Products Approved in FY 2010: New Medical Devices

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval /Partial Change	Classification Generic Name	Notes
1	Aug. 23, 2010 Total review time: 1055 days Regulatory review time: 385 days	Aug. 2, 2004 Domestic clinical study results	1	Bausch&Lomb Ortho-k (B.L.J. Company, Ltd.)	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 of the lens. A clinical study was conducted to confirm the efficacy and safety of this product. (The original product is in a reexamination period)
1	Sep. 1, 2010 Total review time: 908 days Regulatory review time: 517 days	Jun. 7, 2004 Domestic clinical study results	2	My Emerald (Technopia Co., Ltd.)	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 of the lens. A clinical study was conducted to confirm the efficacy and safety of this product. (The original product is in a reexamination period)
1	Sep. 1, 2010 Total review time: 908 days Regulatory review time: 170 days	Jun. 7, 2004 No clinical study results	3	Visual Emerald (Technopia Co., Ltd.)	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 of the lens. Application for multiple brand name of "My Emerald". (The original product is in a reexamination period)
1	Mar. 9, 2011 Total review time: 538 days Regulatory review time: 182 days	Aug. 9, 1996 Domestic clinical study results	4	Cochlear Baha System (Cochlear Ltd.)	Approval	Instrument & apparatus 73 Bone-anchored hearing aid	A bone-anchored hearing aid that transmits sound vibrations to the bone to improve the ability to hear environmental sounds and speech sounds. A clinical study was conducted to evaluate the efficacy and safety of this product in patients who are not expected to achieve improvement with existing treatments.
3-1	Apr. 2, 2010 Total review time: 119 days Regulatory review time: 104 days	Sep. 22, 2006 No clinical study results	5	Angioguard (Johnson & Johnson K.K.)	Change	Instrument & apparatus 51 Emboli-capturing catheter in the central circulatory system	A device to prevent distal emboli by capturing and removing embolic substances including thrombi while a stent is placed in the carotid artery. Application for a partial change to add Rapid Exchange (RX) type to the delivery system. (A partial change in the reexamination period)
3-1	Apr. 30, 2010 Total review time: 458 days Regulatory review time: 223 days	Aug. 11, 2004 Foreign clinical study results	6	Merci Retriever (Century Medical,Inc.)	Approval	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. A clinical study was conducted to evaluate its efficacy and safety in thrombectomy for cerebral infarction. [Priority review]
3-1	Jul. 6, 2010 Total review time: 617 days Regulatory review time: 162 days	Oct. 31, 2007 Foreign clinical study results	7	GuardWire Protection System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Emboli-removal catheter in the central circulatory system	A balloon-type device to prevent distal emboli by capturing and removing embolic substances including thrombi released while a stent is placed in the carotid artery. The efficacy (the effect of preventing distal emboli) and safety of this product were evaluated based on a clinical study for a carotid artery stent used in combination with this product. (The original product is in a reexamination period)
3-1	Mar. 9, 2011 Total review time: 439 days Regulatory review time: 202 days	- Domestic and foreign clinical study results	8	Nobori (Terumo Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system for percutaneous coronary stent placement consisting of a stent to be inserted and placed at the site of a lesion to maintain the vascular lumen and a delivery catheter used to deliver the stent to the site of the lesion. The stent is coated with biolimus A9 with cytostatic effect to topically inhibit neointimal proliferation that is thought to be a cause of in-stent restenosis. Clinical studies were conducted to evaluate the efficacy and safety of this product with high-novelty coating.
3-2	Jun. 14, 2010 Total review time: 620 days Regulatory review time: 238 days	Nov. 6, 2007 Foreign clinical study results	9	Bard Agento I.C. (Medicon,Inc.)	Approval	Instrument & apparatus 51 Antimicrobial endotracheal tube	An endotracheal tube inserted into the trachea for airway management. The device has a hydrophilic silver coating with antimicrobial activity to reduce the incidence and delay the onset of ventilator-associated pneumonia (VAP). A clinical study was conducted to verify its effects on reducing the incidence and delaying the onset of VAP.
