and to improve the resistance to wear. Clinical studies were performed in Japan to confirm its efficacy and safety.
8	Oct. 30, 2009 Total review time: 1688 days Regulatory review time: 554 days	Jun. 15, 1999 Overseas clinical study results	31	Medtronic MiniMed CGMS-Gold (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 Glucose monitoring system	A glucose monitoring system to keep continuous record of glucose level in the interstitial fluid which is considered to change in parallel with the blood glucose level, intended for use to obtain information on the fluctuation pattern of blood glucose values necessary to optimize the diabetic treatment. A clinical trial was conducted to compare the correlation between the glucose level in blood and that in the interstitial fluid in order to confirm the clinical performance of this product.
8	Nov. 20, 2009 Total review time: 1169 days Regulatory review time: 677 days	- Domestic clinical study results	32	Ultrasound Bone Densitometer LD-100 (OYO Electric Co., Ltd.)	Approval	Instrument & apparatus 12 Ultrasound bone densitometer	A device to measure the bone density using ultrasound. This product calculates the bone density based on the measurement of arrival times and attenuations of fast wave and slow wave that propagate the radius and arrival times of the reflected waves, while conventional ultrasound bone densitometers measure the speed or attenuation of ultrasonic pulse that propagates the calcaneus. Clinical studies were performed in Japan to confirm its efficacy and safety.

Note: Products submitted for application in 2003 and before are included.