SUMMARY OF:

P030054/S237
EX2000 Software version 6.1M for marlin@home **without the cellular adapter**

P910023/S307
EX2000 Software version 6.1M for marlin@home **without the cellular adapter**
Model MN5000 software version 6.0 for Merlin.net system

St. Jude Medical
Cardiac Rhythm Management Division
701 East Evelyn Avenue
Sunnyvale, CA 94086-6527

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 EX2000 Software version 6.1M for marlin@home; and Model MN5000 software version 6.0 for Merlin.net system be used with the company's implantable devices.

The subject file contains a total of (b) software modifications, and (b) out of (b) (4) were approved by FDA in the past. (b) (4)
(b) (4)

The modifications for the software are: (marlin@home)

1. Add support for new devices Quadra Assura, Fortify Assura DR, Fortify Assura VR and Unify Assura, including their new alert: VT/VF Occurred.

2. Add support for new devices: Ellipse DR, Ellipse VR including their new alert: VT/VF Occurred.

3. Allow inductive Merlin@home transmitters to be configured for use with multiple patients without the need to manually associate it with an IMD Transmitters may be configured for device checks, full follow-ups or trended diagnostics.

4. Provide mechanism for St. Jude Medical Device Monitoring to troubleshoot dial-up connectivity issues for Merlin@home units in the field.

5. (b) (4)

6. (b) (4) [redacted]

7. [redacted]

8. [redacted]

9. [redacted]

10. [redacted]

INDICATIONS FOR USE

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

DEVICE DESCRIPTIONS

The subject PMA/S contains the software modifications only.

The company claims, Model MN5000 version 6.0 software to be used with the Merlin.net System and for the Model EX2000 version 6.1M software for use on Merlin@home devices.

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. 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.

The Merlin PCN 6.1M submission builds upon previously approved Merlin PCN 5.0 program which was approved on July 5, 2011.

THE SUMMARY FOR THE REVIEW

The company claims, there are no change to the hardware, and only the software modifications in the subject file. (b) (4) [redacted]
(b) (4) [redacted]

With above the company has provided the test reports to address the modifications for the subject file. The testing for the subject file is acceptable, and the company claims all the tests are passed without any anomaly.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The company has provided the labeling for this file, and it is acceptable.

CONCLUSION

Based on the information in the file, the company has provided the appropriate data to demonstrate the subject device can be approved, I am recommending the approval of the subject file, (b) (4) [redacted]