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

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

File:	P030054/S153, P910023/S236, P880006/S067, P880086/S189, P030035/S70, and P970013/S34 (PMA Supplements with the Amendments – A01, A02)
Sponsor:	St. Jude Medical, Inc. Ms. Elisabeth Neely [redacted]
Device Name:	Model 3330 Version 11.1 Software for the Model 3650 Merlin Patient Care System
Lead Reviewer:	[redacted], FDA/CDRH/ODE/DCD/PDLB
Date:	February 23, 2011 (Modified on 3/4/2010)

☒ Background/History

This PMA/S was submitted by St. Jude Medical, Inc. (SJM) based on a number of the modifications to the software for the Model 3650 Merlin Patient Care System.

A conference call was conducted on September 10, 2010, it was a scheduled event. FDA notified the company with respect to the issues associated to this file, and the FDA letter was send to the company, dated October 7, 2000.

PMA/S Amendment 01 was received on November 4, 2000, and another FDA letter was send to the company dated December 28, 2000. A number of e-mails were exchanged between the reviewer and the company. In addition, few e-mails were exchanged within the FDA as well.

A conference call was conducted on January 5, 2011 between the reviewer and the company. The conference call min. was submitted in the PMA/S Amendment 2 for the documentation purpose.

PMA/S Amendment 2 was received by FDA on February 1, 2011. A number of the e-mails were exchanged between the reviewer and the company. In addition, another conference call was conducted on February 16, 2011, for resolving remainder issues of this file. All the e-mails were inserted to the file as part of the records.

☒ **Indication for Use**

The company claims all the modifications in this real time PMA/S do not affect the Indication for Use statement, therefore, the following information is provided for documentation:

> The intended use remains the same for Atlas, +/II, Epic, +/II, Current, RF/+, Promote, RF/+, and Unify/Fortify families of ICD/CRT-D devices. These systems are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. For DR and HF devices, AF suppression pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction.
>
> In patients indicated for an ICD, the CRT-D systems are also intended:
>
> - to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration
>
> - to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.

☒ **Device Description (The Changes Related To The Subject File)**

The following is the modifications, which applies to the Model 3330 Version 11.1 Software:

1. Fixed system error which occurs after NIPS (non-invasive programmed stimulation) is repeatedly started and stopped in rapid succession. The NIPS Test allows the clinician to induce or terminate an arrhythmia by delivering trains of pacing bursts to the atrium or ventricle.

2. During the download procedure for Firmware version 1.3.5 the CPU Clock is programmed to a nominal faster speed until the download completes, at which point the CPU is reverted to the trimmed speed.

3. Added logic to retain the latter portion of Stored EGMs (SEGM) for episodes which last longer than 42.5 minutes.

4. Refresh display of parameter values on screen after changing CVRT Therapy Type.

5. Implemented a check for diagnostics data full flags, so the specific diagnostics' full' flags could be cleared if they are detected as being full without clearing the diagnostics. *(Field issue)*

6. Fixed system error by updating the MTR Range as per the new PV and AV delays for Ventricular AutoCapture (VAC) test before calculating new MTR value to be selected. *(Field issue.)*

7. Corrected handling of clinical alerts so an Alert is generated when an HVR or PMT episode with an alert condition is read during the session on Victory devices.

8. Improved the accuracy of the longevity estimate for Victory, Zephyr, and Identity pacemaker devices, so the remaining longevity displayed to the user is in line with the actual remaining longevity. Previously the estimated longevity was too conservative. *(Field issue)*

9. Fixed a small (<0.3 seconds) window of opportunity where if the EVVI or Shock hardkeys were pressed while transitioning from one application to another, the keypress would not be responded to and the hardkeys would become unresponsive until the session was ended.

