Date: April 29, 2010

From: (b)(6) Biomedical Engineer (ODE/DCD/PDLB)

Subject: P030054/S146 Merlin Patient Care System (PCS) programmer model 3650

PMA Holder: St. Jude Medical, CRDM

Contact: Ms. Gina Correa

To: The Record

Background/ Reason for Supplement

St. Jude Medical is submitting a modification to their Merlin Patient Care System (PCS) programmer which would add the new Pacing System Analyzer (PSA) EX 3100 device hardware. In addition, they submitted an amendment on 3-30-10 to add the Model 3330 version 10.1.1 software. This software is based on version 8.1.1 which is used on the Model 3650 Merlin PCS programmer approved under P030054/S135.

Review Team

(b)(6) Lead Reviewer
(b)(6) Software Reviewer
(b)(6) MD, Clinician

Indications For Use

The Indications for Use for the Merlin PCS programmer remain unchanged.

The Merlin™ PSA EX3100 is indicated to assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting. Only use the Merlin PSA with the Merlin PCS.

Device Description

The Merlin Pacing System Analyzer (PSA) Model EX3100 is an accessory to the legally marketed Merlin PCS programmer model 3650. The EX3100 enables the Merlin programmer to connect directly to pacing leads whereas the previous programmer used RF telemetry. The Merlin PCS model 3650 was approved under P030054/S008. Figures 1 and 2 illustrate how to use the EX3100 with the PCS model 3650 programmer.

The EX3100 is capable of assessing intrinsic cardiac amplitudes and slew rates, pacing lead impedances and pacing capture thresholds during implant procedures. In addition to the Merlin PSA Model EX3100, the Merlin PSA system consists of:

- Patient Cable Adapters – The Cable Adapter EX 3170 or “M” Adapter EX 3180 connects the Merlin PSA to patient cables made by St. Jude and Medtronic respectively.
- Merlin Antenna Adapter – EX 3190 connects the currently approved Merlin Antenna 3638 to the Merlin PCS (approved under P030054/S8, 10/12/2005).

By design, the Merlin EX3100 system (the Merlin PSA EX3100 and the accessories) does not make blood tissue contact. Figure 1 below shows the PSA before installation and Figure 2 illustrates proper installation into the Merlin PCS.

Figure 1: Merlin PSA EX3100 unit

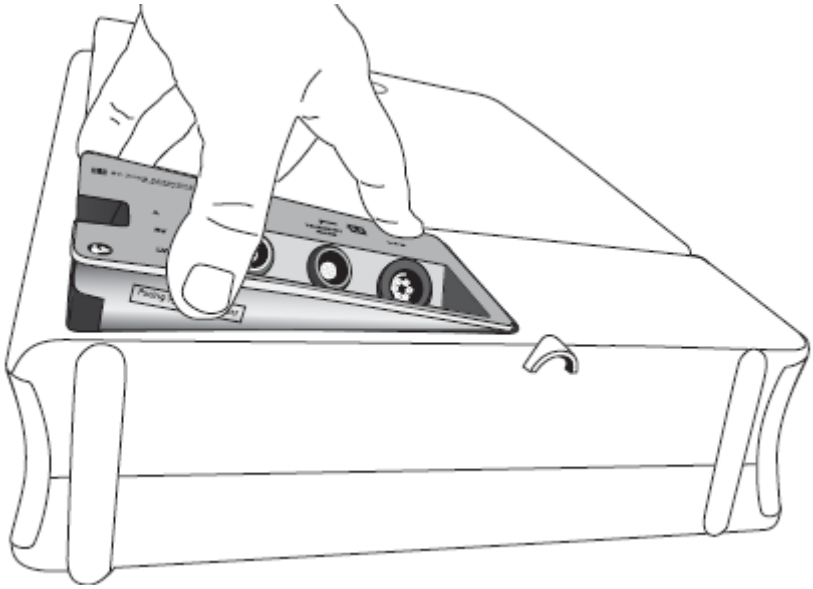

Figure 2: Installation of PSA into the Merlin Patient Care System (PCS)

Cardiac leads are connected via a single connector to the front panel of the Merlin PSA EX3100. The Merlin PSA EX3100 is capable of analyzing three cardiac leads, each having its own dedicated Front-End electronics.

The Front-End Interface Block is responsible for signal acquisition and pace pulse generation. The Front-End Interface Block communicates with the Control Block across an optical interface, to ensure galvanic isolation between the Control Block and the Front End.

The Control Block is responsible for signal processing and communication to the PSA user interface. This communication is facilitated via a USB interface, which is also responsible to power the unit. If there is a power failure via USB, a backup battery is provided as a risk mitigator to ensure uninterrupted functionality. It uses four AA-size LR6 (alkaline) batteries and can support operation at the maximum pulse amplitude settings in all channels and at maximum base rate setting for at least 30 minutes.

