MEMORANDUM

SUMMARY OF:

P910023/S295
P030054/S223
Software Model MN5000 v6.1 for use on Merlin.net System and Model EX2000 v6.1 for use on Merlin@home devices
St. Jude Medical

BACKGROUND

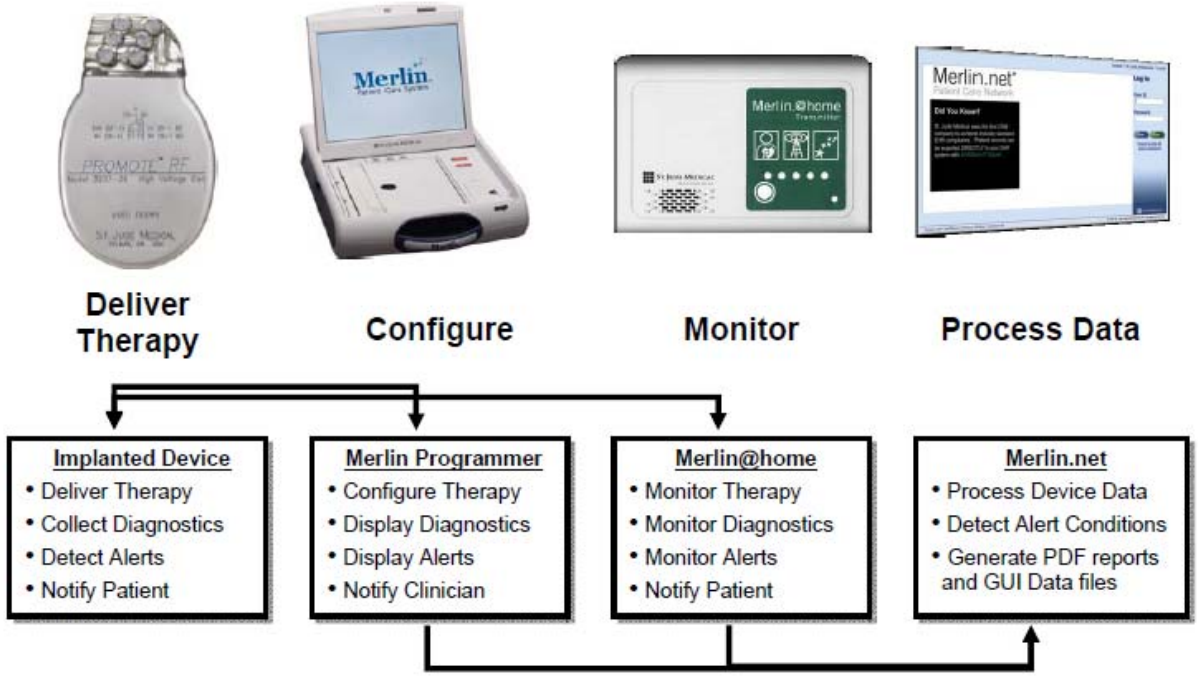
St. Jude Medical (SJM) is submitting a 180-day PMA supplement for approval of Model MN5000 version 6.1 software to be used with the Merlin.net System (P910023) and for the Model EX2000 version 6.1 software to be used on Merlin@home devices (P910023 and P030054). This supplement details modifications to the Merlin.net (MN5000) and Merlin@home (EX2000) software only. There are no hardware changes to the Merlin@home device.

INDICATIONS FOR USE

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. The Merlin@home transmitter device is intended to be used as a tool for collecting diagnostics and EGM data from an implantable device. The Merlin@home will then transfer the collected data to an external receiving station (Merlin.net) where it is stored for review by a clinician. The transmitter does not program the implanted pulse generator. The Merlin.net MN5000 consists of Report Generators which are used to transform data read from implanted devices into the same reports generated in-clinic, detect alert conditions in this data, and repackage device diagnostics and parameters into forms suitable for graphical display and export to clinic Electronic Health Record (EHR) systems.

