Table 2. FY2007 List of Approved Products: New Medical Devices

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Oct. 1, 2007 Total review time: 458 days Regulatory review time: 231 days	1	Excimer Laser Corneal Surgery System EC-5000CXIII (Nidek Co., Ltd.)	Approval	Instrument & apparatus 31 Ophthalmic laser corneal surgical instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism, remove corneal surface opacities, and smooth corneal irregularities by laser ablation of corneal tissue. (The original product is in a reexamination period)
1	Jan. 21, 2008 Total review time: 1060 days Regulatory review time: 717 days	2	O_2OPTIX and 8 other trade names (CIBA Vision K.K.)	Change	Instrument & apparatus 72 Soft contact lenses	Oxygen-permeable soft contact lenses using silicone hydrogel, which are indicated for the correction of visual acuity (myopia and hyperopia). Partial change application to add a new intended use of up to 30-day extended wear, which is the first in Japan, to the approved use of daily wear with a 1 month replacement schedule.
1	Feb. 28, 2008 Total review time: 76 days Regulatory review time: 52 days	3	Menicon Lifely (Menicon Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Oxygen-permeable hard contact lenses, which are indicated for daily or up to 30-day extended wear (trade name divisional application of Menicon Tinu, the original product). (The original product is in a reexamination period)
1	Mar. 6, 2008 Total review time: 1742 days Regulatory review time: 650 days	4	Technolas Excimer Laser System (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 31 Other laser surgical instrument and laser coagulator (ophthalmic excimer laser 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	Mar. 6, 2008 Total review time: 541 days Regulatory review time: 219 days	5	VISX Excimer Laser System (AMO Manufacturing USA, LLC)	Change	Instrument & apparatus 31 Ophthalmic laser corneal surgery instrument	An excimer laser surgical system used in ophthalmology to correct myopia or astigmatism and remove corneal opacities by laser ablation of corneal tissue. Laser-assisted in situ keratomileusis (LASIK) indication was added to previously approved indications, photorefractive keratectomy (PRK) and phototherapeutic keratectomy (PTK). (The original product is in a reexamination period)
3-1	Sep. 28, 2007 Total review time: 457 days Regulatory review time: 245 days	6	ANGIOGUARD XP (Johnson & Johnson K.K.)	Approval	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. The effect on the prevention of distal embolization with the use of the stent and the operability were evaluated in clinical studies. [Priority review]
3-1	Sep. 28, 2007 Total review time: 457 days Regulatory review time: 268 days	7	PRECISE for the Carotid Artery (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 7 Stent for the carotid artery	The first stent for the carotid artery in Japan to dilate carotid stenosis and prevent restenosis.The incidence of complications after treatment was evaluated in a clinical study comparing with surgical therapy. [Priority review]
3-2	Oct. 31, 2007 Total review time: 2638 days Regulatory review time: 1045 days	8	SEAMDURA, NEOSEAM (GUNZE Limited)	Approval	Medical products 4 Bioabsorbable artificial dural substitutes	The first bioabsorbable artificial dural substitutes in Japan to compensate for the dural defect. Their clinical performance as dural substitutes was evaluated in clinical studies.