10. Modified the handling of the telemetry interface when switching between the followup application and PSA to eliminate a rare timing scenario which would cause a failure of telemetry followed by a system error. *(Field issue)*

11. Check for the existence of the Episodes window before updating it to display new episodes, to fix an unlikely error which occurs if the user rapidly alternates retrieving new episodes and canceling that request. *(Field issue)*

12. Save Model and Serial number data locally during a download operation so that those data can be properly restored in case the firmware download operation fails and must be retried. *(Field issue)*

13. Fixed a system error by removing Ready app code which was rendered obsolete by the addition of DeviceAgent.

14. Prevent firmware download when device is at or below ERI. *(Field issue)*

15. The EGM channel automatically turned on by running a Sense test is now turned off at the completion of the sense test so that any subsequent battery and leads measurement will not be improperly affected by an open EGM channel. *(Field issue)*

16. Introduced a new flag to prevent a race condition between two dialogs on the Wrap-up overview. *(Field issue)*

17. Corrected handling of telemetry interruptions during firmware download to properly recognize when the same device is still under the telemetry wand. *(Field issue)*

18. In case of a telemetry interruption, close any open dialogs before displaying the "Telemetry break end session" alert dialog. *(Field issue)*

19. Ensure EVVI operation consistently completes when used to start a device session. *(Field issue)*

20. Ensured that all HOM events are accounted for when Longevity is recalculated during a follow-up session or initially calculated in an ADM session. HOM are "High Output Mode" pacing pulses delivered by AutoCapture and Cap Confirm features. ADM is the "Archive Data Mode" where the clinician can view a Session Record created during an earlier follow-up session.

21. Display "<2.2V" instead of a specific Battery Voltage when the device reaches EOS. *(Field issue)*

22. Ensured the Session Note box is refreshed at interrogation, when viewing clinical alerts, and when printing, so the status messages in that notebox are always up-to-date.

23. Ensure that, even in the presence of a parameter error, the Battery Gauge, Patient Name, and Patient Note are still stored in the session record and correctly displayed during interrogation in ADM.

24. Ensure Lead Impedance measurements configuration matches that on the Summary screen at interrogation of Identity devices. *(Field issue)*

25. Fixed the French language labels for atrial and ventricular pacing percentage labels on the Summary Report.

26. Display the longevity estimate when the Atrial Lead Impedance is not available. (*can be not reported, Field issue)*

27. Ensured that table of basic brady parameters are printed in all scenarios on the FastPath Summary report. *(Field issue)*

28. Ensured that the Ventricular Heart Rate and AV Intervals histograms are displayed on the Fast-path Summary Report. *(Field issue)*

29. Implemented new dialog that will recommend the user to perform the ACap Confirm/Ventricular AutoCapture Setup Test when the test result available in the device is "Not Recommended" or when there is no result.

30. Used the AMS Entry and Exit markers and the episode type to generate AMS markers for the display while the device is pacing in AMS mode.

31. Modified the Nominal Settings programmed to match those in the manual (Unipolar pulse configuration when Lead Type is Unipolar), changed the "Nominal Settings" button in ETP to read "Default Configuration", and changed the Default Pulse Amplitude for both chambers to 5.0V. *(Field issue)*

32. (b) (4) . *(Questionable, 21 CFR Section 814 vs. 812, this issue was reviewed by another reviewer, and the management decided it is acceptable to close this issue for further review.)*

33. Increase measurement resolution from 14.3 to 7.3 for small ventricular cardiac signals.

34. The displayed Programmer calculation of magnet-rate was changed to match the device calculated magnet rate. *(Field issue)*

35. Removed SVT discrimination information from printed report when initial diagnosis is bigeminy since this information is not applicable. *(Field issue)*

36. Preventing parameter values manually selected for the QuickOpt test from being permanently programmed after the test completes. *(Field issue)*

37. Added logic to recheck if the device is in reset after receiving an indication from the device that it is in reset state. . *(Field issue)*

38. The "Ventricular Pacing Chamber" parameter is set to "LV Only" during a QuickOpt LV Pace Measurement test and the Primary Pacing Chamber Pacing Amplitudes and Width are adjusted in the device appropriately. *(Field issue)*

39. Updated PaceArt export to ensure the latest test results are used. *(Field issue)*

☒ **The Review Summary**

Based on the information in this file and the conference call on September 10, 2010, the following are the summary of the review for this file.

