



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

SUMMARY OF:

P880006/S081

P880086/S220

P910023/S297

P970013/S050

P030035/S098

P030054/S226

Merlin Conduct Mobile Software Application

Model 3330 Version 16.1 Software for the Model 3650 Merlin Patient Care

System

St. Jude Medical

BACKGROUND

St. Jude Medical, Cardiac Rhythm Management Division (SJM CRMD) is requesting approval for the MerlinConduct™ Mobile Software Application Model MC version 1.0, which is a software accessory that is supported by the Model 3330 version 16.1 Merlin Patient Care System (PCS) Programmer Software.

The Merlin PCS Programmer (P030054/S8, approved Oct. 12, 2005) is a portable, dedicated programming system designed to interrogate, program, display data, and test St. Jude Medical implantable devices. The Merlin PCS programmer features the Model 3330 programmer software which runs on the Model 3650 programmer hardware.

The Model 3650 programmer hardware currently features a single user interface that is built-in to the programmer, as well as a VGA port that allows use of a wired monitor. A wireless user interface option is being added, through the use of the MerlinConduct mobile software application that simultaneously displays the same screen as the Merlin programmer on a mobile platform (Apple iPad). There has been no change in the intended use of the Merlin PCS Programmer.

In **Amendment A001**, the sponsor changed the correspondent to Michelle Land.

In **Amendment A002**, the sponsor changed the correspondent back to Jennifer Wong and requested an extension.

In **Amendment A003**, the sponsor has provided a response to the deficiencies identified during review of the original submission. The response did not adequately address all of the deficiencies. For this reason, a Not Approvable decision was made.

In **Amendment A004**, the sponsor has provided a response to the remaining deficiency from the Not Approvable decision.

INDICATIONS FOR USE

The MerlinConduct software application is intended as a wireless user interface extension of the Merlin PCS Programmer software. It functions on an iPad within the clinical setting.

The intended use for the Model 3650 Merlin Patient Care System (PCS) remains the same as approved under P030054/S8 on October 12, 2005.

DEVICE DESCRIPTION

The MerlinConduct mobile software application enables a mobile platform (Apple iPad) to function as a wireless user interface for the Merlin PCS programmer in a clinical setting. The application mirrors the Merlin PCS Programmer user interface on the iPad via a secure and direct wireless connection. Clinicians can use the MerlinConduct application, in close proximity to the Merlin PCS programmer, to view and control the programmer user interface. The MerlinConduct software application, for use on an Apple iPad tablet, provides a portable and convenient user interface in the currently crowded clinical environment.

Model 3650 Merlin™ Patient Care System (PCS) has been updated with Model 3330 version 16.1 software to provide support for the MerlinConduct software application. The clinical features of the Merlin PCS programmer remain unchanged.

In the MerlinConduct System, a mobile platform (iPad) with the MerlinConduct mobile software application connects to the Merlin PCS programmer via a secure, peer-to-peer Wi-Fi connection. A peer-to-peer Wi-Fi connection allows wireless devices to connect directly to each other without having to connect to a central access point such as the hospital's local area network (LAN) or to the internet. The wireless communication between the iPad and the Merlin PCS programmer is secured using a strong industry standard Wi-Fi security protocol with AES data encryption. The Wi-Fi security protocol also performs error checking on (b)(4) Trade Secret/CCI ensure the integrity of the transmitted data. For each use of MerlinConduct, a (b)(4) Trade Secret/CCI encryption/decryption (b)(4) Trade Secret/CCI for each connected iPad-Merlin PCS programmer pair. Therefore, only the MerlinConduct application can effectively send/receive data with the connected Merlin PCS programmer.



The direct wireless connection limits the wireless communication range between the iPad and Merlin PCS Programmer to several meters. Therefore, the MerlinConduct application must always be used with the iPad in close proximity to the Merlin PCS programmer. The Merlin PCS programmer and emergency functions are always accessible to the user when the MerlinConduct feature is in use.

To use the MerlinConduct feature, the user must first enable the MerlinConduct setting on the Merlin PCS programmer. The Merlin PCS programmer will not accept any wireless connection requests if the MerlinConduct setting is disabled. When the user enables the MerlinConduct feature, the Merlin PCS programmer will become a wireless network access point that the iPad can connect to. The Merlin PCS programmer will display (b)(4) Trade Secret/CCI The Merlin PCS (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI detect the Merlin PCS (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI . The user must enter the Merlin (b)(4) Trade Secret/CCI For security purposes, each Merlin PCS (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI (b)(4) Trade Secret/CCI displayed on the Merlin PCS programmer that the user must enter into the

MerlinConduct app login screen before wireless screen sharing and control capabilities can begin on the iPad. The (b)(4) Trade Secret/CCI ensures that the user connects to the intended Merlin PCS programmer.

During a MerlinConduct session, the Merlin PCS programmer monitors the Quality of Service (QoS) of the wireless connection between the Merlin PCS programmer and the iPad. The QoS is determined by characteristics of the wireless signal such as data throughput, latency, and data error rates. The QoS status is displayed to the user on the top right hand corner of the Merlin PCS programmer screen and is visible on the iPad once screen sharing has started.