3-2	Feb. 5, 2008 Total review time: 736 days Regulatory review time: 525 days	9	Powerlink Stent Graft System (Cosmotec Co., Ltd.)	Approval	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm to prevent blood flow into the aneurysm and its rupture. The incidence of adverse events after treatment was mainly evaluated in clinical studies. (The original product is in a reexamination period)

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-2	Mar. 12, 2008 Total review time: 492 days Regulatory review time: 248 days	10	GORE TAG Thoracic Endoprosthesis System (Japan Gore-Tex Inc.)	Approval	Instrument & apparatus 7 Aortic stent graft	The first stent graft for thoracic aortic aneurysm in Japan to prevent the blood flow into the aneurysm and its rupture. The incidence of adverse events after treatment was evaluated in a clinical study comparing with surgical therapy. [Priority review]
4	Apr. 13, 2007 Total review time: 71 days Regulatory review time: 55 days	11	SynchroMed EL Pump (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 74 Programmable implantable drug infusion pump	Addition of N'Vision as an applicable programmer to the drug infusion pump indicated for intrathecal baclofen therapy. (Partial change during the reexamination period)
4	May 29, 2007 Total review time: 279 days Regulatory review time: 167 days	12	Concerto C154DWK (Medtronic Japan Co., Ltd)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 285 days	13	QuickSite (St. Jude Medical CRMD)	Approval	Instrument & apparatus 7 Implantable pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 290 days	14	Epic HF (St. Jude Medical CRMD)	Approval	Instrument & apparatus 12 Other defibrillator and related devices (implantable biventricular pacing pulse generator with defibrillator function)	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 290 days	15	Atlas + HF (St. Jude Medical CRMD)	Approval	Instrument & apparatus 12 Other defibrillator and related devices (implantable biventricular pacing pulse generator with defibrillator function)	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Sep. 7, 2007 Total review time: 309 days Regulatory review time: 136 days	16	SynchroMed II Pump (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 74 Programmable implantable drug infusion pump	Drug infusion pump indicated for intrathecal baclofen therapy. (The original product is in a reexamination period)
4	Sep. 28, 2007 Total period: 605 days Regulatory review time: 326 days	17	Intravascular OCT ImageWire (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Intravascular optical tomographic catheter	An intravascular optical tomographic catheter that irradiates the vascular wall with near infrared light through internal optical fibers and images for testing the lumens and superficial walls of the coronary arteries by optical coherence tomography (OCT). This is the first medical device in Japan to use OCT for intravascular observation.
4	Sep. 28, 2007 Total review time: 605 days Regulatory review time: 326 days	18	Intravascular OCT Imaging System (Goodman Co., Ltd.)	Approval	Instrument & apparatus 12 OCT diagnostic imaging instrument	A diagnostic imaging system using near infrared light as a light source that images for testing the lumens and superficial walls of the coronary arteries by OCT. This is the first medical device in Japan to use OCT for intravascular observation.

Category	Approval Date Review time		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Dec. 7, 2007 Total review time: 308 days Regulatory review time: 163 days	19	Concerto C174AWK (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	Implantable pulse generator that delivers CRT, with function of defibrillator. (The original product is in a reexamination period)
4	Dec. 27, 2007 Total review time: 202 days Regulatory review time: 83 days	20	Novacor Left Ventricular Assist System (Edwards Lifesciences LLC)	Change	Instrument & apparatus 7 Implantable ventricular assist device	Partial change application to add a new battery because of discontinued battery production and change the controller accordingly. (A partial change during a reexamination period)
4	Feb. 26, 2008 Total review time: 333 days Regulatory review time: 173 days	21	ACUITY Steerable (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (The original product is in a reexamination period)
4	Feb. 28, 2008 Total review time: 183 days Regulatory review time: 180 days	22	QuickSite (St. Jude Medical CRMD)	Change	Instrument & apparatus 7 Implantable defibrillator/pacemaker lead	OTW(Over-The-Wire) type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy). (Partial change application for extension for shelf life) (The original product is in a reexamination period)
5	Apr. 13, 2007 total review time: 437 days Regulatory review time: 236 days	23	Cool-tip RF System (Tyco Healthcare Japan, Inc.)	Change	Instrument & apparatus 29 Therapeutic electrosurgical unit	A device to coagulate/ablate nonresectable liver tumors using a radiofrequency current (480 kHz). Partial change application mainly to make the generator conform to IEC60601-1-2 (2001). (A partial change during the reexamination period)
5	Apr. 23, 2007 Total review time: 1103 days Regulatory review time: 384 days	24	Given Diagnostic Imaging System (Given Imaging Ltd.)	Approval	Instrument & apparatus 25 Other medical endoscope (capsule electronic endoscope system)	A small intestinal image recording system that consists mainly of a capsule-shaped image transmitter, a sensor array for receiving image data, an image data recorder, and a RAPID workstation for reviewing recorded image data. This is the first medical device in Japan to provide diagnostic images of the small intestinal mucosa through a capsule swallowed by the patient.