3-2	Aug. 23, 2010 Total review time: 320 days Regulatory review time: 213 days	Jun. 27, 2008 No clinical study results	10	TALENT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for thoracic aortic aneurysm used to prevent blood flow into the thoracic aortic aneurysm and its rupture. Application for a partial change to alter the delivery system and the method of sterilization. (A partial change in the reexamination period)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval /Partial Change	Classification Generic Name	Notes
4	Apr. 30, 2010 Total review time: 497 days Regulatory review time: 251 days	Dec. 7, 2007 Foreign clinical study results	11	The Crosser System (USCI Japan, Ltd.)	Approval	Instrument & apparatus 51 Oscillating peripheral artery recanalization catheter system	A medical device used to facilitate guidewire recanalization with mechanical vibration for a stenotic lesion in the peripheral vessel that a conventional guidewire for angioplasty cannot cross in percutaneous transluminal angioplasty. A clinical study was conducted to confirm its efficacy and safety in the treatment of a stenotic lesion that a conventional guidewire for angioplasty cannot cross.
4	Jun. 14, 2010 Total review time: 766 days Regulatory review time: 476 days	Aug. 13, 2002 Domestic clinical study results	12	ELVeS Laser (Integral Corporation)	Approval	Instrument & apparatus 31 Diode laser	A system intended for endovenous laser treatment of varicose veins of lower extremities. Endovenous laser irradiation obstructs a target vessel and blocks blood flow in the saphenous vein that causes varicose veins of lower extremities. A clinical study was conducted to confirm its efficacy and safety using stripping, a standard treatment, as a control.
4	Dec. 8, 2010 Total review time: 447 days Regulatory review time: 127 days	− Domestic and foreign clinical study results	13	DuraHeart Left Ventricular Assist System (Terumo Corporation)	Approval	Instrument &apparatus 7 Implantable ventricular assist device	An implantable left ventricular assist device intended for use to improve the blood circulation in patients with end-stage heart failure who require cardiac transplantation. In addition to clinical studies conducted in Europe, where it was used earlier than in Japan, clinical studies were also conducted to investigate the efficacy and safety of this product to the target patients and to confirm the conformity to the medical environment in Japan. [Orphan device]
4	Dec. 8, 2010 Total review time: 688 days Regulatory review time: 160 days	− Domestic clinical study results	14	Implantable Ventricular Assist System EVAHEART (Sun Medical Technology Research Corp.)	Approval	Instrument &apparatus 7 Implantable ventricular assist device	An implantable left ventricular assist device intended for use to improve the blood circulation in patients with end-stage heart failure who require cardiac transplantation. Clinical studies were conducted to investigate the efficacy and safety of this product to the target patients and to confirm the conformity to the medical environment in Japan. [Orphan device]
6	Jun. 11, 2010 Total review time: 49 days Regulatory review time: 18 days	Jul. 2, 1998 No clinical study results	15	KYPHON BKP System (Medtronic Sofamor Danek Co., Ltd.)	Change	Instrument & apparatus 58 Single-use vertebral body restoration device	A treatment system used in percutaneous kyphosis correction in acute painful spinal compression fracture performed for restoration of the height of fractured vertebral body, fixation of the vertebral body, and pain relief. Addition of a manufacturing site. (A partial change in the reexamination period)
6	Jun. 14, 2010 Total review time: 500 days Regulatory review time: 373 days	Aug. 8, 2006 Foreign clinical study results	16	X-STOP PEEK Implant (Medtronic Sofamor Danek Co., Ltd.)	Approval	Medical products 4 Single-use interspinous implant device	An implant to be implanted 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. A clinical study was conducted to verify its efficacy and safety with regard to the mechanism to physically broaden the gap between the upper and lower spinous processes.
