Table 2. FY 2008 List of Approved Products: New Medical Devices

Category	Approval Date Review time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Apr. 9, 2008 Total review time: 1107 days Regulatory review time: 320 days	Aug. 11, 2006 Domestic clinical study results	1	Excimer Laser System MEL80 (Carl Zeiss Meditec 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	Jun. 25, 2008 Total review time: 56 days Regulatory review time: 46 days	May 23, 2003 No clinical study results	2	Star S4 IR Excimer Laser (AMO Manufacturing USA, LLC)	Change	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. The addition of the manufacturing site. (A partial change during the reexamination period)
1	Dec. 22, 2008 Total review time: 574 days Regulatory review time: 162 days	Apr. 14, 2000 (For myopia) Oct. 11, 2006 (For hyperopia) Domestic and overseas clinical study results	3	Excimer Laser Corneal Surgery System EC-5000 (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, and 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.
3-1	Sep. 26, 2008 Total review time: 1276 days Regulatory review time: 601 days	Jul. 21, 2005 Overseas clinical study results	4	ONYX Liquid Embolic System LD (ev3, K.K.)	Approval	Instrument & apparatus 51 Other tube and catheter related auxiliary devices (vascular embolization 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). [Priority review]
3-1	Jan. 28, 2009 Total review time: 303 days Regulatory review time: 195 days	Oct. 10, 2008 Overseas clinical study results	5	Taxus Libertè Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with paclitaxel coating to be used for dilating and holding a stenotic site of the coronary artery in symptomatic ischemic heart disease. (The original product is in a reexamination period)
3-1	Mar. 24, 2009 Total review time: 685 days Regulatory review time: 367 days	Feb. 1, 2008 Domestic and overseas clinical study results	6	Endeavor Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A drug-eluting coronary stent system with zotarolimus coating to be used for dilating and holding the stenotic site of the coronary artery in symptomatic ischemic heart diseases.
3-2	Jul. 22, 2008 Total review time: 481 days Regulatory review time: 421 days	Dec. 20, 2002 No clinical study results	7	Excluder Bifurcated Stent Graft System (Japan Gore-Tex Inc.)	Change	Instrument & apparatus 7 Aortic stent graft	A stent graft for abdominal aortic aneurysm to be deployed in the lesion in order to prevent the enlargement and rupture of aneurysm by blocking the blood flow into the aneurysm. A change of the manufacturing site and the addition of the applicable size. (A partial change during the reexamination period)
3-2	Dec. 26, 2008 Total review time: 848 days Regulatory review time: 517 days	May 14, 2003 Amplatzer Duct Occluder Amplatzer Delivery System Apr. 25, 2007 Amplatzer TorqVue Delivery System Overseas clinical study results	8	PDA Occlusion Set (Japan Lifeline Co., Ltd.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	The first device in Japan dedicated for the closure of patent ductus arteriosus (PDA) by the deployment of the duct occluder in the PDA site percutaneously using the delivery system.
4	Apr. 4, 2008 Total review time: 175 days Regulatory review time: 137 days	May 12, 2006 No clinical study results	9	Concerto C154DWK (Medtronic Japan Co., Ltd)	Change	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 bilateral ventricles electrically for a long time), with the function of a defibrillator. (A partial change during the reexamination period)
4	May 7, 2008 Total review time: 138 days Regulatory review time: 117 days	Mar. 17, 2008 Overseas clinical study results	10	Consulta CRT-D (Medtronic 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 original product is in a reexamination period)

Category	Approval Date Review time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Jul. 1, 2008 Total review time: 489 days Regulatory review time: 79 days	Dec. 9, 1997 (12 Fr) Sep. 4, 1998 (14 Fr/16 Fr) Jan. 25, 2002 (16 Fr SLSⅡ) May 2, 2002 (12/14 Fr SLSⅡ) Overseas clinical study results	11	Excimer Laser Cardiac Lead Removal System (DVx Inc.)	Approval	Instrument & apparatus 7 Pacemaker / defibrillator lead extraction 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 the dedicated excimer laser system. [Priority review]
4	Jan. 26, 2009 Total review time: 395 days Regulatory review time: 353 days	－ No clinical study results	12	Intravascular OCT ImageWire (Goodman Co., Ltd.)	Change	Instrument & apparatus 51 Intravascular optical tomographic catheter	A catheter utilizing optical coherence tomography (OCT) for monitoring of the vascular lumen and the vascular wall surface in the coronary artery. A change in the shape of the joint with the dedicated OCT diagnostic imaging instrument. (A partial change during the reexamination period)
4	Jan. 26, 2009 Total review time: 395 days Regulatory review time: 351 days	－ No clinical study results	13	Intravascular OCT Imaging System (Goodman Co., Ltd.)	Change	Instrument & apparatus 12 OCT diagnostic imaging instrument	An optical coherence tomography (OCT) diagnostic imaging instrument for monitoring of the vascular lumen and the vascular wall surface in the coronary artery. The addition of a unit for connection with the dedicated catheter, and a change in the pullback speed. (A partial change during the reexamination period)
