PMA Decisions Rendered for April 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
PMA Original Approvals			
P050046 **4/13/07**	ACUITY™ Steerable Lead Models 4554, 4555 and 4556	Guidant CRM St. Paul , MN 55112	Approval for the ACUITY™ Steerable Lead Models 4554, 4555, and 4556. The Guidant ACUITY™ Steerable IS-1 coronary venous, steroid-eluting, dual-electrode pace/sense leads are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using ACUITY™ Steerable with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.
PMA Supplemental Approvals			
P900023/S046 **4/24/07** **Real-Time**	AB5000/BVS 5000 Circulatory Support System	Abiomed, Inc. Danvers , MA 01923	Approval for modifications to the AB5000 Ventricle cannula restraint system, extended shelf life (2 years) for the AB5000 Ventricle, and reclassification of a precaution to a warning for the BVS 5000.
P990001/S030 **4/25/07** **Real-Time**	L289-010A/B Integrated Circuit Controller for the Vitatron C- and T-Pacemaker Models C60A3, C20A3, T60A1, and T20A1	Medtronic, Inc. / Vitatron, B.V. Shoreview , MN 55123	Approval for the L289-010A/B Integrated Circuit Controller for the Vitatron C- and T- pacemaker Models C60A3, C20A3, T60A1, and T20A1.
P000039/S012 **4/25/07** **180-Day**	AMPLATZER Septal Occluder	AGA Medical Corp. Golden Valley , MN 55427	Approval for a new delivery system and modifications to the device packaging. The devices, with the modified delivery systems, will be marketed under the trade name TorqVue™ Delivery and Exchange Systems.
P010031/S057 **4/17/07** **180-Day**	Medtronic Concerto Models C154DWK and C164AWK ICD Systems and Concerto-Virtuoso v1.2 Software Application Model SW002	Medtronic, Inc. Minneapolis , MN 55432	Approval for the Medtronic Concerto Models C154DWK and C164AWK ICD systems and Concerto-Virtuoso v1.2 Software Application Model SW002. The device, as modified, will be marketed under the trade name Medtronic Concerto Models C154DWK and C164AWK ICD systems and is indicated as follow: The Concerto is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial

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			tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction £ 35% and a prolonged QRS duration. Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.
P020024/S010 4/25/07 180-Day	AMPLATZER Duct Occluder	AGA Medical Corp. Golden Valley , MN 55427	Approval for a new delivery system and modifications to the device packaging. The devices, with the modified delivery systems, will be marketed under the trade name TorqVue™ Delivery and Exchange Systems.
P020026/S004 4/13/07 Real-Time	CYPHER™ Sirolimus-Eluting Coronary Stent on the RAPTOR™ Over-the-Wire Delivery System or RAPTORRAIL® Rapid Exchange Delivery System (CYPHER Stent)	Cordis Corporation Miami , FL 33102	Approval for a new elution test method and revised elution specifications.
P020045/S021 4/18/07 Real-Time	Freezor Cardiac CryoAblation Catheters - Freezor Xtra and Freezor MAX Surgical CryoAblation Catheters and CCT.2 CryoConsole System	Applied Physics Santa Fe , MN 87594	Approval for changes to the leak detection system in the Freezor catheter and Freezor Xtra devices from a single bare stainless steel wire to a duplex insulated wire made of two electrodes.
P030031/S004 4/23/07 Real-Time	NaviStar™ ThermoCool® Deflectable Diagnostic/Ablation Catheter and	Biosense Webster, Inc. Diamond Bar , CA 91765	Approval for merging the labeling for the two approved indications for the NaviStar ThermoCool Diagnostic/Ablation Catheters (atrial flutter under P030031, and ventricular tachycardia under P040036) and updating the labeling for the Celsius ThermoCool which remains approved for treatment of atrial flutter only.

PMA Decisions Rendered for April 2007

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	Celsius™ ThermoCool® Deflectable Diagnostic/Ablation Catheter		
P040036/S002 4/23/07 Real-Time	NaviStar™ ThermoCool® Deflectable Diagnostic/Ablation Catheter and Celsius™ ThermoCool® Deflectable Diagnostic/Ablation Catheter	Biosense Webster, Inc. Diamond Bar , CA 91765	Approval for merging the labeling for the two approved indications for the NaviStar ThermoCool Diagnostic/Ablation Catheters (atrial flutter under P030031, and ventricular tachycardia under P040036) and updating the labeling for the Celsius ThermoCool which remains approved for treatment of atrial flutter only.
30-Day Notices (135 Day Supplement was not required)			
P020009/S037 4/4/07	Express 2 Monorail (MR) & Over-the-Wire (OTW) Coronary Stent System	Boston Scientific Corporation Maple Grove , MN 55311	Removal of a redundant inspection step in the manufacture of the device.
P020009/S038 4/4/07	Express 2™Coronary Stent System	Boston Scientific Corporation Maple Grove , MN 55311	Modification to the proximal weld in-process acceptance criteria in the manufacture of the device.
P020047/S009 4/4/07	MULTI-LINK VISION® RX Coronary Stent System and MULTI-LINK MINI VISION® RX Coronary Stent System	Abbott Vascular Cardiac Therapies Temecula , CA 92591	Replacement of the existing bonding equipment with a new heat bonder.
P030005/S043 4/13/07	CONTAK RENEWAL TR Family of Cardiac Resynchronization Therapy Pacemakers (CRT-P)	Guidant Corporation St. Paul , MN 55112	Two new suppliers of resistors used in the CONTAK RENEWAL TR family of devices.

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P030025/S045 4/4/07	Taxus Express 2™ Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove , MN 55311	Removal of a redundant inspection step in the manufacture of the device.
P030025/S046 4/4/07	Taxus™ Express 2 Paclitaxel-Eluting Coronary Stent System	Boston Scientific Corporation Maple Grove , MN 55311	Modification to the proximal weld in-process acceptance criteria in the manufacture of the device.
P040002/S010 4/4/07	Powerlink System with Visiflex Delivery Catheter System	Endologix, Inc. Irvine , CA 92618	Change to the front sheath subassembly of the Visiflex Delivery System.
P040002/S011 4/13/07	Powerlink System with Visiflex Delivery Catheter System	Endologix, Inc. Irvine , CA 92618	Alternate supplier of ePTFE graft used in the Powerlink System stent gräf subassembly.
P040016/S023 4/4/07	Liberté™ Coronary Stent System	Boston Scientific Corporation Maple Grove , MN 55311	Modification to the proximal weld in-process acceptance criteria in the manufacture of the device.
P040042/S010 4/13/07	IBI Therapy™ Dual 8™ Ablations Catheters	Irvine Biomedical, Inc. Irvine , CA 92614	Change to add a new supplier for the isolation transformer for the 1500T6 (USA) RT Generator.