Specified Partial Change	Jan. 27, 2011 Total review time: 90 days Regulatory review time: 75 days	2003/5/14 No clinical study results	17	PDA Occlusion Set (Japan Lifeline Co., Ltd.)	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 that transdermally places an occluder at the site of patent ductus arteriosus using a delivery system for occlusion of the arterial canal. Addition of an outside manufacturer of the raw material for an occluder end screw and a delivery cable screw. (A partial change in the reexamination period)
Biologics	Mar. 18, 2011 Total review time: 310 days Regulatory review time: 240 days	- No clinical study results	18	Jace (Japan Tissue Engineering Co., Ltd.)	Change	Instrument & apparatus 7 Human autogenous transplant	An autologous-cultured epidermis in the shape of a sheet, which is manufactured by culturing keratinocytes isolated from patients' skin tissue, using Green's technique. It is applied to the wound surface of severe burn patients for wound closure through epithelialization. Application for a partial change to alter the method of mycoplasma testing and the subculture process for keratinocytes, etc in the manufacturing process. (A partial change in the reexamination period)

Products Approved in FY 2010: Improved Medical Devices (with Clinical Data)

Review Category	Approval Date	Date Approved in US Clinical Study Results: Domestic/Foreign	No.	Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Jun. 2, 2010 Total review time: 789 days Regulatory review time: 426 days	Aug. 16, 2006 Clinical evaluation report	1	Intralase FS Laser (AMO Japan K.K.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	A Nd:Glass laser (wave length 1053 nm) surgical instrument used for creation of a corneal flap in LASIK (laser in-situ keratomileusis) and for cut/resection in keratoplasty. Creation of a corneal flap, lamellar and penetrating cut/incision can be performed with this product, instead of using a keratome or scalpel, in LASIK and keratoplasty. A clinical evaluation report summarizing the results of post-marketing clinical studies conducted by the manufacturer in the USA and literature searches were submitted to evaluate its efficacy and safety.
1	Jul. 21, 2010 Total review time: 411 days Regulatory review time: 186 days	Dec. 6, 2005 Domestic clinical study results	2	Aime Aquafinity (Asahi Kasei Aime Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correcting visual acuity	A soft contact lens using silicone hydrogel for correcting visual acuity in myopia, hyperopia and astigmatism. The lens is made from a novel material that aims to improve the comfort in wearing while maintaining high oxygen permeability.
1	Nov. 22, 2010 Total review time: 423 days Regulatory review time: 243 days	Jan. 30, 2007 Domestic clinical study results	3	Alcon Acrysof IQ Restor Single-Piece (Alcon Japan Ltd.)	Change	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal posterior chamber lens to be inserted into an aphakic eye after cataract surgery for correcting near and distance visual acuity. A model with an additional power of 3.0D (focal distance: approximately 40 cm) was added in this application, while the additional power of the existing model is 4.0D (focal distance: approximately 30 cm). A clinical study was conducted to evaluate the efficacy and safety of the additional model.
1	Feb. 2, 2011 Total review time: 92 days Regulatory review time: 13 days	- Domestic clinical study results	4	Fall in Eyez (Destiny International Co., Ltd.)	Approval	Instrument & apparatus 72-2 Reusable colored contact lenses not for correcting visual acuity	A reusable colored contact lens that is not for correcting visual acuity that is indicated for daily wear and replaced monthly. Since equivalence to the approved product was not demonstrated with regard to the compounding ratio of the raw material monomer and cross-linker, a clinical study was conducted to evaluate its efficacy and safety.
