PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
PMA Original Approvals			
P050004 **5/8/07**	EMS Swiss Dolorclast®	Electro Medical Systems (EMS) S.A. Nyon , Switzerland CH-1650	Approval for the EMS Swiss Dolorclast®. The EMS Swiss Dolorclast® is a non-surgical alternative indicated for the treatment of chronic proximal plantar fasciitis for patients 18 years of age or older with symptoms for 6 months or more and a history of unsuccessful conservative therapy. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medical calcaneal tuberosity.
PMA Supplemental Approvals			
P820003/S079 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P830045/S105 **5/9/07** **135-Day**	Paragon / Phoenix Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P830045/S106 **5/4/07** **135-Day**	Paragon / Phoenix Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P830045/S107 **5/7/07** **Real-Time**	Paragon / Phoenix Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P830045/S108 **5/7/07** **Real-Time**	Paragon / Phoenix Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P830045/S109 **5/9/07** **180-Day**	Paragon / Phoenix Family of Pacemakers	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P850051/S065 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P880006/S048 **5/9/07** **135-Day**	Sensolog / Dialog / Regency Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P880006/S049 **5/4/07**	Sensolog / Dialog / Regency Family of	St. Jude Medical, CRMD Sylmar , CA	Approval for alternate automated test equipment (ATE).

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
135-Day	Pacemakers	91342	
P880006/S050 **5/7/07** **Real-Time**	Sensolog / Dialog / Regency Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P880006/S051 **5/7/07** **Real-Time**	Sensolog / Dialog / Regency Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P880006/S052 **5/9/07** **180-Day**	Sensolog / Dialog / Regency Family of Pacemakers	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P880086/S140 **5/9/07** **135-Day**	Affinity / Integrity / Victory Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P880086/S141 **5/4/07** **135-Day**	Affinity / Integrity / Victory Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P880086/S142 **5/7/07**	Affinity / Integrity / Victory Family of	St. Jude Medical, CRMD Sylmar , CA	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
Real-Time	Pacemakers	91342	circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P880086/S143 **5/7/07** **Real-Time**	Affinity / Integrity / Victory Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P880086/S145 **5/9/07** **180-Day**	Affinity / Integrity / Victory / Zephyr Family of Pacemakers	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P880086/S146 **5/9/07** **Real-Time**	Affinity / Integrity / Victory / Zephyr Families of Pacemakers	St. Jude Medical CRMD Sunnyvale , CA 95086	Approval for the Zephyr XL SR Model 5626 Pacemaker which utilizes the XL battery Model 9438 which is currently approved for use with the marketed Zephyr XL DR 5826 Pacemaker. The device, as modified, will be marketed under the trade name Zephyr XL SR Model 5626 and is indicated for single chamber rate adaptive pacing.
P890003/S116 **5/4/07** **Real-Time**	Carelink Monitor Model 2490C, Model 2491 DDMA and CardioSight Reader Model 220A	Medtronic, Inc. Cardiac Rhythm Disease Management Shoreview , MN 55126	Approval for updates to the CareLink v1.1 Device Data Management Application to (1) provide support for Concerto with atrial therapies; (2) allow transmission of an “Alert” signal for AT/AF Burden and Fast V Response observations if there is an associated alert; (3) output the type of episode log for invalid

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			episodes so CareLink can properly display invalid episodes as Arrhythmia Episodes or Ventricular Sensing Episodes; and (4) correct a problem where the Cardiac Compass “Ventricular Rate During AT/AF” graph does not always print the Mean Ventricular Rate.
P890003/S117 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P900061/S072 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P910023/S133 **5/7/07** **Real-Time**	Cadence Family of ICDs	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P910023/S134 **5/7/07** **Real-Time**	Cadence Family of ICDs	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P910023/S138 **5/9/07** **180-Day**	Cadence Family of ICDs	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P930022/S005 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P960013/S025 **5/7/07** **180-Day**	OptiSense Model 1699T/TC Leads	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the OptiSense Model 1699T and 1699TC Leads. The device, as modified, will be marketed under the trade name OptiSense Model 1699T and 1699TC Leads and are designed for permanent sensing and pacing in the right atrium, in combination

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			with a compatible pulse generator. An active fixation lead such as the model 1699 may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage .
P970012/S027 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P970013/S015 **5/9/07** **135-Day**	Microny Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P970013/S016 **5/4/07** **135-Day**	Microny Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for alternate automated test equipment (ATE).
P970013/S017 **5/7/07** **Real-Time**	Microny Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36,

