Transparency Memorandum

DATE: June 20, 2011

FROM: , Scientific Reviewer
FDA/CDRH/ODE/DCD/PDLB

SUBJECT: P030054/S181
Epic HF/Atlas+ HF/Promote/Unify Family of CRT-Ds

P910023/S257
Cadence/Current/Fortify Family of ICDs

Update to v.5.0 of Merlin.net and Merlin@Home Software
St. Jude Medical, Cardiac Rhythm Management

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TO: The Record

RECOMMENDATION: **APPROVAL**

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, Lead Reviewer, PDLB Date

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, Chief, PDLB Date

EXECUTIVE SUMMARY

This supplement represents the commercial version of the Merlin.net and Merlin@Home "5.0A" software. A supplement for an (b) (4) ((b) (4)) included similar changes to the software and is designated as version "5.0D". The software changes for the (b) (4) were approved on 5/17/2011. St. Jude has stated that the (b) (4) was a superset of the changes provided in this PMA-S and that all changes in the PMA-S were included in the (b) (4) (b) (4) t. The additional changes to the (b) (4) only pertained to the (b) (4) and (b) (4) . Also, access to the (b) (4) are controlled on a (b) (4) basis and each (b) (4) is granted access to the (b) (4) information on the website. Therefore, (b) (4) that are not (b) (4) will not see (b) (4) related information. After reviewing the (b) (4) software

consult, this submission, and interaction with the sponsor, I feel the sponsor should receive an **approval** letter.

BACKGROUND

The purpose of this submission is to gain approval to upgrade the Merlin.net/Merlin@home remote monitoring system software to version 5.0. This submission spans two PMA Supplements, P030054/S181 for the Epic HF/Atlas+ HF/Promote/Unify families of CRT-Ds and P910023/S257 for the Cadence/Current/Fortify Family of ICDs. This supplement represents the commercial version of the Merlin.net and Merlin@Home "5.0A" software. A supplement for an (b) (4)) included similar changes to the software and is designated as version "5.0D". The software changes for the (b) (4) were approved on 5/17/2011. St. Jude has stated that the (b) (4) was a superset of the changes provided in this PMA-S and that all changes in the PMA-S were included in the (b) (4) . The intended use of the Merlin.net and Merlin@home transmitter has not changed. The Merline.net system is a transtelephonic system used for remote device follow-up and is intended to be used to collect diagnostic and EGM data from an implanted device at the patient's home. Healthcare providers can view the follow-up data through the Merlin.net portal. The device does not provide any programming capabilities for the device.

INDICATIONS FOR USE

The Indications for Use for the Merlin.net and Merlin@home software have not changed.

CONTRAINDICATIONS

The Contraindications for the Merlin.net and Merlin@home software have not changed

DESCRIPTION OF CHANGES

Tables 1 and 2 in the submission identify the changes being made. The tables provide traceability for the software modifications. Each identified software modification in the table is traced to the relevant system and/or software requirement, design specification, verification and validation tests and their test results, pointers to hazards, if any, and their mitigators. Table 1 consists of non-field related changes and Table 2 contains changes made due to issues reported from field use of a previous version of the system. Table 1 contains 114 different changes and table 2 contains 22 different changes. The details of the changes are described in Table 1 and 2 of the submission.

BIOCOMPATIBILITY/MATERIALS

This submission only contains software changes; therefore not biocompatibility/materials review was necessary.

MECHANICAL SAFETY

There are no changes to the mechanical safety of the device and therefore no mechanical safety review was necessary.

PACKAGING, SHELF LIFE, AND STERILIZATION

This submission only contains software changes; therefore not biocompatibility/materials review was necessary.