6	Mar. 25, 2008 Total review time: 2281 days Regulatory review time: 437 days	25	Dornier Epos Ultra (Dornier MedTech Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Other therapeutic or surgical instruments (electromagnetic induction-type extracorporeal shock wave therapy system)	A low-energy extracorporeal shock wave therapy system for orthopedic use. This is the first device in Japan to relieve the pain of chronic plantar fasciitis with reduced output of the conventional electromagnetic induction-type extracorporeal shock wave lithotripter.
Office of Biologics II	Oct. 29, 2007 Total review time: 1118 days Regulatory review time: 540 days	26	JACE (Japan Tissue Engineering Co., Ltd.)	Approval	Medical products 4 Other surgical/orthopedic materials (autologous cultured epidermis)	Autologous cultured keratinocytes using Green's technique in which keratinocytes derived from the patient's own skin tissue are co-cultured with irradiated 3T3-J2 cells derived from mouse fetuses as a feeder to form a sheet in approximately three to seven layers thick. This is indicated for the treatment of serious large burns that cannot be provided with a sufficient area of donor skin for autologous skin grafting, and of burns in which the total area of deep second-degree (deep dermal) and third-degree (full-thickness) burn is 30% or more of the total body surface area. It is the first medical device of processed human cellullar/tissue product in Japan. [Priority review]

Table 3. FY2007 List of Approved Products: Medical Devices Approved with Clinical Data (Other Than New Medical Devices)

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	May 22, 2007 Total review time: 475 days Regulatory review time: 347 days	1	SEED UV-1 (SEED Co., Ltd.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Hard contact lenses that are made mainly of methacrylate monomers and that are indicated for daily or up to 1-week extended wear. These lenses have been specially designed to ensure sufficient oxygen permeability and strength. They use a new raw material constituted of a new combination of four already-approved monomers in a new ratio. Clinical studies were mainly conducted to evaluate the safety of these lenses in the eyes.
1	Jun. 19, 2007 Total review time: 627 days Regulatory review time: 335 days	2	Alcon AcrySof ReSTOR Single-Piece (Alcon Japan Ltd.)	Approval	Instrument and apparatus 72 Multifocal posterior chamber lens	Foldable multifocal posterior chamber lens with 12 toric diffraction regions in the anterior center. A new lens design with a diffraction structure that diffracts the incident light into near and far fields is used, and the lens has two focal points. Clinical studies were conducted to evaluate whether the structure provides the expected performance, efficacy, and safety of this product.
1	Jun. 28, 2007 Total review time: 1651 days Regulatory review time: 711 days	3	Moistear and 5 other trade names (Koken Co., Ltd)	Approval	Medical products 4 Other ophthalmic products and related products (punctal plug)	A punctal plug made of atelocollagen to retain tear volume by lacrimal duct occlusion as a symptomatic treatment for aqueous tear deficiency (dry eye). Unlike the conventional silicone plug, the atelocollagen solution is the first medical device intended to achieve embolization by gelatinizing the solution injected into the lacrimal duct at body temperature. Clinical studies were conducted to evaluate the efficacy of this product and the safety of atelocollagen in the eyes.
1	Feb. 5, 2008 Total review time: 427 days Regulatory review time: 302 days	4	O_2OPTIX 2-Week (CIBA VISION K.K.)	Approval	Instrument & apparatus 72 Reusable colored contact lenses for correction of visual acuity	Soft contact lenses indicated for daily or up to 2-week extended wear, made of a new raw material, silicone hydrogel, with a new combination of the raw materials used in the approved product O_2OPTIX (approval no., 21600BZY00383000) for higher water content. Both spherical and toric lens designs were used. Because a new raw material is used, comparative clinical studies were conducted to evaluate the safety of this product.
1	Feb. 25, 2008 Total review time: 1083 days Regulatory review time: 503 days	5	HiResolution Bionic Ear System (Nihon Bionics Co., Ltd.)	Approval	Instrument & apparatus 7 Other sensory assisting instrument (cochlear implant system)	A cochlear implant system with a new sound processing strategy (HiRes) with higher stimulation rates. Clinical studies were mainly conducted to evaluate the efficacy of HiRes and the safety of this implant whose material and shape differ from those of the conventional product.
