DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

Date: 25 March 2011

From: (b)(6), Biomedical Engineer, FDA/CDRH/ODE/DCD/CEMB

Subject: St. Jude Medical
P030054/S177
Epic HF/Atlas+HF Family of CRT-Ds

P030035/S075
Frontier/Frontier II Family of CRT-Ps

P910023/S254
Cadence Family of ICDs

P970013/S038
Microny Family of Pacemakers

P880086/S195
Affinity/Integrity/Victory Family of Pacemakers

P880006/S070
Sensolog/Dialog/Regency Family of Pacemakers

Consultants: Software- (b)(6), Biomedical Engineer, FDA/CDRH/ODE/DCD/CEMB
Clinical- (b)(6), MD, FDA/CDRH/ODE/DCD/PDLB

Contact: Elizabeth Neely, Regulatory Affairs

To: The Record

Recommendation: **Approval**

(b)(6), Lead Reviewer, CEMB Date

(b)(6), PDLB Date

Background/ Reason for Supplement

This PMA supplement was submitted to gain approval for Model 3330 Version 12.1 Software for the Model 3650 Merlin Patient Care System

Review Team

Clinical: (b)(6), MD, FDA/CDRH/ODE/DCD/PDLB
Engineering: (b)(6) FDA/CDRH/ODE/DCD/CEMB

Indications For Use

The indications for use for the Model 3650 Merlin Patient Care System remain the same as approved under P030054/S008

The changes described in this supplement do not affect the indications. There are no issues with this part of the review.

Device Description

The Model 3650 Merlin PCS programmer is a portable, dedication programming system designed to interrogate, program, display data, and test St. Jude Medical implantable devices.

The following list describes the changes made to the software for this device for this version:

- Update nominal values of VT and VF detection parameters and SVT Discrimination parameters
- Change the default first therapy in the VT2 zone
- Change the parameters related to duration of stored EGMs for automatic morphology template updates
- Ensure that the Interval Stability Window size is less than the Number of Intervals to Detect VT2
- Support display of stored EGMs collected at higher resolutions
- Correct programmer error related to value programmability

Preclinical/Bench

Software

The firm supports the approval of the new software version with appropriate software documentation which includes the documentation recommended in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The engineering review was performed by CDRH/ODE reviewer (b)(6) and documented in a review memo dated 18 March 2011.

The engineering information was only for software as this was the only change to the device. The following areas were reviewed and found to be adequate:

- Software/Firmware description
- Device Hazard Analysis
- Software Requirements Specifications
- Architecture Design Chart
- Design Specifications
- Traceability Analysis/Matrix
- Development
- Verification & Validation Testing
- Revision level history

- Unresolved anomalies

Summary of Software Review: The sponsor provided information on the specific changes made to the software in terms of requirements and description but also provided the context of the changes in terms of the device hazard analysis, the architecture and design information. The verification and validation testing demonstrated that the software performed as intended. The software information was complete. There were no issues identified

Biocompatibility
Since the application only involved software, this following area was not reviewed and information on this area was not needed.

Sterilization/Packaging/Shelf Life
Since the application only involved software, this following area was not reviewed and information on this area was not needed.

Biocompatibility
Since the application only involved software, this following area was not reviewed and information on this area was not needed.

Mechanical or Electrical Engineering Safety
Since the application only involved software, this following area was not reviewed and information on this area was not needed.

Animal Studies
Since the application only involved software, this following area was not reviewed and information on this area was not needed.

Clinical Data

The clinical review was performed by CDRH/ODE reviewer (b)(6), MD, and documented in a review memos dated 31 January 2011 and 18 March 2011. Dr. (b)(6) has reviewed the information related to the new default parameters used in this submission.

Summary of Clinical Review: St. Jude has provided results from EGM clips to validate the accuracy of the new settings. These tests demonstrate that the new settings improve the accuracy and the sensitivity with only a modest change in specificity. Dr. (b)(6) had several clarifying questions regarding how the new settings were determined. These were asked interactively. St. Jude responded with adequate explanation and justification for the selections. As a result of the initial information presented in the submission and the additional information provided in the interactive response, it appears that the new settings are approvable.

Labeling

The labeling for the PCS Help Manual for the proposed device was provided in the submission.

CLINICAL REVIEWER COMMENTS: A review of the PCS Help Manual shows that the changes were minor and that the information is acceptable. The sponsor has described the new nominal settings appropriately. The changes to the labeling are adequate.

Summary of interactive Review/correspondence

March 1, 2011: Clinical questions emailed to firm
March 2, 2011: Email question responses received

Conclusion

The firm has provided documentation of software development for the proposed changes to the device and has provided clinical justifications for the new default parameters. The firm responded adequately to initial deficiencies concerning the default parameter through an interactive review. No concerns remain, and I recommend approval of this submission.