DEVICE DESCRIPTION

The system is depicted in the figure below. The software modifications described in this supplement affect the Merlin@home and the Merlin.net products only. There are no changes to the Merlin programmer or the implanted device.



The Merlin.net software (Model MN5000) version 6.1 builds upon previously approved Merlin.net software version 6.0A (P030054/S287) which was approved on April 6, 2012. The Merlin@home software (Model EX2000) version 6.1 builds upon previously approved Merlin@home software version 5.0 (P0910023/S257) which was approved on July 5, 2011.

CHANGES

The primary reason for the software modifications is to add physician alerts/monitoring for RV lead functionality. This monitoring will be an additional tool for physicians to use in monitoring patients' leads, including recalled Riata leads. In addition to adding alerts/monitoring for RV leads, minor changes are being made to the Merlin@Home software in order to improve user workflow and system robustness. The table below summarizes the changes made within Merlin PCN version 6.1.

Software Change Description	Device Modified
Enhance remote monitoring capability for right ventricular leads by adding the following physician alerts: -VT/VF Episode Occurred -Non-sustained VT Episode Occurred -Non-sustained VF Episode Occurred -Ventricular Noise Reversion	Merlin.net and Merlin@home
Changes to improve workflow: • Improve alert notification and alert clearing logic. This change improves the clinician's workflow by eliminating duplicate reporting of alerts and improves usability by updating clearing rules to be consistent with the behavior of the Merlin Programmer. • Improve the device pairing and Merlin@home software upgrade workflows. This change will streamline pairing with the Merlin@home when a patient's implanted medical device is replaced, or receives a firmware upgrade. • Enhance the security certificate by replacing the common manufacturing certificate with a unique certificate for each transmitter which is upgraded automatically, rather	Merlin@home

Software Change Description	Device Modified
than requiring a new software release to update the certificate.	
Changes for system robustness: • Improve robustness of Merlin@home RF telemetry to avoid intermittent communication issues and follow-up restarts in rare scenarios. Changes are being made to the RF telemetry initialization sequence and response handling for telemetry breaks occurring under communication edge conditions. • Improved the robustness of network connections including cellular and Wi-Fi, thereby improving the usability of Merlin@home in environments with noisy Wi-Fi network connection.	Merlin@home

The physician alerts that have been added to Merlin.net version 6.1 include information that is already available to the clinician, either on the Merlin programmer and/or in an existing Merlin.net report. Thus these alerts do not present any new information to the clinician but instead simply notify the clinician about the occurrence of some specific types of episodes outside of the standard follow-up schedule. There are no patient alerts being added.

The table below summarizes the information that is provided through these new alerts and also includes details on where this information is currently made available for the clinicians in the approved and legally marketed devices.

Physician Alert Being Added to Merlin PCN	Additional Information on the Alert	Why Alert Does not Represent New Information for Clinician
VT/VF Episode Occurred	This alert was added to complement the existing alerts for HV Therapy Delivered and Successful ATP therapy. In the case that a clinician is interested in being notified for any diagnosed VT/VF including those that occur in a monitor zone, this alert can be selected along with or in place of the existing VT/VF related alerts.	Information regarding new VT/VF episodes is included on the Merlin programmer FastPath Summary Screen and report.
Non-sustained VT Episode Occurred	This alert was added to complement the existing alerts for HV Therapy Delivered and Successful ATP therapy. This alert is triggered if the device detects a non- sustained VT episode which is an episode diagnosed by the device as VT, but which terminates prior to therapy delivery.	Clinicians already have access to these episodes via episode details in the Merlin.net reports. The addition of the alert simply allows for notification of the occurrence of these types of episodes outside of the standard follow-up schedule.
Non-sustained VF Episode Occurred	This alert was added to complement the existing alerts for HV Therapy Delivered and Successful ATP therapy. This alert is triggered if the device detects a non- sustained VF episode which is an episode diagnosed by the device as VF, but which terminates prior to therapy delivery.	Clinicians already have access to these episodes via episode details in the Merlin.net reports. The addition of the alert simply allows for notification of the occurrence of these types of episodes outside of the standard follow-up schedule.
Ventricular Noise Reversion	Entry into Ventricular Noise Reversion occurs when the device detects the presence of noise > 50 Hz on the standard ventricular sensing channel.	The occurrence of these types of episodes are already indicated as an alert on the Merlin programmer. The addition of this alert as an option in Merlin.net simply allows for notification of the occurrence of these types of episodes outside of the standard follow-up schedule.