1	Mar. 3, 2008 Total review time: 987 days Regulatory review time: 539 days	6	Cataract Surgery INFINITI Vision System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 12 Cataract and vitreous surgery instrument	A surgical system used for extracapsular cataract extraction and anterior vitrectomy that performs various functions such as irrigation, aspiration, phacoemulsification, vitrectomy, and cauterization or coagulation. This product is a system that adds the AquaLase function which delivers balanced saline solution (BSS) to fragment cataracts with fluidic pulses to the approved Ultrasonic Cataract Surgery INFINITI Vision System (approval No. 21500BZY00342000). Because the AquaLase function was introduced for the first time in Japan, clinical studies were conducted to evaluate its clinical use.
1	Mar. 25, 2008 Total review time: 795 days Regulatory review time: 578 days	7	HOYA Airy One month (HOYA Corporation)	Approval	Instrument & apparatus 72 Reusable colored contact lens for correction of visual acuity	Silicone hydrogel soft contact lenses made of a new silicone-containing monomer that are indicated for daily or up to 30-day extended wear. Lenticular lens designs were used. Clinical studies were mainly conducted to evaluate the safety of the lenses made of a new raw material.
3-1	Jun. 7, 2007 Total review time: 1224 days Regulatory review time: 329 days	8	Angio-Seal STS PLUS (Getz Bros. Co., Ltd. [Japan])	Approval	Medical products 4 Bioresorbable local hemostatic device	A device to achieve hemostasis at the femoral artery puncture site after percutaneous catheterization by sandwiching the vascular wall between the anchor from the inside of the punctured vascular wall and the collagen sponge and bioresorbable suture from the outside. This product improves ease of use and suture knotting than the conventional product. Clinical studies were mainly conducted to evaluate whether the device has a hemostatic effect comparable to that of the conventional product.
3-1	Jul. 11, 2007 Total review time: 378 days Regulatory review time: 228 days	9	Express LD Vascular Stent (Boston Scientific Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent for iliac arteries	A balloon-expandable stent for iliac arteries. Delivery of this stent is easier because the delivery catheter of this stent has a smaller diameter than those of the conventional products of other companies. The clinical performance (including restenosis rate) of the stent was evaluated in clinical studies.

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
3-1	Oct. 23, 2007 Total review time: 337 days Regulatory review time: 256 days	10	NSE PTCA Balloon Catheter (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Balloon-expandable catheter for coronary angioplasty	A device in which slipping on balloon expansion is reduced by placing elements along the balloon of the PTCA balloon catheter. Clinical studies were conducted to evaluate the slipping-reducing effect of this product and the safety of the elements.
3-1	Jan. 18, 2008 Total review time: 505 days Regulatory review time: 336 days	11	AngioSculpt PTCA Balloon Catheter (USCI Japan Ltd.)	Approval	Instrument & apparatus 51 Balloon-expandable catheter for coronary angioplasty	A PTCA balloon catheter with a wire outside the balloon to reduce the slipping on expansion. The slipping-reducing effect and safety of the improved product were evaluated in clinical studies.
4	Jun. 1, 2007 Total review time: 914 days Regulatory review time: 285 days	12	Aescula (St. Jude Medical CRMD)	Approval	Instrument & apparatus 7 Implantable pacemaker lead	Left ventricular lead with stylet used with implantable pulse generators such as CRT-D in CRT(Cardiac Resynchronization Therapy).
4	Jun. 4, 2007 Total review time: 349 days Regulatory review time: 290 days	13	Sleep Recorder SD-101 (Kenzmedico Co., Ltd.)	Approval	Instrument & apparatus 21 Instrument for sleep evaluation	A simple testing instrument for sleep apnea syndrome that records and analyzes respiratory waveforms during sleep. It can be used at home as well as in hospitals. It is placed on a mattress, detects subtle pressure changes in parts of the body surface associated with respiration, and expresses them as waveforms. It can measure pressure changes for up to 10 hours under unrestrained conditions. Because this product uses a novel method of detecting respiratory waveforms, it was compared in clinical studies with polysomnography (PSG), the standard test method for sleep apnea syndrome.