1. This file contains a total of 39 changes, and 22 of the 39 changes are the result of documented/known field issues. Those are: 5, 6, 8, 10, 11, 12, 14, 15, 15, 17, 18, 21, 24, 27, 28, 31, 34, 35, 36, 37, 38, and 39. The company shall provide the root cause analysis for all the above changes. In addition, FDA may have additional questions based on the root cause analysis. *(FDA 10/7/2000, deficiency #1)*

REVIEW SUMMARY (for the original PMA/S):
The subject file contains a total of 39 software modifications as it stated in the Table 1 of the submission. In addition, the company claims the following changes are reported by the field (post market). Those are: 5, 6, 8, 10, 11, 12, 14, 15, 15, 17, 18, 21, 24, 27, 28, 31, 34, 35, 36, 37, 38, and 39. The subject file did not contain the root cause of any field reported event for any of the above listed changes. FDA should review the root cause of all the above changes, and the root cause report should contain the detailed analysis for every field issue.

REVIEW SUMMARY (for the PMA/S A01):
The company responded to the this issue in the PMA/S Amendment 1, dated 11/04/2011. The company provided a table which contains the change summary, the existing software behavior (the problem),the proposed software behavior (solution/fix),a summary of root cause for the subjected change, why and how does the subjected issue occurred, the rationale for the change and the clinical impact, a summary of the hazard analysis for the subjected change, etc. Based on this table, the majority of the proposed changes in the subject are acceptable, however, few of the proposed changes need to be clarified. The one needed to be clarified are listed in the draft version of the FDA letter. For example: the change 32 will be addressed separately.

> *REVIEW SUMMARY (for the PMA/S A02):*
> *The change 32 will be addressed in the deficiency #2.*
> *The changes 8 and 34 will be addressed in deficiency #3.*

With above, this deficiency can be closed.

2. Change 32 should be reviewed as part of the IDE review process, not as part of the PMA review process. (b) (4) ; and if the subject device is transfer back to the 21 CFR Section 814, then the subject device shall (must) meet all the PMA regulation.

REVIEW SUMMARY (for the original PMA/S):
The above change number 32, should be removed. The subject change is NOT related to the 21 CFR 814 (PMA). (b) (4) .

REVIEW SUMMARY (for the PMA/S Amendment 01):
The company provided the meeting min., dated March 9, 2010, with FDA management. Since the reviewer was NOT part of this meeting, therefore, the reviewer (b) (5) *). With above. SINCE MANAGEMENT MADE THE DECISION ON THIS ISSUE, THEREFORE, THIS ISSUE IS CLOSED.*

3. A number of changes are associated to the device longevity, the device longevity calculation shall be provided for review. FDA shall assess the labeling change for this issue.

REVIEW SUMMARY (for the original PMA/S):
The modification for the implantable device's longevity should be based a number of the factors, however, NONE of those factors are in the subject file.

The longevity calculation is based on the pacing modes; pacing pulse such as width, rate, amplitude, etc.; the total DC current leakage for the implantable device, this should be based on the 'worst' operation conditions; the usage of the DC current while the device is in the operation such as EGM, telemetry, reformat the capacitors, reformat the battery, wireless interfacing, home monitoring, shell life, self-testing/monitoring, alarm feature, etc., the assumptions should be justified as part of the 'estimated' device longevity calculation; the lead Impedances shall be based on a number of cases such as the (b) (4) *etc.; For the ICD/CDRT-D, the defibrillation feature shall not be part of the estimated device longevity calculation. (For the ICD/CRT-D: The* (b) (4) *; and the* (b) (4) (b) (4) *;* (b) (4) *.)*

As always, the modification of the device longevity 'shall' impact the device labeling. However, the company claims, it has no impact at all for the device labeling. Therefore, the additional information may be required pending the responses from the company for this deficiency.

<u>REVIEW SUMMARY (for the PMA/S Amendment 01):</u>
The company did not address the FDA deficiency. Therefore, this deficiency will be (b) (5) (b) (5) *FDA letter to the company.*

<u>REVIEW SUMMARY (for the PMA/S Amendment 02):</u>
A number of the e-mails were exchanged, which is related to the battery, and the company claiming the battery information was NOT changed. In addition, as I have stated in my early e-mails to the company, and stated in to the company again during the conference call that, the root cause is NOT the application software. The programmer application software was coded correctly in the past and the present.