SOFTWARE

Version: Model MN5000 Software Version 5.0 (for Merlin.net System) Model EX2000 Software Version 5.0 (for Merlin@home devices)		
Level of Concern: Moderate (this is appropriate for this type of device and is consistent with other similar devices)		
	Yes	**No**
Software/Firmware description: St. Jude Medical (SJM) is submitting a 180-day PMA supplement for approval of Model MN5000 version 5.0 software to be used with the Merlin.net System (P910023) and for the Model EX2000 version 5.0 software for use on Merlin@home devices (P910023 and P030054). This supplement details modifications to the Merlin.net and Merlin@home software only. There are no hardware changes to the Merlin@home device. The intended use of the Merlin.net system and the Merlin@home transmitter has not changed. The Merlin.net system is a transtelephonic system used for remote device follow-up. Healthcare providers can view the follow-up data/device data via the SJM web portal (Merlin.net). The Merlin@home transmitter device is intended to be used as a tool for collecting diagnostics and EGM data from an implantable device at the patient's home. The device will then transfer the collected data to an external receiving station (Merlin.net) where it is stored for review by a clinician. The device does not program the implanted pulse generator.	X	
Device Hazard Analysis: At St. Jude Medical, risk/hazard analysis is done at the system level. The Merlin.net and Merlin@home Risk Management Reports include Software Risks. Refer to Appendix D: Merlin.net and Merlin@home System Risk Management Report for details of the device hazard analysis for Software ver 5.0. There are two risk management reports, one for Merlin.net and one for Merlin@home. The reports document the hazards and the mitigations of the risks associated with operation of the system. The risk analysis is appropriate for this type of system. After reviewing the analysis I feel all of the identified system hazards have an acceptable level or risk or have been mitigated.	X	

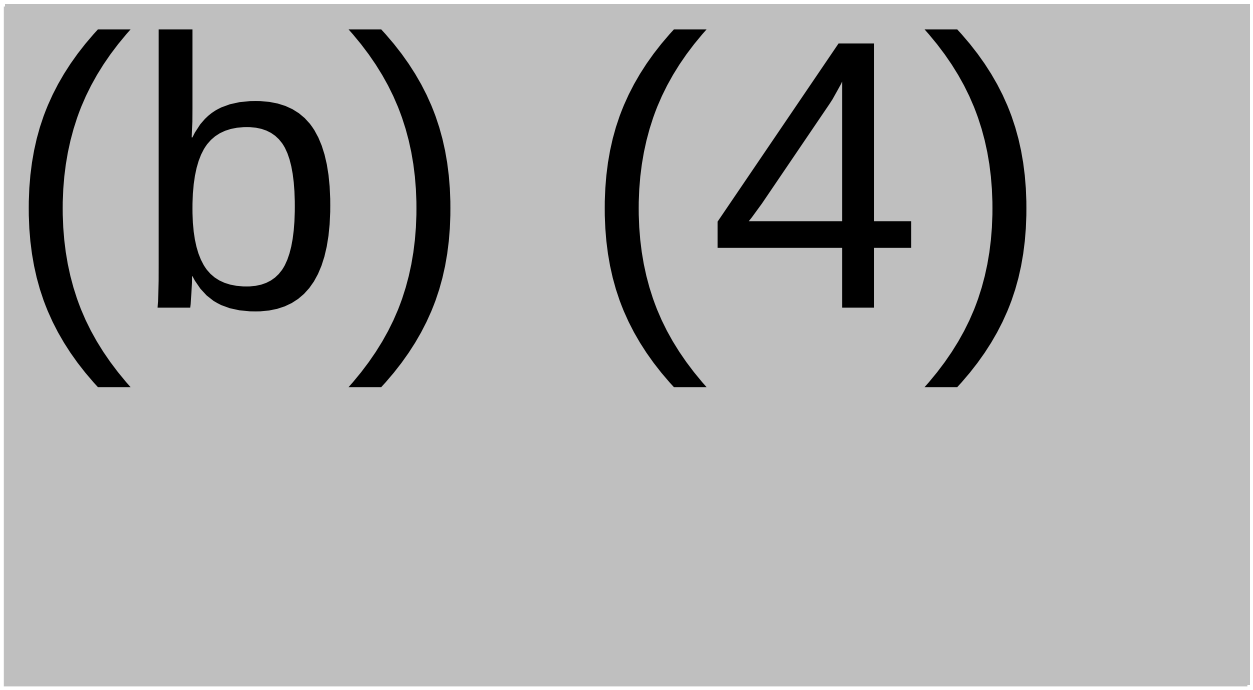
Software Requirements Specifications:

The complete SRS is provided in the original PMA/PMA-S submission and only a modified version of the software requirements were provided in the Delta SRS (Appendix E of this submission). See Traceability Analysis section (Section IV) for the traceability of the changes to the new or modified requirements. The complete SRS is on file at SJM and is available upon request. X

The requirements appear to adequately define the software functionality associated with the Merlin System. Even though the submission only provided the changes to the SRS, it was complete and is adequate.

Architecture Design Chart:

The following image illustrates the overall software architecture:



Appendix F of the submission goes into detail about the architecture and design summary. After reviewing this section it seems that the sponsor has provided adequate information detailing the architecture design.

Design Specifications:

Appendix F of the submission goes into detail about the design specifications. After reviewing this section it looks to be very similar to the (b) (4) . There are no outstanding concerns with this portion of the submission and the information provided is adequate. X

Traceability Analysis/Matrix:

In the submission, Tables 1 and 2 provide traceability for the software modification for the Merlin.net and Merlin@home system software. Each identified software modification in the table is traced to the relevant system and the software requirement, design X

specification, verification and validation tests and results, pointer to hazards, if any, and their mitigators. Table 1 consists of non-field related changes and Table 2 contains changes made due to issues reported from the field of the previous version of the system. The tables show each of the changes, design requirements, design specifications, tests and test results. The information demonstrates that the requirements were tested during verification. The information is adequate.		
Development: The overall software development environment has not changed as compared to version 4.6 for the changes in this software version. At a high level, the software used in the Merlin.net system and Merlin@home software Development Life Cycle (SDLC) is comprised of several stages which are designed to build upon one another, taking the output from the previous stage, and adding additional effort to produce more results and greater refinement. Details of the software development environment can be found in the submission Appendix B. The information provided seems appropriate and consistent with other submissions.	X	
Verification & Validation Testing: The Software Verification Reports (SVRs) summarize the results of the software verification activities conducted. The SVRs contain a description of the design reviews, unit testing, integration, testing and requirements testing activities and test results. The SVRs include a description of modification made to the software as a result of failed tests, and the test results that demonstrate the modifications were effective. Details of the Software Verification Reports can be found in the submission in Appendix A. It looks like all software requirements have been covered in the verification and validation section. An appropriate traceability analysis links all of the validation and requirements and testing seems to be appropriate. The information reviewed seems appropriate	X	
Revision level history: Tables 4, 5, and 6 in Section VIII provide the software revision level history for the Merlin.net Software Web App, Merlin.net Software Data Loading Service, and Merlin@Home software, respectively. This information appears to be complete and is adequate.	X	
Unresolved anomalies: Six postponed software anomalies for Merlin.net were identified during formal testing. These anomalies were determined to have no impact on safety and effectiveness. The table below provides a complete list of all postponed anomalies detected which were not fixed in the final software product release. One postponed software anomaly for Merlin@home was identified during formal testing. This anomaly was determined to have no impact on safety and effectiveness. The table below provides a description of the postponed anomaly detected which was not fixed in the final software product release. After review of the anomalies and the justification for postponing the correction, it seems that these anomalies will not have an impact on safety and effectiveness.	X	