4	Jul. 9, 2007 Total review time: 830 days Regulatory review time: 279 days	14	IBI Cardiac Ablation System II (Getz Bros Co., Ltd.)	Approval	Instrument & apparatus 31 Medical cautery instrument	An instrument that electrophysiologically detects the abnormal conduction pathways in the heart with arrhythmia and that ablates these pathways. Major improvements in this product as compared to the conventional product include two temperature sensors for the ablation site to ensure safety and the ability increase the output up to 100 W. Clinical studies were conducted to evaluate the safety of the increased output.
4	Jul. 26, 2007 Total review time: 437 days Regulatory review time: 122 days	15	Revolution (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Intravascular ultrasonic catheter for the central circulatory system	A catheter for intravascular ultrasonic diagnostic imaging that incorporates an ultrasonic transducer for ultrasound imaging of the vascular lumen and wall. The ultrasonic frequency was improved to 45 MHz. Clinical results were submitted mainly to evaluate the adverse events associated with the use of this system.
4	Jul. 26, 2007 Total review time: 437 days Regulatory review time: 118 days	16	Volcano In-Vision Gold Imaging System (Goodman Co., Ltd.)	Approval	Instrument & apparatus 12 Cardiovascular ultrasonic diagnostic imaging instrument	A diagnostic imaging instrument intended to image and test the vascular lumen and wall using ultrasound. The ultrasonic frequency has been improved to 45 MHz. Clinical studies were mainly conducted to evaluate the adverse events associated with the use of this system.
4	Oct. 1, 2007 Total review time: 579 days Regulatory review time: 247 days	17	Navistar DS (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used in myocardial with radiofrequency current and for the electrophysiological examination of the heart to treat type I atrial flutter. It has one 8-mm tip electrode, two temperature sensors, and a maximum power output of 70 W. Clinical studies were conducted because both the electrode length and output in this product is different from that in the conventional product.
4	Nov. 21, 2007 Total review time: 307 days Regulatory review time: 148 days	18	Medtronic Virtuoso DR (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12 Dual-chamber automatic implantable defibrillator	Implantable defibrillator used to automatically detect and treat atrial fibrillation/tachycardia and ventricular fibrillation/tachycardia. Clinical study results were submitted to evaluate the MVP function (to give priority to self atrioventricular conduction and inhibit unnecessary ventricular pacing), atrial cardioversion function, and atrial antitachycardia pacing function.

Category	Approval Date Review Time		Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
5	Nov. 7, 2007 Total review time: 854 days Regulatory review time: 522 days	19	Toraysulfone HDF (Toray Industries, Inc.)	Approval	Instrument & apparatus 7 Hemodialysis filter	A hemodiafilter using hollow fibers made of polysulfone resin to remove metabolites (including urea, creatinine, water, etc.) in blood during hemodiafiltration for patients with acute and chronic renal failure. Clinical investigation was conducted to evaluate its efficacy and safety because it was the first time that polysulfone resin was used as a raw material of hollow fibers of hemodiafilter.
6	May 8, 2007 Total review time: 768 days Regulatory review time: 253 days	20	CentPillar TMZF Stem (Striker Japan K.K.)	Approval	Medical products 4 Hip prosthesis	A cementless stem made of a titanium alloy for use as a femoral component in hip replacement. The proximal portion of the stem is subjected to surface roughening by plasma spraying of pure titanium followed by plasma coating with hydroxyapatite. Because of the novelty of the raw material and special surface treatment method employed, clinical studies were conducted to evaluate the efficacy and safety of this product in clinical use.