With above, the device longevity algorithm, and the labeling were questioned. The company claiming the algorithm used in the application software is (b) (4) (b) (4) *for the labeling, except the measurement technique is unique with respect to each other. Therefore, it is my view that, <u>how to calculate the device longevity will be the major point.</u>*

Question: Based on the above, why the improvement (SW modification from Version 7 to Version 11) will not impact the labeling, specially, the modified algorithm in SW Version 11 will not be identical to the algorithm that was used in the existed labeling.

The company claiming the labeling does not required to be changed, because the measurement technique. With above, a conference call was conducted on February 16, 2011, to address this.

NOTE: (b)(4), (b)(5) .

Justifications: Point (1): (b)(4), (b)(5)

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Point (2): (b)(4), (b)(5)

Point (3): The post market performances shall be the feedback to the device longevity calculation process as an improvement for the battery information, and/or the algorithm, and/or the labeling.

During the conference call, the company claiming the error pf margin between the two measurement techniques is about 10%, and the updated application software is within the 10% error limits. In addition the company claims, it has verified the implantable device with the modified application software. Therefore, the labeling does not required to be changed.

With above, I am recommending to close this issue, since the modification is within the error margin.

4. It appears, some of the changes may be involved with the firmware (embedded software of the implantable devices), therefore, the confirmation is required for the possibility of the firmware modification, and additional questions may be raised in the future.

REVIEW SUMMARY (for the original PMA/S):
Some of the software modifications in the subject file appear (may be) having the impacts to the implantable device features, however, the company did not provide any detailed information to be reviewed. With above, the confirmation is required to make sure 'the firmware' is NOT part of this PMA/S.

REVIEW SUMMARY (for the PMA/S Amendment 01):
The company claims, the subject PMA/S is for the application software of the programmer only. With this confirmation, this issue is closed.

5. It appears, some of the changes may be involved with the labeling modification(s), therefore, the confirmation is required for the possible labeling modification(s), and additional questions may be raised in the future.

REVIEW SUMMARY (for the original PMA/S):
Some of the software modifications in the subject file appear (may be) having the impacts on the device labeling, however, the company did not provide any detailed information to be reviewed. With above, the confirmation is required to make sure 'the labeling' is NOT part of this PMA/S, as it is claimed by the company.

REVIEW SUMMARY (for the PMA/S Amendment 01):
The company claims, no labeling change in this file. However, due to the fact that, the implantable device longevity may be impacted (change 8),therefore, another confirmation is required.

REVIEW SUMMARY (for the PMA/S Amendment 02):
The company claims, no labeling change in this file, since this file is related to the application software only. I do agree with the company that, the labeling for the application software will NOT be required to change. However, the labeling for the implantable devices will be another issue due to change 8.

With above, this issue shall be addressed with the Deficiency 3 above.
Recommendation: Move this issue as part of the Deficiency 3 above.

6. The company claims the final releasable version for the software is, PR32.50. Therefore, the final record run shall be conducted with the final software version PR 32.50, and the test report shall be submitted for review.

REVIEW SUMMARY (for the original PMA/S):
Based on the information in the file, the test report starts at the page 67 of the submission. The company did not conduct the full and completed record run for the final version of this software. In addition, the software modifications started at the version PR32.22, every incremental software version will contain the 'additional' software modification(s), and has not been fully tested. The partial testings should not be acceptable.

Please note: the final version of the software must be fully tested. The partial testing in between the software version PR32.22 to the final version PR32.50, shall not be accepted as the fully tested for the final version of the software.

REVIEW SUMMARY (for the PMA/S Amendment 01):
The company did not provided the responses with a final test report, It re-stated its position again. A deficiency will be generated again.

REVIEW SUMMARY (for the PMA/S Amendment 02):
A number of the e-mails were exchanged after the 2nd. FDA letter, dated December 28, 2000, and a conference call was conducted on January 5, 2011 to address this issue. In PMA/S Amendment 2, the company provided the 'summary test report' for the software. The company claims in this summary test report was based on the additional testing that was conducted after the conference all on January 5, 2011. In addition, the company claiming the tested version is the final version PR32.50.

The company claims all the test cases were passed the test, with one postponed software anomaly. The summary test report did not providing the detail of the test cases, however, the company claims the specifications were met, and the subject final testing has cover the changes of this file only.