5	Sep. 2, 2008 Total review time: 1257 days Regulatory review time: 267 days	－ Domestic clinical study results	14	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Adsorption apheresis device	The Adacolumn is an adsorptive type extracorporeal leukocyte apheresis device. An indication is added for the promotion of remission in patients with moderate to severe active Crohn's disease who are refractory to conventional treatment methods. [Orphan device]
5	Sep. 8, 2008 Total review time: 602 days Regulatory review time: 266 days	Sep. 14, 2007 Domestic clinical study results	15	Olympus Capsule Endoscope System (Olympus Medical Systems Corp.)	Approval	Instrument & apparatus 25 Capsule electronic endoscope system	An endoscopic system comprised of a capsule endoscope (26 x 11 mm) and a monitoring unit. To be used for monitoring and diagnosis of the small bowel. (The original product is in a reexamination period)
6	Dec. 22, 2008 Total review time: 208 days Regulatory review time: 71 days	Aug. 18, 2004 Overseas clinical study results	16	VEPTR System (Synthes K. K.)	Approval	Medical products 4 Internal fixation system	An implantable device made of standard medical grade titanium to be used in patients with thoracic insufficiency syndrome to stabilize their thorax while correcting chest wall malformations in order to help the growth of their thorax and lungs. [Priority review]

Table 3. FY 2008 List of Approved Products: Medical Devices Approved with Clinical Data (Other Than New Medical Devices)

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
1	Sep. 8, 2008 Total review time: 992 days Regulatory review time: 343 days	Mar. 22, 2004 Domestic clinical study results	1	Bausch & Lomb Microkeratome System (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 34 Electric keratome	An electric keratome used in ophthalmic surgeries such as laser *in-situ* keratomileusis (LASIK) for lamellar corneal incisions. A clinical study was conducted to evaluate the safety of this product in LASIK.
1	Aug. 5, 2008 Total review time: 594 days Regulatory review time: 228 days	Sep. 14, 2005 (Colorless); Dec. 16, 2005 (Yellow) Overseas clinical study results	2	Alcon AcrySof Toric Single Piece (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	An intraocular lens with its posterior face having a cylindrical optical power for correcting corneal astigmatism. Clinical studies were conducted to evaluate the efficacy and safety of this astigmatic (toric) intraocular lens.
1	Aug. 5, 2008 Total review time: 461 days Regulatory review time: 209 days	- Domestic clinical study results	3	Tecnis Multifocal IOL (AMO JAPAN K. K.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	A multifocal intraocular lens with its anterior face having an aspheric mechanism and the posterior face having a diffractive multifocal mechanism. Clinical studies were conducted to evaluate the efficacy and safety of this multifocal intraocular lens.
1	Oct. 31, 2008 Total review time: 283 days Regulatory review time: 251 days	Nov. 22, 2006 Domestic clinical study results	4	Proclear 1 Day (CooperVision Japan, Inc.)	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 and MPC is used as lens material. A clinical study was conducted to evaluate the efficacy and safety of this product.
1	Nov. 28, 2008 Total review time: 561 days Regulatory review time: 264 days	Oct. 30, 2007 Overseas clinical study results	5	Tecnis 1-Piece IOL (AMO Japan K. K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	An one-piece intraocular lens utilizes the raw materials of the optical zone of the existing intraocular lens in the haptic zone as well. Clinical studies were conducted to evaluate the efficacy and safety of this product including the performance of the haptic zone.
2	Jan. 29, 2009 Total review time: 427 days Regulatory review time: 331 days	- Domestic clinical study results	6	µ-one HA Implant (Yamahachi Dental MFG, Co.)	Approval	Medical products 4 Intraosseous dental implant	An intraosseous dental implant made of titanium with a hydroxyapatite (HA) coating (1 - 2 µm). Clinical studies were conducted to evaluate the efficacy and safety of this product coated with HA.
3-1	Jul. 4, 2008 Total review time: 463 days Regulatory review time: 334 days	Sep. 10, 2004 Overseas clinical study results	7	MULTI-LINK Mini Vision Coronary Stent System (Abbott Vascular Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Coronary stent	A coronary stent for reference vessel diameters ranging from 2.25 mm to 2.5 mm.Clinical trials were conducted to evaluate the efficacy and safety of the stent for bailout use in small vessels.
3-1	Mar. 26, 2009 Total review time: 1945 days Regulatory review time: 553 days	- Domestic clinical study results	8	Coroflex (B. Braun Aesculap Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Stent	A stainless-steel balloon-expandable coronary stent. Clinical studies were conducted to evaluate the clinical performance (e.g. restenosis rate) of the stent.