Preclinical/Bench

General product verification testing was conducted for:

- Merlin PSA EX 3100 Mechanical Verification Test
- Merlin PSA EX 3100 Electronics Verification Test
- Merlin PSA EX 3100 system EMC Compliance
- Merlin PSA EX3100 system Safety Compliance Test
- Adapter EX3170 Verification Test
- Adapter EX3180 Verification Test
- Adapter EX3190 Verification Test
- Adapter EX3170/80 Shipping Test
- Software Verification (PSA Firmware)
- System Verification
- Usability Engineering

One substantial modification in this device is the ability to use backup battery power. Adequate testing and risk analysis for external power sources and compatibility of power sources has been provided. The following validation tests address this issue:

- PVS_003 verified IEGM function and patient connections when switching between USB and battery power
- PVS_004 verified safety on patient connectors when applying reversed voltage on the battery connectors – i.e. incorrect battery installation
- PVS_006 verified safety on patient connectors when applying overvoltage on the battery connectors
- PVS_081 verified that charges on patient connectors do not exceed the requirements when applying an overvoltage on the USB connector
- PVS_007 verified that battery supply is not drained when the PSA is powered via USB
- PVS_008 verified volt meter accuracy for battery status indicator
- PVS_014 verified 60 minutes of full pacing on battery power

The system verification testing has adequately verified that the design meets the specified system requirements.

Biocompatibility/Materials

Not Applicable

Animal Studies

Not Applicable

Electrical Safety

Safety Compliance testing in accordance with IEC 60601-1:1998, am 1 and am 2 was performed at an accredited test lab – (b)(4) (b)(4) This report assesses the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead implantation. Some of the tests covered in this report include environmental conditions, requirements related to classifications, abnormal operation and fault conditions and excessive temperatures.

EMC Compliance testing in accordance with IEC 60601-1-2:2007 was performed at an accredited test lab – (b)(4) (b)(4). The performance was verified by observing the display and pacing pulses on an oscilloscope. The PSA EX3100 was tested after each immunity test to see if it had the original settings and to make sure that it was not blocked or changed in any way.

Mechanical Safety

Hardware testing on product level, including electronic, mechanical and accessories verified requirements defined in the hardware, electronics, mechanical and accessories requirement specifications. Shipping test, covering product packaging and accessories, were included in the mechanical verification testing for Merlin PSA EX3100, in the verification report for EX3190 and in a combined shipping test report for EX3170 and EX3180.

The System Verification Report and Usability Engineering Report, include system level testing of the Merlin PCS to ensure that it functions properly with the PSA installed. It confirms that the EX3100 can function properly without impacting the functionality of the Merlin programmer. PSA sessions can be initiated or suspended at any time to use non-PSA functions such as RF interrogation by the programmer.

Software

Version: 10.1.1		
Level of Concern: SJM indicated that the software for the Programmer Model 3650; Model 3330 v10.1.1 SW is a **MAJOR** level of concern. The designation is appropriate for this type of device and is consistent with how other devices of this type have been reviewed. The Level of Concern is acceptable.		
Acceptable for Approval?		**No**
Software description: A high level description of the features implemented in software is provided in the Executive Summary. Further, SJM provides a detailed description within SW Architecture Document. The submitted SW description is acceptable.	X	
Device Risk Analysis: A risk analysis detailing the overall risk is provided. The overall evaluation of risk appears to be of appropriate detail and scope. The submitted risk analysis is acceptable.	X	
Software Requirements Specifications (SRS): The submission includes software requirements documents. The overall requirements of the device appear to be well-defined. The submitted SRS is acceptable.	X	
Architecture Design Chart: The software architecture provided by includes system diagrams, context diagrams, and various functional diagrams. The data provided thoroughly details FW performance among the electronics. The submitted architecture design chart is acceptable.	X	
Design Specifications: Design specifications are not referenced nor provided. Given the scope of the SW, the approach is acceptable. Based on evaluation of the Architecture and SRS, the SDS is not required at this time.	X	
Traceability Analysis/Matrix: A traceability matrix linking various testing activities and system requirements is provided: The document fails to fully link all documents (SRS, SDS, Architecture, etc). However, given the limited scope of the subject (FW only), the submitted documentation is nominally acceptable. Note: A meeting to discuss the overall SW Development Life Cycle documentation is scheduled for 09 February 2010.	X	
Development Environment: SJM indicates continued use of (b)(4). Since SW proposed in the subject relates to fixed programs/data structures intended to control the electronics within the PSA, extensive details related to the development environment are not necessary. The information submitted is acceptable.	X	

Verification & Validation Testing: SJM provided test results for the requirements listed within the SRS. Each of the tests is cross referenced in terms of the SRS Requirement Tag and feature. All testing passed. The information submitted is acceptable.	X	
Revision Level History: The proposed software reflects a novel SW package. Thus, a revision level history detailing modifications by version is not required. As a note, SJM does report revisions within the current SW iteration. While not required, it is notable that the detail is consistent with an effective SDLC. The submitted information is	X	
Unresolved Anomalies: SJM reports five unresolved anomalies associated with the release of the PSA SW. The submitted information is acceptable.	X	

The software review recommends approval and I concur with the recommendation.

Clinical Data

Not applicable

Summary of Interactive Review/Correspondence

None

Conclusion

The sponsor has adequately addressed all modifications in this file. The review team has no remaining questions or concerns.

Recommendation: I recommend that the supplement be Approved.

(b)(6) Lead Reviewer Date

Mitchell Shein, Chief PDLB Date