There is no change to the method of configuring and receiving notification for these alerts as compared to the previously approved alerts.

The physician can configure and receive notification of an alert type by using the DirectAlerts settings. The physician can also specify whether the alert notification is to be sent to the patient's medical team.

The screenshot below highlights the new alerts that have been added.

(b) (4)

The physician can specify to receive the notification of alerts via fax, email, text message, or phone.

(b) (4)

CLINICAL

The clinical reviewer found that the software modifications to allow new physician alerts and methods for notification are appropriate. He found no deficiencies with this approach.

Also after further discussion with the clinical reviewer, we found that the value of detection of multiple episodes of VT/VF may be a surrogate for lead malfunction, but this is not unique to the Riata lead. Therefore, no specific Riata lead testing is required.

SOFTWARE

The Merlin.net software (Model MN5000) version 6.1 builds upon previously approved Merlin.net software version 6.0A (P030054/S287) which was approved on April 6, 2012. The Merlin@home software (Model EX2000) version 6.1 builds upon previously approved Merlin@home software version 5.0 (P910023/S257) which was approved on July 5, 2011.

The Level of Concern for the software used in the Merlin.net and Merlin@home is moderate based on the type of information being transmitted. Merlin.net merely stores and presents data transmitted from the implantable device via the programmer or transmitter (e.g., Merlin@home). The Merlin.net website does not program the implanted pulse generator.

The documentation provided by the sponsor was reviewed in accordance to the guidance document, *Content of Premarket Submissions for Software Contained in Medical Devices*, May 11, 2005. The following areas were reviewed:

- Level of Concern
- Software Description
- Device Hazard Analysis
- Software Requirements Specification (SRS)
- Architecture Design Chart
- Software Design Specification (SDS)
- Traceability Analysis
- Software Development Environment Description
- Verification and Validation Documentation
- Revision Level History
- Unresolved Anomalies

Review Comment: This information was reviewed and found to be acceptable.

LABELING

The modifications included within Merlin.net software (MN5000) version 6.1 and Merlin@home software (EX2000) version 6.1 did not require any updates to the labeling.

The DirectAlert section within the manual describes the method to select and configure the notification for all alerts. The instructions for selecting and configurating the new physician alerts, that have been added within this release, have not changed and thus get covered within the DirectAlert section of the manual.

Review Comment: This information was reviewed and found to be acceptable.

MANUFACTURING

The updates made to the Merlin.net and Merlin@home includes software only changes. There are no hardware changes made to the Merlin@home device. Therefore there is no change to the manufacturing of the Merlin@home transmitter.

Review Comment: This information was reviewed and found to be acceptable.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Hardware/Firmware
- Biocompatibility
- Packaging/Sterilization
- Shelf-Life
- EMC/EMI
- Human Factors
- Post-market issues

CONCLUSION/RECOMMENDATION

The sponsor provided a good description of the changes. The additional alerts should prove useful in monitoring lead function. The value of detection of multiple episodes of VT/VF may be a surrogate for lead malfunction, but this is not unique to the Riata lead. Therefore, no specific Riata lead testing is required.

The testing and documentation of the test results were found to be appropriate and acceptable for the changes being made. The sponsor has shown that the modifications to Merlin.net and Merlin@home are safe and effective at this time.

I recommend that the sponsor receive an **APPROVAL** letter.