

Table-19. A List of Approved Articles in 2005 (New Medical Devices)

Category	Date of Approval	Trade Name (Name of Company)	Approval/Partial	Classification Japanese Accepted Name	Notes
4	6-Jul-05	1 Contak CD, and another trade name (Guidant Japan KK)	Approval	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	6-Jul-05	2 Contak CRTD, and another trade name (Guidant Japan KK)	Approval	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	Same as above
4	6-Jul-05	3 Easytrack Lead, and another trade name (Guidant Japan KK)	Approval	Other heart pacemaker (implantable cardioverter defibrillator/pacemaker lead)	The first OTW(Over The Wire) type lead (used with CONTAK CD, etc., a chest implantable pulse generator for CRT)
4	6-Jul-05	4 Easytrack CS, and another trade name (Guidant Japan KK)	Approval	Other heart pacemaker (implantable cardioverter defibrillator/pacemaker lead)	Same as above
4	6-Jul-05	5 Attain OTW Lead (Medtronic Japan Co., Ltd.)	Approval	Lead for an implantable heart pacemaker	The first OTW (over the wire) type lead to be used with an implantable cardiac pacemaker with a port for a left ventricular lead
4	20-Jul-05	6 Medtronic InSync 8040 (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Addition of OTW type lead (Attain OTW lead) to list of leads usable with implantable heart pacemaker for CRT [Partial change during re-examination period]
4	15-Nov-05	7 Medtronic InSync ICD (Medtronic Japan Co., Ltd.)	Approval	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	15-Nov-05	8 Attain Lead (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Medtronic InSync ICD is added to list of devices usable with this lead [Partial change during the re-examination period]
5	8-Dec-05	9 Cool-tip RF System (Tyco Healthcare)	Approval	Electric surgical instrument	A device with a new indication for coagulating hepatic tumor by high-frequency current of the radio-frequency waves (480 kHz). Since the attached electrode is of the straight needle type with beveled tip, the intermittent high-frequency electrification as well as the internal electrode cooling mechanism are adopted in order to prevent an increase in temperature at the tip. [Prompt review]
5	9-Dec-05	10 Cool-tip RF System (Valleylab, a division of Tyco Healthcare Group LP)	Partial	Electric surgical instrument for treatment	Electric surgical instrument on high-frequency current of radio-frequency waves (480 kHz), the indication of which was changed to "for coagulating hepatic tumor" [Prompt review]
6	1-Mar-06	11 Super Fixorb 30, and another trade (TAKIRON Co., LTD.)	Partial	absorbable osteosynthesis device	Addition of shapes (product with medium size, larger core diameter), dye (marker) and packaging materials to absorbable osteosynthesis devices (major ingredients: poly lactic acid, hydroxyapatite) [Partial change in the approved items during the re-examination period]