With above, this deficiency is marginally acceptable, this issue is closed.

NOTE: Based on the information provided to me during the January 5. 2011 conference call, it appears this company lacks the SW control policy such as (b) (4)

(b) (4) *. This company seems to have the SW CM issue with respect to the* (b) (4) *. The above SW CM issue can be related to the e-mail from the company in the PMA/S Amendment 2.*

7. Based on page 81 of this submission, they are (b) (4) false positive issues will be postponed for the correction. The company shall provide the description for all those changes, and based on the description, FDA may ask for additional information in the future.

<u>REVIEW SUMMARY (for the original PMA/S):</u>
Based on the information in the file, page 81 of the submission, the company claiming a total of (b) (4) *issues are classified as false positive issues, and did NOT provide any additional information for any (or all) of the issues.*

<u>REVIEW SUMMARY (for the PMA/S Amendment 01):</u>
The company did not address this deficiency, therefore, this deficiency is generated again as part of the 2nd FDA letter to the company.

<u>REVIEW SUMMARY (for the PMA/S Amendment 02):</u>
Since the deficiency in the 2nd FDA was modified by the management prior to the letter been send to the company. This deficiency is re-word and combined with the deficiencies #7, #8, and #9); and removed the reviewer's request for asking the detailed of every issue, it replaced with a general request only.

With above, the company provided a general responses in the PMA/S A02 for the deficiencies 7, 8, and 9. Therefore, without the details, it is impossible to assess and determine those three deficiencies.

Since management made the decision to request the general information and decided the information is acceptable based on another reviewer ( ), therefore, this issue is closed. (3/4/11)

8. Based on page 81 of this submission, they are (b) (4) issues has been classified as opportunity for future enhancement. The company shall provide the description for those issues.

<u>REVIEW SUMMAR (for the original PMA/S):</u>
Based on the information in the file, page 81 of the submission, the company claiming a total of (b) (4) *issues are classified as future enhancements, and did NOT provide any additional information for any (or all) of the issues*

<u>REVIEW SUMMARY (for the PMA/S Amendment 01):</u>
The company did not address this deficiency, therefore, this deficiency is generated again as part of the 2nd FDA letter to the company.

<u>REVIEW SUMMARY (for the PMA/S Amendment 02):</u>

Since the deficiency in the 2nd FDA was modified by the management prior to the letter been send to the company. This deficiency is re-word and combined with the deficiencies #7, #8, and #9); and removed the reviewer's request for asking the detailed of every issue, it replaced with a general request only.

Since management made the decision to request the general information and decided the information is acceptable based on another reviewer ( ), therefore, this issue is closed. (3/4/11)

9. Based on page 83 of this submission, they are (b) (4) issues has been classified as documentation/internal tools/cosmetic issues. The company shall provide the description for those issues.

REVIEW SUMMARY (for the original PMA/S):
Based on the information in the file, page 83 of the submission, the company claiming a total of (b) (4) issues are classified as cosmetic issues, and did NOT provide any additional information for any (or all) of the issues

REVIEW SUMMARY (for the PMA/S Amendment 01):
The company did not address this deficiency, therefore, this deficiency is generated again as part of the 2nd FDA letter to the company.

REVIEW SUMMARY (for the PMA/S Amendment 02):
Since the deficiency in the 2nd FDA was modified by the management prior to the letter been send to the company. This deficiency is re-word and combined with other deficiencies (Deficiency 7, 8, and 9); and removed the reviewer's request for asking the detailed of every issue, it replaced with a general request only.

Since management made the decision to request the general information and decided the information is acceptable, this includes information in page 8, and all the information in Tables 2, 3, and 4 located in PMA/S A02, therefore this issue is closed based on the management 's decision. (3/4/11)

☒ **Labeling**

The company claiming that, no labeling change is required.

☒ **Animal Studies**

N/A

☒ **Statistical**

N/A.

☒ **Shelf Life, Packaging Change**

N/A.

☒ **Post market issue**

N/A

☒ **Recommendation:**

The issues have been fully reviewed by the reviewer are recommended to be approval, and the issues decided by the management to be acceptable are considered to be approved.

Date	**Date**
Reviewer	Branch Chief, PDLB