3-2	Aug. 25, 2008 Total review time: 858 days Regulatory review time: 599 days	Sep. 26, 2006 Overseas clinical study results	9	Arista AH (Senko Medical Trading Co.)	Approval	Medical products 4 Bioresorbable local hemostatic device	An absorbable hemostat consisting of microporous polysaccharide hemospheres (MPHs) to be used for the local management of bleeding wounds. Clinical studies were conducted to evaluate the hematostatic ability and safety of this product compared with a similar product.
4	Jul. 11, 2008 Total review time: 280 days Regulatory review time: 150 days	Nov. 21, 2007 Overseas clinical study results	10	Medtronic Reveal DX (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 21 ECG monitor	An insertable cardiac monitor to be implanted under the skin in patients for whom the diagnosis was not made from the test(s) the physician considered necessary. The device is intended for use in patients with unexplained syncope for the purpose of recording and storing the ECGs for diagnosis. The documents on clinical evaluation were submitted concerning the efficacy and safety of electrocardiography using this product.
4	Jul. 16, 2008 Total review time: 610 days Regulatory review time: 140 days	Feb. 10, 2000 Domestic clinical study results	11	INOvent (Air Water Inc.)	Approval	Instrument & apparatus 6 Nitric oxide management system	A device to be used for patients with respiratory failure to allow the dilution of nitric oxide inhalant to a certain concentration and its stable supply to the patient. Clinical studies were conducted to compare the predefined concentration of nitric oxide and the concentration of inhaled nitric oxide and to evaluate the concentration of inhaled nitrogen dioxide.

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Jul. 16, 2008 Total review time: 181 days Regulatory review time: 141 days	Apr. 7, 2009 Overseas clinical study results	12	Attain Ability Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	Over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as cardiac resynchronization therapy defibrillator (CRT-D). The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Jul. 16, 2008 Total review time: 166 days Regulatory review time: 121 days	Dec. 7, 2006 Overseas clinical study results	13	Lumax 300 HF-T (BIOTRONIK Japan, Inc.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers cardiac resynchronization therapy (CRT), with the function of a defibrillator. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Jul. 16, 2008 Total review time: 166 days Regulatory review time: 121 days	Dec. 7, 2006 Overseas clinical study results	14	Lumax 340 HF-T (BIOTRONIK Japan, Inc.)	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 documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Oct. 14, 2008 Total review time: 459 days Regulatory review time: 316 days	Nov. 17, 2004 (V-343) Jun. 30, 2004 (V-340) Overseas clinical study results	15	Atlas + HF (St. Jude Medical Japan CRMD)	Change	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 bilateral ventricles electrically for a long time), with the function of a defibrillator. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Oct. 14, 2008 Total review time: 459 days Regulatory review time: 316 days	Nov. 17, 2004 (V-337) Jun. 30, 2004 (V-338) Overseas clinical study results	16	Epic HF (St. Jude Medical Japan CRMD)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	An implantable pulse generator that delivers CRT, with the function of a defibrillator. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Dec. 15, 2008 Total review time: 410 days Regulatory review time: 227 days	Nov. 5, 2004 Overseas clinical study results	17	Navistar Thermocool (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Cardiovascular ablation catheter	An electrode catheter used in myocardium with radiofrequency current and for the electrophysiological study of the heart to treat type I atrial flutter. Clinical studies were conducted to evaluate the novel irrigation feature of this product that allows saline flushing from the tip electrode to aviod increasing tip electrode-tissue interface temperature.
4	Jan. 29, 2009 Total review time: 482 days Regulatory review time: 353 days	Jul. 25, 2007 Overseas clinical study results	18	QuickFlex (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as CRT-D for CRT. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Feb. 10, 2009 Total review time: 215 days Regulatory review time: 166 days	Jun. 13, 2008 Overseas clinical study results	19	Attain StarFix Lead (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable defibrillator/ pacemaker lead	An over-the-wire (OTW) type of left ventricular lead used with implantable pulse generators such as CRT-D for CRT. The documents on clinical studies were submitted for evaluation of the efficacy and safety of this product.
4	Mar. 17, 2009 Total review time: 404 days Regulatory review time: 251 days	Zephyr DR: Mar. 29, 2007 Zephyr XL DR: Mar. 29, 2007 Overseas clinical study results	20	Zephyr DR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual-chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 17, 2009 Total review time: 404 days Regulatory review time: 251 days	Zephyr SR: Mar. 29, 2007 Zephyr XL SR: May 9, 2007 Overseas clinical study results	21	Zephyr SR (St. Jude Medical Japan Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A single-chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 24, 2009 Total review time: 358 days Regulatory review time: 260 days	Apr. 29, 2005 Overseas clinical study results	22	Frontier II (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. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.
