**SUMMARY OF:**

**Model 3330 Version 18.1 software for the Model 3650 Patient Care System (PCS) Programmer;**

**Model EX2000 Version 7.0 Rev. 1 Software for Models EX1100 and EX1150 MERLIN@HOME transmitters; and**

**Model MN5000 Version 7.1 Software for the Merlin.net System.**

**For the following implantable devices:**

P910023/S323
Ellipse/Fortify Assura Family of ICDs

P030054/S254
Quadra Assura/Unify Assura Family of CRT-Ds

P030035/S115
Frontier/ Frontier II/Anthem Family of CRT-Ps

P970013/S057
Microny Family of Pacemakers

P880086/S237
Affinity/Integrity/Victory/Zephyr/Accent Family of Pacemakers

P880006/S087
Sensolog/Dialog/Regency Family of Pacemakers

St. Jude Medical
Cardiac Rhythm Management Division
645 Almanor Ave.
Sunnyvale, CA 94085

**BACKGROUND/REASON FOR SUPPLEMENT**

The 180-day PMA/S (subject file) was submitted by St. Jude Medical (the company) for requesting the approval of the above referenced devices.

The company claims the Model 3330 Version 18.1 software is based on the past FDA approved software version 17.1.1 (P880086/S230)

The following are the modifications for the Model 3330 Version 18.1 software, in addition to correct a total of eight existed issues. Those modifications are:

1. Added support for the Optisure High Voltage Right Ventricular lead family and associated model numbers in the Patient Data workspace. (NOTE: This change applies to all high voltage device families.)
2. Made changes to allow more than six freeze captures to be saved and viewed in the Session Records.
3. Added the (b)(4) TS/CCI interface for testing left ventricular quadripolar leads with results reported in the (b)(4) TS/CCI (b)(4) TS/CCI. The user interface includes: (a). RV to LV Conduction Measurement screen to measure and display the conduction times for all four quadripolar electrodes. (b). MultiVector Testing screen to measure and display capture threshold and phrenic nerve stimulation (PNS) in all fourteen low voltage quadripolar vectors.
4. For Quadripolar High Voltage device families, (b)(4) TS/CCI (b)(4) TS/CCI Left Ventricular Lead Impedance configuration on Fast Path screen and report.
5. For all Unity High Voltage device families, corrected (b)(4) TS/CCI in the End Session confirmation dialog when a telemetry interruption occurs.
6. Provided enhanced security (b)(4) TS/CCI between Merlin Programmer to RF Wand as follows: (a). to prevent access to the RF wand from unauthorized users, and (b). to protect data transmitted from the Merlin Programmer to the RF Wand.
7. For Accent single chamber Low Voltage device families, added a (b)(4) TS/CCI (b)(4) TS/CCI to ensure AutoSense (b)(4) TS/CCI.
8. For Quadra Assura, Unify Assura, Fortify Assura, and Ellipse device families, added a (b)(4) TS/CCI to a value known to be supported by all leads when the Lead model number is cleared.
9. For Assurity, Assurity+, Endurity single chamber device families, corrected the Test Results Large Freeze report to consistently display (b)(4) TS/CCI.
10. Removed the availability (b)(4) TS/CCI (b)(4) TS/CCI on all High Voltage device families.
11. Removed the Battery Remaining Capacity to Elective Replacement Indicator (ERI) for all Low Voltage (LV) devices from screen display and printout.
12. All Non-sustained Lead Noise (NSLN) display labels changed to Nonsustained Oversensing (NSO) on-screen display and reports.
13. The programmer software was updated to prevent system errors and freeze screens which can occur in nonclinical scenarios.
14. For all Unity Low Voltage device families, corrected stored EGMs (SEGMs) (b)(4) TS/CCI after printing if requested by the user.
15. Programmer software was updated to address a memory management issue in the Media Manager (b)(4) TS/CCI
16. Added a malware detection program to the Programmer software (b)(4) TS/CCI (b)(4) TS/CCI
17. Updated the Merlin programmer software installation procedure to minimize chance of data loss, occurring only when software is repeatedly downgraded from Linux 2.6 to Linux 2.4.
18. Provided routine update to operating system security patches.
19. The programmer software (b)(4) TS/CCI in Ellipse device family.

The following are the modifications for the Merlin 7.1 Remote Care System, in addition to correct a total of two existed issues. Those modifications:

1. Provide remote care support for Endurity, Assurity, Assurity+, Allure, and Allure Quadra pacemakers consistent with Merlin Programmer Model 3330 v18.1 or later.
2. Enhance pairing options by allowing the user to manually initiate pairing based on the transmitter's model/serial number registered in Merlin.net.
3. Provide support for alternate cellular adapter.
4. Update report data to be consistent with Merlin Programmer Model 3330 version 18.1.
5. Include Magnet Response (b)(4) TS/CCI file used in the Direct EHR feature.
6. Enhance the user interface behavior using audio tones and LED light patterns on the Merlin@home unit so that the device connection status is identifiable.
7. Add the capability to reset the Merlin@home to its initial state by holding the front button and reset button simultaneously.
8. Eliminate sending duplicate transmissions in the rare case when a patient initiates a followup transmission while their scheduled follow-up transmission is pending completion.
9. Allow the Merlin@home button to be active following a Read Error recovery sequence.
10. Upon completion of the transmitter setup process when initiated by a 10 second button press on the Merlin@home, Merlin@home will notify Merlin.net so that it may notify clinicians of the successful completion.
11. Enhance the software to reduce the amount of time the communication channel is in use (b)(4) TS/CCI
12. Enhance the software to ensure all device interactions are scheduled by using the existing patient schedule when an updated one cannot be retrieved from the Merlin.net server.
13. Update the internal timestamp logged in session records to more closely match the interrogation start time.
14. Optimize transmitter bootup sequence by allowing the presence of the modem to be optional.
15. Improve handling of transmissions that contain episodes created from an in-clinic fibrillation induction test.

**INDICATIONS FOR USE**

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S.

**DEVICE DESCRIPTIONS**

The Merlin Patient Care System (PCS) Programmer is a portable, dedicated programming system designed to interrogate, program, display data, and test St. Jude Medical implantable devices, listed above. The company claims, the intended use for the Merlin PCS Programmer remains the same as approved in P030054/S008 on October 12, 2005. The company claims,

the Merlin PCS Programmer Software has been updated to Version 18.1 in order to provide safety and functionality enhancements. The Merlin 18.1 PCS Programmer Software is based on version 17.1.1. The Merlin 17.1.1 PCS Programmer Software was approved.

The Merlin 7.1 Remote Care System is composed of the Merlin@home Transmitter software and the the Merlin.net Patient Care Network (PCN) software. The company claims, the intended use of the Merlin Remote Care System has not changed; and the intended use of the Merlin Remote Care System is as a transtelephonic system used for remote device follow-up. Healthcare providers can view the follow-up data/device data via the St. Jude Medical 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. 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 Merlin Remote Care System does not program the implanted device. The software updates proposed in the subject file affects the Merlin@home Transmitter software and Merlin.net Patient Care Network software only. The company claims, there are no hardware changes to the approved Merlin@home Transmitter as a result of the software update in the4 subject file.

**THE SUMMARY FOR THE REVIEW**

The subject PMA/S contains the software only, therefore, it is not required to have any hardware, EMC/EMI testing. The company has provided the software and system testing in the subject file. The subject contains the documents for the requirements (sample), device hazard analysis, level of the concerns, trace matrix, descriptions for the software development process, test reports (software and system), and the labeling.

For Model 3330 Version 18.1 software:

The company claims, the overall software development environment has not changed due to the modifications made in this software version. The Merlin 18.1 PCS Programmer Software was developed using an iterative development life cycle.

The company claims, at a high level, the Programmer 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. The title of the document for this process is, (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI

The Software Verification Report (SVR) summarizes the results of software verification activities conducted for Merlin PCS 18.1 Programmer Software version. The SVR contains a description of testing activities and test results. The SVR includes a description of modifications made to the software as a result of any failed tests, and test results demonstrating that any necessary modifications were effective. This is acceptable with few known minor software issues are still open. The tile of the report is, (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI

The company claims, the system validation was completed, and it is the delta between the subject software version vs. the last software version. The title of this delta system validation process is documented with the title of, (b)(4) Trade Secret/CCI The test report for this delta system validation is included in the subject file, with the title of, (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI company claims , all the delta system testing was successful. This is acceptable.

The company claims, the passing results of the software and system verification and validation testing demonstrate that the software performs as intended.

For Merlin 7.1 Remote Care System (Merlin@Home &Merlin.Net) Software

The company claims, the overall software development environment has not changed due to the modifications in this software version. The Merlin 7.1 Remote Care System Software was developed using an iterative development life cycle.

At a high level, the Remote Care System 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. The Merlin@home Transmitter Software and Merlin.net Patient Care Network (PCN) Software have been combined into one Merlin 7.1 Remote Care System Software Development Environment Description.

The details regarding the Software Development Environment are documented with the documentation title of, (b)(4) Trade Secret/CCI

The Software Verification Report (SVR) summarizes the results of software verification activities conducted for the Merlin 7.1 Remote Care System Software. The SVR contains a description of testing activities and test results. The SVR includes a description of modifications made to the software as a result of any failed tests, and test results demonstrate this is acceptable with few minor (known) software issues. The test reports are documented with the titles of, (b)(4) Trade Secret/CCI

The company claims, the system verification and validation testing was also completed for both Merlin @Home; and Merlin.net. The yest reports are documented as, (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI and (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI The company claims, all Merlin 7.1 Remote Care System testing was successful passed. This is acceptable.

**BIOCOMPATIBILITY:** N/A

**ANIMAL STUDY:** N/A

**CLINICAL DATA:** N/A

**LABELING:**

The subject file contains the draft version of the labeling for the devices. This is acceptable.

## CONCLUSION

Based on the information in the file, the company has provided the appropriate data to demonstrate the subject device is safe and effective for the pre-market review process. Therefore, it is recommended to be approved.