2	Jun. 2, 2010 Total review time: 1098 days Regulatory review time: 610 days	- Clinical evaluation report	5	Oral Moisture Checking Device Mucus (Life Co., Ltd.)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A device used as a diagnostic aid that quantifies dryness of oral mucosa by converting an impedance level at the dorsum of the tongue measured by bioelectrical impedance analysis (BIA) technique to an amount of water. Quantification using this product is different from conventional gum test and Saxon test in that the measurement time is as short as approximately 2 seconds and measurement is possible regardless of the presence or absence of patient's consciousness. A clinical evaluation report summarizing the results of literature searches was submitted with regard to the appropriateness of a cut-off level for the degree of dryness and a correlation with the existing methods.
2	Aug. 31, 2010 Total review time: 1516 days Regulatory review time: 768 days	The main body is not subject to regulatory control as a medical device. January 5, 2005 (only resin part for gingival protection) Domestic clinical study results	6	Tion In Office (GC Corporation)	Approval	Dental 2 Dental bleaching material	A dental bleaching agent exclusively designated for office bleaching containing hydrogen peroxide solution and urea hydrogen peroxide as major ingredients. This product was improved to achieve efficient bleaching using a reactor containing visible light-titanium oxide. A clinical study was conducted to evaluate the bleaching performance and safety of this product in discolored human teeth.
3-1	Dec. 2, 2010 Total review time: 308 days Regulatory review time: 258 days	Oct. 10, 2008 Jul. 13, 2009 (38 mm added) Foreign clinical study results	7	Taxus Liberté Stent System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a stent and delivery catheter. The stent is coated with antineoplastic agent paclitaxel to topically inhibit neointimal proliferation. Application for a partial change to add a product with a stent length of 38 mm to the existing products for extending the target lesion length from 28 mm to 34 mm. A clinical study was conducted to evaluate the efficacy and safety of a 38-mm-long stent.
3-1	Dec. 14, 2010 Total review time: 595 days Regulatory review time: 345 days	Dec. 11, 2008 Foreign clinical study results	8	Express SD Renal Artery Dilatation Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Stent for blood vessel	A balloon dilating stent system developed for maintaining vascular patency of an atherosclerotic lesion occurring at the opening of the renal artery. A clinical study was conducted to evaluate the efficacy and safety of this product in maintaining vascular dilatation when it was placed at an atherosclerotic lesion occurring at the entrance of the renal artery.
3-1	Feb. 23, 2011 Total review time: 1052 days Regulatory review time: 600 days	Jun. 26, 2006 Foreign clinical study results	9	COOK Vascular Stent (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Stent for iliac artery	This product consists of a stent and delivery system used for treatment of symptomatic vascular diseases such as a stenotic lesion with a reference vessel diameter of 5-9 mm in the iliac artery. A clinical study was conducted to evaluate the efficacy and safety of this product in maintaining vascular patency when it was placed at a stenotic lesion in the iliac artery.
3-2	Apr. 28, 2010 Total review time: 1083 days Regulatory review time: 829 days	Sep. 21, 2006 Foreign clinical study results	10	ASD Occlusion System (Japan Lifeline Co., Ltd.)	Change	Medical products 4 Prosthetic material for artificial cardiac membrane	A device used for occlusion of ostium secundum atrial septal defect by transdermally placing an occluder (septal occluder) made from a nickel-titanium alloy wire in an atrial septal defect (ASD). This is a partial change approval application to add a septal occluder MF type with a smaller waist diameter to enable placement of the device at multiple atrial septal defects. A clinical study was conducted to evaluate the occlusion performance of this product in multiple defects of the atrial septum.

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3-2	Jun. 14, 2010 Total review time: 377 days Regulatory review time: 152 days	Apr. 5, 2007 Foreign clinical study results	11	Tegaderm CHG Dressing (3M Health Care Limited)	Approval	Medical products 4 Antibacterial catheter dressing and protecting material	A catheter dressing and protecting material that covers and protects an insertion site of a vascular catheter. A gel pad included in this device contains an antibacterial agent chlorhexidine gluconate that inhibits regrowth of skin bacterial flora at the insertion site. A clinical study was conducted to evaluate whether use of this product inhibited regrowth of skin bacterial flora on normal skin and the performance of fixation of a catheter with this product in patients inserted with a catheter.