6	Jun. 4, 2007 Total review time: 809 days Regulatory review time: 186 days	21	Trident HA Acetabular Cup System (Striker Japan K.K.)	Approval	Medical products 4 Hip prosthesis	A component system consisting of a shell, dome-hole plug, and ceramic liner used as a acetabular component in hip replacement. Beacuse of the novelty of the ceramic liner into which ceramic and metal layers are integrated and the special shell surface treatment employed, clinical studies were conducted to evaluate the efficacy and safety of this product in clinical use.
6	Jun. 11, 2007 Total review time: 1200 days Regulatory review time: 250 days	22	LactoSorb (Biomet Microfixation, Inc.)	Approval	Medical products 4 Bone setting assembly	An absorbable bone setting assembly made of the copolymer of L-lactate and glycolate. This product was given overseas manufacturing approval as screws, plates, and mesh used for bone setting and reconstruction to treat cranial and facial bone trauma. The improvement in this device is that an absorbable coplymer which has not yet been approved for use as a raw material is used as the raw material. Clinical studies were conducted to evaluate whether the absorption rate of this product is safe for clinical use.
6	Aug. 3, 2007 Total review time: 855 days Regulatory review time: 251 days	23	K-MAX AHT HIP System (Japan Medical Materials Corporation)	Approval	Medical products 4 Hip prosthesis	A system consisting of a titanium alloy stem, an outer cup (both cementless), and screws used for the total hip replacement, partial hip replacement, etc. The proximal portion of the stem and the surface of the outer cup are subjected to surface roughening by spraying pure titanium followed by alkaline heat treatment, and the screw heads are subjected to alkaline heat treatment. Because of the novelty of the surface treatment employed, clinical studies were conducted to evaluate whether this product is effective and safe for clinical use.
6	Oct. 1, 2007 Total review time: 1084 days Regulatory review time: 561 days	24	Aquacel Ag (Bristol-Myers Squibb K.K.)	Approval	Medical products 4 Antimicrobial material	An antimicrobial dressing consisting of 100% fibrous sodium carboxymethylcellulose and silver used to protect wounds deep into the subcutaneous fat tissue, while maintaining a moist environment, promoting healing, and relieving pain. Expected secondary effects include antimicrobial effect of the silver ion on the bacteria existing inside the dressing and at the wound contact area. Clinical studies were conducted to evaluate the antimicrobial activity, wound-healing effect, and safety of this product.
6	Nov. 21, 2007 Total review time: 1274 days Regulatory review time: 299 days	25	Sterile CFRP Cage (Medtronic Sofamor Danek, Co., Ltd.)	Approval	Medical products 4 Bone setting assembly	A spinal cage made of a carbon fiber-reinforced polymer (CFRP). Because the material used in this product is different from that in the approved product, which is made of a titanium alloy, clinical studies were conducted to evaluate whether the product is effective and safe for clinical use.
8	May 30, 2007 Total review time: 1098 days Regulatory review time: 406 days	26	Proton Beam Therapy System PROBEAT (PT-W01) (Hitachi, Ltd.)	Approval	Instrument & apparatus 83 Other medical charged-particle radication therapy system (Proton beam therapy system)	A radiotherapy system using high-energy proton beam. It can shape the dose distribution of proton beam emitted from a synchrotron accelerator (beam energy, 80–200 MeV) to conform three-dimensionally to the size and shape of the affected site, and irradiate the site horizontally and vertically. (On application, the original product is in a reexamination period)
8	Jan. 23, 2008 Total review time: 1784 days Regulatory review time: 944 days	27	Noninvasive Hemoglobin Analyzer R02M (Sysmex Corporation)	Approval	Instrument & apparatus 21 Other single-person bioinformation monitor and related instruments (noninvasive hemoglobin analyzer)	This device irradiates a finger with infrared to near-infrared light and noninvasively measures the amount of light absorption by hemoglobin in the peripheral blood. The pulse oxymeter uses a similar principle to show the oxygen saturation in the arterial blood, whereas the new device is intended for use in screening for severe and moderate anemia and uses a new indicator correlating with blood hemoglobin concentration to show hemoglobin levels in five levels. Clinical studies were conducted to evaluate whether it can be used in screening for anemia as an indicator of hemoglobin levels.