Merlin.net Software v.5.0 Postponed Anomalies during Final Run			
Item	**Application**	**Anomaly Description**	**Justification for Postponing**
1	EPHF Web	Weight and blood pressure readings may be displayed twice in the mouse-over text with certain user actions; they should only be displayed once.	Data is not lost and the user must take specific actions of closing the details window and scrolling left on the trend to see duplicate data. No impact to patient safety or clinical efficacy.
2	EPHF Web	Informational text showing the expected format for entering dates is not displayed when user does not properly supply the starting date for temporary scheduling.	Temporary scheduling is used rarely by clinics. The template for date entry is provided on the main screen for permanent scheduling and in the actual field in which the user is entering the date. There is no risk to patient safety or clinical efficacy.
3	EPHF Web	Shipped Date in the Patient Profile Transmitter Settings page does not factor in the time of shipment when adjusting the date based on Clinic's time zone. Instead it uses time of 00:00:00 (hours:mins:secs) and determines the time zone adjusted date on that.	Time of shipment may not be known and provides limited value. The date displayed for when a transmitter was shipped to a patient will be less than a day off. The value of this date is for general information to the user and does not drive any other system behavior. No clinical impact.
4	EPHF Web	For US clinics having multiple locations, the state of the main clinic is not pre-populated on the page for viewing other locations, instead it is shown as blank.	The clinic locations page is typically set up once and not part of a daily workflow. Not having the state automatically pre-populated may cause a one-time annoyance but poses no risk to patient safety or has any clinical impact.
5	EPHF Web	Options to disallow unscheduled patient-initiated transmissions are not saved for patients with inductive transmitters. As a result patients could repeatedly send unnecessary transmissions.	Resultant behavior for inductive devices is the same as currently supported with HouseCall transmitters and inductive patients are not likely to repeatedly initiate uploads. No patient safety or clinical impact.
6	EPHF Web	Minor display issues with Japanese text: Titles at the right hand navigation panel in Japanese are clipped on top, Furigana name is not displayed on Messages page when a message is about an overdue follow-up.	Japanese reviewers agreed the clipped text was readable and Kanji names are displayed and patient's device model and serial number are available for sorting and filtering the Messages page. This poses no risk to patient safety; no clinical impact.

Merlin@home Software v.5.0 Postponed Anomalies during Final Run		
Item	**Anomaly Description**	**Justification for Postponing**
1	During the initial pairing with a Legacy IMD, when the patient profile contains an invalid parameter value, the corresponding entry in the EventHistory.log file is 'Invalid Patient Profile parameter(s)'. Per requirement, the long entry should be 'IMD pairing failed'.	There is no impact on clinical safety or effectiveness since this is strictly a logging issue and the correct information is displayed to the user when this condition is encountered.

LABELING

Changes were made to the Merlin.net Patient Care Network Website User's Manual due to updates to the software for version 5.0 and to correct typos/provide clarification. Changes were also made to the Merlin@home Inductive QSG and are therefore being resubmitted to provide further clarification. Additionally, a new wireless kit is being provided in version 5.0 for Merlin@home patients to use with their broadband internet connection instead of a landline or cell phone connection. This new

wireless kit includes a USB wireless adapter and cable, wireless access point and Ethernet cable attached to the wireless access point as well as a wireless access point power supply. A new label and RF set-up Guide for the wireless kit are provided in Appendix H. Finally a new Merlin@home Inductive and RF sticker, to be provided by St. Jude Medical's Sales force to clinics and patients, provides a snapshot of the Merlin@home QSG.

The information was reviewed and was found acceptable.

ANIMAL STUDIES

There were no animal studies presented or required.

CLINICAL DATA

There was no pre-clinical information presented or required.

RECOMMENDATION

This submission is very similar to the (b) (4) reviewed by on May 6, 2011. I contacted the sponsor to determine the differences between this submission and (b) (4). The sponsor replied by email on June 8, 2011 stating that the (b) (4) was a superset of this PMA-S and that all changes incorporated in the PMA-S were included in (b) (4). The (b) (4) included updates for the (b) (4), and (b) (4) peripherals. Also, since access to the (b) (4) are controlled on a (b) (4) bases through the Merlin.net website, only the appropriate (b) (4) have access to the (b) (4) vices. Clinics that are not (b) (4) will never see the (b) (4) related information. The changes in (b) (4) were approved on May 17, 2011. After review of the changes between (b) (4) and PMA-S submission it seems that the changes in the PMA-S are an adequate subset of the approved (b) (4) and should be approved.

Based on (b) (4) review, my own review of this submission, and interaction with the sponsor, I recommend that the sponsor receive an **approval** letter.