4	Mar. 30, 2009 Total review time: 364 days Regulatory review time: 264 days	Apr. 29, 2005 Overseas clinical study results	23	Frontier CRT-P (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable biventricular pacing pulse generator without defibrillator function	An implantable pulse generator that delivers CRT. Optimization of interventricular timing of biventricular pacing therapy was evaluated in the clinical studies.

Category	Approval Date Review Time	Date Approved in US Clinical study results: Domestic/Overseas		Brand Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Notes
4	Mar. 24, 2009 Total review time: 397 days Regulatory review time: 257 days	- Overseas clinical study results	24	Emprise SR+ (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A single chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
4	Mar. 24, 2009 Total review time: 397 days Regulatory review time: 257 days	- Overseas clinical study results	25	Emprise DR+ (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 7 Implantable cardiac pacemaker	A dual chamber implantable cardiac pacemaker. Its ventricular autocapture algorithm was modified to reduce the possibility of the misdetection of electrochemical polarization voltage that occurs in the conventional product. Clinical studies were conducted chiefly to evaluate the modified algorithm.
5	May 7, 2008 Total review time: 894 days Regulatory review time: 489 days	- Domestic clinical study results	26	Asahi Hollow Fiber Hemodiafilter (Asahi Kasei Medical Co., Ltd.)	Approval	Instrument & apparatus 7 Hemodiafilter	A hemodialfilter using hollow fibers made of polysulfone resin to remove metabolites in blood during hemodiafiltration for patients with acute and chronic renal failure. Clinical studies were conducted because it was the first time to use polysulfone resin as a raw material of hollow fibers for hemodialfilter, although it had been approved for hemodialyzer.
5	Dec. 18, 2008 Total review time: 875 days Regulatory review time: 519 days	- Domestic clinical study results	27	Flow Star (JMS Co., Ltd.)	Approval	Instrument & apparatus 7 Slow continuous hemofilter	A hemofilter used for treatment and purification of body fluid in patients with acute renal failure accompanying acute hepatic insufficiency, acute on chronic renal failure, perioperative period, sepsis, multiple organ failure, acute respiratory failure, or acute circulation failure. Clinical studies were conducted because it was the first time to use polyethersulfone (PES) as a raw material of hollow fibers.
6	May 22, 2008 Total review time: 2586 days Regulatory review time: 376 days	Mar. 1, 1996 Overseas clinical study results	28	Integra Dermal Regeneration Template (Century Medical, Inc.)	Approval	Medical products 4 Other surgical or orthopedic materials (dermal regeneration graft)	A two-layered matrix consisting of a cross-linking layer of bovine-derived collagen and shark-derived glycosaminoglycan and a silicone layer. To be indicated for the postexcisional treatment of full-thickness or partial-thickness thermal injuries. The product contains glycosaminoglycan, which is a novel feature unseen in existing products. Clinical studies were conducted to evaluate the efficacy and safety of this product.
6	Sep. 17, 2008 Total review time: 504 days Regulatory review time: 253 days	Mar. 14, 2007 Domestic clinical study results	29	Super Fixsorb MX30 (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation screw	Absorbable screws composed of poly L-lactide and hydroxyapatite. A partial change for the addition of the skull to the target site of Super Fixsorb MX30. Clinical studies were conducted to evaluate the efficacy and safety concerning the added target site.
6	Sep. 17, 2008 Total review time: 37 days Regulatory review time: 28 days	Mar. 14, 2007 No clinical study results	30	Osteotrans Plus 30 Screw (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation screw	A partial change for application of another brand name of Super Fixsorb MX30.
6	Sep. 17, 2008 Total review time: 491 days Regulatory review time: 240 days	Mar. 14, 2007 Domestic clinical study results	31	Super Fixsorb MX40 (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation plate	Absorbable plate composed of poly L-lactide and hydroxyapatite. A partial change for the addition of the skull to the target site of Super Fixsorb MX40. Clinical studies were conducted to evaluate the efficacy and safety concerning the added target site.
6	Sep. 17, 2008 Total review time: 37 days Regulatory review time: 28 days	Mar. 14, 2007 No clinical study results	32	Osteotrans Plus 40 Plate (Takiron Co., Ltd.)	Change	Medical products 4 Absorbable internal fixation plate	A partial change for application of another brand name of Super Fixsorb MX40.
6	Mar. 23, 2009 Total review time: 682 days Regulatory review time: 509 days	- Domestic clinical study results	33	Neobone X (MMT Co., Ltd.)	Approval	Medical products 4 Artificial bone implant	A composite type of synthetic hydroxyapatite bone substitute made of interconnected porous and solid parts. The product is used with the inner and outer fixation devices at the load bearing site. Clinical studies were conducted to evaluate its efficacy and safety in patients with cortical bone defect.