3-2	Sep. 29, 2010 Total review time: 2009 days Regulatory review time: 676 days	Apr. 23, 1998 (IDE Approval) Domestic clinical study results	12	Bioglue Surgical Adhesive (Century Medical, Inc.)	Approval	Medical products 4 Surgical adhesive	A surgical adhesive containing bovine serum albumin and glutaraldehyde as major ingredients. This product is used for adhesion and hemostasis at an artificial blood vessel suture site associated with closure of aortic dissection and aortic dissection lumen (including dissecting aneurysm of the aorta). A clinical study was conducted to evaluate the degree of adhesion (efficacy) and safety of this product in such surgeries.
3-2	Dec. 17, 2010 Total review time: 521 days Regulatory review time: 216 days	Apr. 15, 2008 Jul. 15, 2008 (change to the current product) Foreign clinical study results	13	TALENT Abdominal Stent Graft System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm used to prevent blood flow into abdominal aortic aneurysm and prevent rupture of aortic aneurysm. A clinical study was conducted to evaluate the efficacy and safety of stent graft treatment for abdominal aortic aneurysm.
3-2	Mar. 16, 2011 Total review time: 866 days Regulatory review time: 215 days	May. 21, 2008 Foreign clinical study results	14	COOK Zenith TX2 TAA Endovascular Graft (Cook Japan Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	This product consists of a stent graft and delivery system used for endovascular treatment of descending thoracic aortic aneurysm. It consists of a self-expanding stainless-steel stent and polyester graft. A clinical study was conducted to evaluate the efficacy and safety of stent graft treatment for thoracic aortic aneurysm.
4	Jun. 23, 2010 Total review time: 545 days Regulatory review time: 289 days	May. 16, 2008 Foreign clinical study results	15	Acuity Spiral (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A spirally-molded lead to be placed in the coronary vein for CRT. A clinical study was conducted to demonstrate that the safety and efficacy of this product were within an acceptable range compared to the existing products.
4	Jul. 5, 2010 Total review time: 1036 days Regulatory review time: 528 days	May. 21, 2004 Foreign clinical study results	16	ZOLL AED Plus Automated External Defibrillator (Zoll Medical Corporation)	Approval	Instrument & apparatus 12 Automatic defibrillator for non-healthcare professionals	A semi-automatic external defibrillator using biphasic defibrillation waveform dedicated for use by non-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.
4	Aug. 23, 2010 Total review time: 482 days Regulatory review time: 302 days	Oct. 1, 2004 Foreign clinical study results	17	Precision Plus SCS System (Boston Scientific Japan K.K.)	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. A clinical study was conducted to evaluate the safety and efficacy of this product for relief of chronic pain.
4	Sep. 3, 2010 Total review time: 1326 days Regulatory review time: 229 days	Jun. 20, 2005 Foreign clinical study results	18	Revolution 2 (Volcano Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system intravascular ultrasound catheter	A catheter for intravascular ultrasound diagnostic imaging with a built-in ultrasound transducer for imaging intravascular lumen and vascular wall using ultrasound. The ultrasonic frequency of this product is 45 MHz. A clinical study was conducted to primarily evaluate system-related adverse events.
4	Oct. 8, 2010 Total review time: 259 days Regulatory review time: 157 days	- Foreign clinical study results	19	Attain Ability Straight Leads (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A tined lead to be placed in a coronary vein for CRT. A clinical study was conducted to demonstrate that the safety and efficacy of this product were within an acceptable range compared to the existing products.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	20	Accent DR ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	21	Accent RF DR ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.

