

FY2006 List of Approved Products: New Medical Devices

Category	Approval Date	Trade Name (Applicant Company)	Approval/ Partial Change	Classification Generic Name	Note
1	25-Oct-06	1 Excimer Laser Corneal Surgery System EC-5000 (Nidek Co., Ltd.)	Approval	Other laser surgical instrument and laser coagulator (ophthalmic excimer laser surgical instrument)	A excimer laser surgical system used in ophthalmology to correct myopia with and without astigmatism, remove corneal opacity and smooth corneal surface irregularities, by laser ablation. Addition of a new intended use for Laser-assisted in situ Keratomileusis (LASIK) to the already approved uses for photorefractive keratectomy (PRK) and phototherapeutic keratectomy (PTK).
1	25-Oct-06	2 Menicon Tinu, and other 16 trade names (Menicon Co. Ltd.)	Approval	Hard contact lenses	Rigid gas permeable hard contact lenses, which are indicated for daily or up to 30 days extended wear for correction of visual acuity (myopia, hyperopia, and/or aphakia).
2	23-Jan-07	3 Carisolv (D-PAC Co., Ltd.)	Approval	Unclassified dental material (a supplemental solution for hand-held cutting instruments)	A supplemental solution with a main component of sodium hypochlorite that makes removal of caries easy by softening the carious dentin.
3	11-Jul-06	4 Cook Zenith AAA Endovascular Graft (Medico's Hirata Inc.)	Approval	Other artificial blood vessel (endovascular graft)	A synthetic vascular prosthesis with stents intended for use to prevent further growth and rupture of an abdominal aortic aneurysm by blocking the blood flow into the aneurysm.
3	18-Jul-06	5 Micro-Driver Coronary Stent System (Medtronic Japan Co., Ltd.)	Approval	Coronary stent	A coronary stent, which is made from a new alloy (MP35N), indicated to treat small coronary arteries.
3	22-Jan-07	6 Excluder Bifurcated Stent Graft (Japan Gore-Tex, Inc.)	Approval	Other artificial blood vessel (stent graft)	An artificial blood vessel with stents intended for use to prevent further growth and rupture of an abdominal aortic aneurysm by blocking the blood flow into the aneurysm.
3	23-Jan-07	7 Triplex (Terumo Corporation)	Approval	Artificial blood vessel made from synthetic fibers	The graft is 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.
3	15-Mar-07	8 Cypher Stent (Johnson & Johnson K.K.)	Partial	Coronary stent	A drug-eluting stent coated with sirolimus for use to prevent restenosis after percutaneous coronary intervention. (revision made during reexamination period)
3	15-Mar-07	9 ASD Closure Set (Japan Lifeline Co., Ltd.)	Partial	A prosthetic material used as artificial pericardium	A fine wire mesh device indicated for use to percutaneously close the atrial septal defect. (revision made during reexamination period)
3	30-Mar-07	10 TAXUS Express 2 Stent (Boston Scientific Japan K.K.)	Approval	Coronary stent	A coronary stent coated with paclitaxel intended to reduce arterial restenosis.
4	03-Apr-06	11 Attain OTW Lead (Medtronic Japan Co., Ltd.)	Partial	Implantable cardioverter 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).
4	11-May-06	12 Heart Laser (Imatron Japan Inc.)	Approval	Carbon dioxide laser surgical instrument and laser coagulator	A laser surgical instrument and its accessories intended for use to treat severe ischemic heart diseases; the instrument irradiates carbon dioxide laser from the epicardial side to create a transmural channel through the cardiac muscle that facilitates revascularization of the muscle.

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4	18-May-06	13 Medtronic InSync III Marquis (Medtronic Japan Co., Ltd.)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	14 CONTAK RENEWAL 4 HE, and other 1 trade name (Guidant Corporation)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	15 CONTAK RENEWAL 4, other 1 trade name (Guidant Corporation)	Approval	Other defibrillator and accessories (implantable biventricular pacing pulse generator with defibrillator function.)	Implantable pulse generator that delivers CRT, with function of defibrillator.
4	31-Aug-06	16 Easytrak 2 CS Lead (Guidant Corporation)	Approval	Other pacemaker (implantable defibrillator/pacemaker lead)	OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
4	31-Aug-06	17 Easytrak 2 Lead (Guidant Corporation)	Approval	Other pacemaker (implantable defibrillator/pacemaker lead)	OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
4	06-Sep-06	18 Medtronic InSync III (Medtronic Japan Co., Ltd.)	Approval	Implantable biventricular pacing pulse generator without defibrillator function.	Implantable pulse generator that delivers CRT, without function of defibrillator.
4	26-Jan-07	19 SynchroMed EL Pump (Medtronic Japan Co., Ltd.)	Partial	Programmable drug infusion pump	Drug infusion pump indicated for intrathecal baclofen therapy in patients with severe spasticities resulted from cerebrospinal disorders.
4	09-Feb-07	20 Attain Bipolar OTW Lead (Medtronic Japan Co., Ltd.)	Approval	Implantable defibrillator/pacemaker lead	Bipolar OTW type of left ventricular lead used with implantable pulse generators such as CRT-D in CRT.
5	19-Oct-06	21 MucoUp (Seikagaku Corporation)	Approval	Other inactive therapeutic component used with endoscopes (sub-mucosal layer injection solution used with endoscopes)	Sub-mucosal layer injection solution used with endoscopes to improve the operativity of endoscopic mucosal resection and separation: by injecting the adequate dose into the sub-mucosal layer at the lesion, viscoelasticity of sodium hyaluronate solution exerts force to separate the sub-mucosal layer and muscle layer.
6	10-May-06	22 Super-Fixsorb MX30 (Takiron Co., Ltd.)	Approval	Osteosynthesis Material	Bioresorbable screws made of a composite of 30wt% hydroxyapatite particles and 70wt% poly-L- lactide.
6	10-May-06	23 Super-Fixsorb MX40 (Takiron Co., Ltd.)	Approval	Osteosynthesis Material	Bioresorbable plates made of a composite of 40wt% hydroxyapatite particles and 60wt% poly-L- lactide.