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P970013/S018 **5/7/07** **Real-Time**	Microny Family of Pacemakers	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P970013/S019 **5/9/07** **180-Day**	Microny Family of Pacemakers	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P980016/S096 **5/4/07** **Real-Time**	Virtuoso Models D154AWG / D154VWC Implantable Cardioverter Defibrillators	Medtronic, Inc. Cardiac Rhythm Disease Management Shoreview , MN 55126	Approval for updates to the CareLink v1.1 Device Data Management Application to (1) provide support for Concerto with atrial therapies; (2) allow transmission of an “Alert” signal for AT/AF Burden and Fast V Response observations if there is an associated alert; (3) output the type of episode log for invalid episodes so CareLink can properly display invalid episodes as Arrhythmia Episodes or Ventricular Sensing Episodes; and (4) correct a problem where the Cardiac Compass “Ventricular Rate During AT/AF” graph does not always print the Mean Ventricular Rate.
P980016/S098 **5/3/07** **Real-Time**	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
	Pacemaker and ICD Models		
P980035/S072 5/3/07 Real-Time	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P980037/S022 5/10/07 Real-Time	AngioJet® Rheolytic™ Thrombectomy System – Spiroflex® Thrombectomy Set	Possis Medical, Inc. Minneapolis , MN 55433	Approval for the Spiroflex Thrombectomy Set.
P980050/S027 5/3/07 Real-Time	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P990001/S029 5/3/07 Real-Time	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
	Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models		
P010015/S027 5/3/07 Real-Time	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.
P010031/S064 5/4/07 Real-Time	Concerto Models C154DWK / C164AWK Cardiac Resynchronization Therapy Defibrillators	Medtronic, Inc. Cardiac Rhythm Disease Management Shoreview , MN 55126	Approval for updates to the CareLink v1.1 Device Data Management Application to (1) provide support for Concerto with atrial therapies; (2) allow transmission of an “Alert” signal for AT/AF Burden and Fast V Response observations if there is an associated alert; (3) output the type of episode log for invalid episodes so CareLink can properly display invalid episodes as Arrhythmia Episodes or Ventricular Sensing Episodes; and (4) correct a problem where the Cardiac Compass “Ventricular Rate During AT/AF” graph does not always print the Mean Ventricular Rate.
P010031/S066 5/3/07 Real-Time	Software Enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer	Medtronic, Inc. Minneapolis , MN 55432	Approval for software enhancements to the Medtronic Model 9986 Desktop BOSS (Version 1.6) for the Medtronic Model 2090 CareLink Programmer for all currently approved Medtronic and Vitatron Pacemaker and ICD Models.

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
	for all currently approved Medtronic and Vitatron Pacemaker and ICD Models		
P030035/S028 **5/7/07** **Real-Time**	Frontier / Frontier II Family of CRT-Ps	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P030035/S029 **5/7/07** **Real-Time**	Frontier / Frontier II Family of CRT-Ps	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P030035/S031 **5/9/07** **180-Day**	Frontier / Frontier II Family of CRT-Ps	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.
P030054/S051 **5/7/07** **Real-Time**	Epic HF / Atlas+ HF Family of CRT-Ds	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for modifications to the Epic and Atlas Families of ICDs and CRT-Ds, including: addition of an over-current protection circuit; added capability for RAM operation with ROM backup with Defibrillation Only (DFO) in the hardware backup mode; addition

PMA Decisions Rendered for May 2007

APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
			of daily high-voltage lead impedance measurements; addition of LV ring to RV coil pacing pulse configuration; addition of Ventricular Intrinsic Preference feature; and modifications to programmer software and display enhancements. The devices as modified will be marketed under the trade names Promote CRT-D device model numbers 3107-36 and 3107-30, and Current DR and VR ICD device model numbers 2107-36, 2107-30 and 1107-36, 1107-30, and will be supported by the Model 3650 Merlin PCS with Model 3330 Version 6.0 software.
P030054/S052 **5/7/07** **Real-Time**	Epic HF / Atlas+ HF Family of CRT-Ds	St. Jude Medical, CRMD Sylmar , CA 91342	Approval for the Model 3330 Version 6.1.0 Software for the Model 3650 Merlin Patient Care System and the Model 3307 Version 6.4.0 Software for the Model 3510 Programmer.
P030054/S056 **5/9/07** **180-Day**	Epic HF / Atlas+ HF Family of CRT-Ds	St. Jude Medical Sunnyvale , CA 94086	Approval for the Model 3330 Version6.1.1 Software for the Model 3650 Merlin™ Patient Care System and Model 3307 Version 6.4.1 Software for the Model 3510 Programmer which enables V-V timing, AF Suppression and QuickOpt Timing Cycle Optimization in the Frontier II Model 5586 CRT-P device. The device, as modified, will be marketed under the trade names as specified in the device families and is indicated for rate adaptive pacing, cardioversion and defibrillation and/or treatment of heart failure with cardiac resynchronization therapy.