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4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	22	Anthem ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 7, 2010 Total review time: 326 days Regulatory review time: 173 days	Jan. 29, 2010 Foreign clinical study results	23	Anthem RF ACC (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 9, 2010 Total review time: 324 days Regulatory review time: 168 days	Jan. 29, 2010 Foreign clinical study results	24	Nuance DR RF (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 9, 2010 Total review time: 324 days Regulatory review time: 168 days	Jan. 29, 2010 Foreign clinical study results	25	Nuance DR (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	Dual-chamber implantable cardiac pacemaker. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 14, 2010 Total review time: 897 days Regulatory review time: 377 days	May. 15, 2008 Foreign clinical study results	26	Ovatio CRT-D (Sorin CRM)	Approval	Instrument & Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. A clinical study was conducted to evaluate the efficacy and safety of this product as a CRT-D system.
4	Dec. 14, 2010 Total review time: 482 days Regulatory review time: 226 days	Oct. 27, 2009 Foreign clinical study results	27	Paradym CRT-D (Sorin CRM)	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. A clinical study was conducted to evaluate the efficacy and safety of this product as a CRT-D system.
4	Dec. 17, 2010 Total review time: 366 days Regulatory review time: 168 days	- Foreign clinical study results	28	AnalyST Accel RF VR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Automatic implantable defibrillator	Automatic implantable defibrillator with the function of single-chamber bradycardia pacing. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular threshold were submitted to evaluate the efficacy and safety of this function.
4	Dec. 17, 2010 Total review time: 365 days Regulatory review time: 167 days	- Foreign clinical study results	29	AnalyST Accel RF DR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	Automatic implantable defibrillator with the function of dual-chamber bradycardia pacing. Results from clinical studies of a different model with a function to automatically adjust pulse amplitude according to a change in patient's ventricular and atrial thresholds were submitted to evaluate the efficacy and safety of this function.
4	Dec. 17, 2010 Total review time: 365 days Regulatory review time: 167 days	Jan. 29, 2010 Foreign clinical study results	30	Promote Accel RF (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. A clinical study was conducted to evaluate the efficacy and safety of a function to automatically adjust pulse amplitude according to a change in the patient's biventricular and atrial thresholds.
4	Mar. 29, 2011 Total review time: 456 days Regulatory review time: 161 days	- Foreign clinical study results	31	Situs 2 OTW Lead (Sorin CRM)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	A bipolar left ventricular pacing lead for coronary veins and its accessory connected to CRT-P and CRT-D and used during cardiac resynchronization treatment. The first left ventricular pacing lead of the company. Results from clinical studies were submitted to evaluate its efficacy and safety.
5	Apr. 30, 2010 Total review time: 231 days Regulatory review time: 151 days	- Domestic clinical study results	32	Cellsorba E (Asahi Kasei Kuraray Medical Co., Ltd.)	Change	Instrument & apparatus 7 Purifie for blood cell removal	Application for a partial change to add a miniaturized column to the approved product "Cellsorba E (approval No.: 21300BZZ00440000)."A clinical study was conducted to evaluate the efficacy and safety of this product in patients with pediatric active ulcerative colitis.

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5	Sep. 14, 2010 Total review time: 487 days Regulatory review time: 255 days	- Domestic clinical study results	33	PTEG Kit (Akita Sumitomo Bakelite Co., Ltd.)	Approval	Instrument & apparatus 51 Enteral feeding kit for long-term use	An enteral feeding tube and its insertion kit used in a procedure for percutaneous trans-esophageal insertion and placement of a catheter in the gastrointestinal tract to provide enteral feeding and decompression to patients for whom it is difficult to perform gastrostomy. A clinical study was conducted to evaluate the efficacy and safety of percutaneous trans-esophageal gastro-tubing (PTEG) in patients receiving enteral feeding or decompression.
5	2010/10/21 Total review time: 325 days Regulatory review time: 200	- Domestic clinical study results	34	Toraylight NV (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hollow-fiber dialyzer	A hollow fiber dialyzer. Because equivalence to the approved products was not demonstrated with regard to the semipermeable membrane material, a clinical study was conducted to evaluate its efficacy and safety.
5	Dec. 1, 2010 Total review time: 404 days Regulatory review time: 248 days	- Domestic clinical study results	35	Maxiflux (Nipro Corporation)	Approval	Instrument & apparatus 7 Hemodiafilter	A hollow fiber membrane hemodiafilter. Because equivalence to the approved products was not demonstrated with regard to the semipermeable membrane material and performance profile, a clinical study was conducted to evaluate its efficacy and safety.
5	Feb. 2, 2011 Total review time: 687 days Regulatory review time: 344 days	- Domestic clinical study results	36	Fibroscan (InterMedical Co., Ltd.)	Approval	Instrument & apparatus 12 Versatile ultrasound diagnostic imaging device	A device to measure non-invasively liver stiffness using ultrasonic waves, etc. A clinical study was conducted to evaluate whether it could qualitatively measure the stiffness of the liver.
6-1	Sep. 14, 2010 Total review time: 837 days Regulatory review time: 329 days	Sep. 5, 2002 Domestic clinical study results	37	Trabecular Metal Modular Acetabular System (Zimmer K.K.)	Approval	Medical products 4 Artificial hip joint, acetabular component	A locking ring used to fix a titanium alloy acetabular cup and liner that are used at the pelvic side to replace the function of the hip joint during hip replacement arthroplasty (including revision hip replacement arthroplasty). The outer surface is coated with a consecutive 3-D dodecahedron porous structure made from tantalum to ensure direct fixation to the bone. A clinical study was conducted to evaluate the efficacy and safety of this device with this novel surface structure.
6-1	Nov. 9, 2010 Total review time: 855 days Regulatory review time: 237 days	Jul. 19, 2001 Feb. 12, 2002 Domestic clinical study results	38	Trabecular Metal Monoblock (Zimmer K.K.)	Approval	Medical products 4 Artificial knee joint, patellar and tibial component	A tibia component to be implanted at the tibial side to reconstruct the function of the knee joint and a patellar component to be implanted in the patella during knee replacement arthroplasty (including revision knee replacement arthroplasty). While the shape and size of this product are equal to those of the approved product, a metal part and ultrahigh molecular weight polyethylene part are compressed to form an integrated architecture. In addition, improved bone fixation and reduced stress shielding on bone are expected because of a new raw material (consecutive 3-D dodecahedron porous structure made from tantalum) used in this product. A clinical study was conducted to evaluate the efficacy and safety of this device with improved structure, etc.
6-2	Jan. 6, 2011 Total review time: 1011 days Regulatory review time: 496 days	- Domestic clinical study results	39	Biohesive (Alcare Co., Ltd.)	Approval	Medical products 4 Antibacterial wound dressing and protecting material	A wound dressing and protecting material used to protect wound reaching subcutaneous adipose tissue, maintain a moist environment, promote healing and relieve pain. With hydrocolloid material as a base material, this product contains sulfadiazine silver 0.05% to improve hygiene inside the dressing material. Since equivalence to the approved product was not demonstrated with regard to this structure, a clinical study was conducted to evaluate its efficacy and safety.
8	Feb. 23, 2011 Total review time: 208 days Regulatory review time: 67 days	- Domestic clinical study results	40	Visceral Fat Area Measurement Device HDS-2000 (Omron Healthcare Co., Ltd.)	Approval	Instrument & apparatus 21 Body constituent analysis instrument	A body constituent analysis instrument that estimates and shows a cross-sectional area of visceral fat based on bioelectrical impedance level and major axis and minor axis of cross-sectional area of the abdomen. It is indicated for secondary screening (detection of cross-sectional area of visceral fat $\leqq$100 cm^2) of patients who are tested positive according to the diagnostic criteria using abdominal circumference, one of the diagnostic criteria for metabolic syndrome. A clinical study was conducted to evaluate the estimation precision of the cross-sectional area of visceral fat in relation to correlation with the cross-sectional area of visceral fat obtained from CT images.