The user may use this information to position the iPad in an area with a strong QoS signal. When the QoS drops below the system-defined threshold, screen sharing and control will end on the iPad and the user will be notified that the MerlinConduct session has ended. While this scenario will occur infrequently when using the MerlinConduct feature as intended, the system has several safe guards to ensure safe operation of the Merlin PCS programmer. If the wireless connection is dropped due to a weak QoS signal, and if the last screen input came from the iPad, then the Merlin PCS programmer will cancel any ongoing implantable device (pacer/ICD) tests, and the implantable device will safely return to the programmed device settings. In addition, if pacing system analyzer (PSA) capture threshold tests are ongoing when the wireless connection ends, and the last screen input is from the iPad, then the Merlin PCS programmer will initiate VVI pacing at a high output voltage to ensure the patient has continuous pacing support. The user may also continue to control implantable device operations directly using the Merlin PCS programmer at any time.

The clinician can end the MerlinConduct session at any time by disabling the MerlinConduct feature on either the iPad or the Merlin PCS programmer. The system will also automatically disable the MerlinConduct feature after a system-defined period of inactivity on the MerlinConduct application.

CHANGES

The Model 3650 programmer hardware currently features a single user interface that is built-in to the programmer, as well as a VGA port that allows use of a wired monitor. A wireless user interface option is being added, through the use of the MerlinConduct mobile software application that simultaneously displays the same screen as the Merlin programmer on a mobile platform (Apple iPad).

Model 3650 Merlin Patient Care System (PCS) has been updated with Model 3330 version 16.1 software to provide support for the MerlinConduct feature.

CLINICAL

The Clinical reviewer conducted the original clinical review of the MerlinConduct mobile software application. His comments were:

I believe the firm has developed a reasonable list of the hazards at stake.

*Given that the *idea* is that the patient is directly before a physician and the screen on the iPAD looks identical to the programmer, I believe the goals of this submission are reasonable and the risk considerations on track.*

That said, this is first-of-a-kind and the risks are really yet to be fully understood. For that reason, I believe that getting a better understanding of the system operation and logistics is important, such as through a demonstration by the firm. I have never considered such an extension of a programmer before, and I don't know that I'd immediately be able to conceive of every manner in which such an extension of the programmer could go awry.

My guess is that the proposal is reasonable and introduces little new safety concerns. My recommendation, however, is that the firm come in to FDA, demonstrate this first-of-a-kind use of the iPAD

and help us assure ourselves that the risks are indeed acceptable given that the benefits, modest as they may be, are probably real.

As a result of his comments, a teleconference was setup between the sponsor and FDA to discuss the operation of the MerlinConduct Mobile application on the iPad. The sponsor described the system and answered FDA's questions. As a result of this discussion, FDA still had a number of concerns with usage of the system. Prior to the teleconference, SJM also sent a short video about the MerlinConduct mobile application; however; this video had minimal value because it was just a marketing video.

For the next step, a PDLB rounds discussion was held with other members of PDLB. The application was discussed and there were still questions remaining regarding the operation of the application as well as the user testing performed by the sponsor.

As a result of this teleconference and PDLB rounds discussion, it was decided to have a videoconference where the sponsor could demonstrate the basic use scenarios of the MerlinConduct system to FDA. FDA was able to see the actual device in use. The sponsor also answered FDA's questions during the meeting.

In summary and as a result of the review of the submission, the sponsor teleconference, internal FDA discussion, and the sponsor videoconference, there were deficiencies identified for the sponsor which need addressing. Based on further discussion with Mitchell Shein, the human factors testing plan deficiency was modified to ask for the results also.

In **Amendment A003**, the sponsor responded to these deficiencies. The Clinical reviewer reviewed the responses to deficiencies #4 ~#5. He found that the sponsor responses addressed his deficiencies and found them acceptable. However, an internal meeting was held to discuss the human factors testing further which is described in the Human Factors section of this memo.

HUMAN FACTORS

An internal meeting was held with the Clinical reviewer, IEDB Branch Chief, and me to further discuss the human factors testing completed by the sponsor. The sponsor had completed a modest, confirmatory human factors study which consisted of (b) (4). As a result of this meeting, the sponsor was asked for additional information regarding the concerns identified and how each concern was mitigated.

Review Comment: The sponsor response was reviewed the Clinical reviewer and me. We found that the table needed some clarification. As a result, a teleconference was held with the sponsor. The table was walked through and explained by the sponsor. The sponsor summarized the discussion. As a result of the discussion, we have no additional questions and no further concerns. It appears that every user concern identified was adequately mitigated by the design of the system.

SOFTWARE

Details of the MerlinConduct app and Model 3330 Software have been provided, according to the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005), in Sections 3 and 4 of the submission, respectively.

The following areas were reviewed for MerlinConduct Mobile Software Application version 1.0:

- 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

Reviewer Comment: No deficiencies were identified during the initial review of this documentation. The sponsor provided documentation was found acceptable and there were no further concerns.

In Amendment A003, the sponsor has made the following FDA requested change (from deficiency #4 in the October 17, 2012 letter) to the MerlinConduct App (resulting in Model MC v1.1):

- Incorporate a screen warning indicating that Emergency operations must be operated from the programmer.

Additionally, since the FDA requested change was being made, the MerlinConduct App has also been modified to:

- Make minor usability improvements to the capability for resuming previously terminated sessions. These changes were implemented to improve usability when attempting to re-enter application after disconnects, by making the behavior for remembering the session code more consistent.
- Update/control the versions of the operating system and hardware that can be used with the MerlinConduct App (includes iOS 6.0 and higher).

The associated documentation (i.e. requirements delta, updated Risk Management Report, verification, system validation) for all changes described above, as incorporated into MerlinConduct App v1.1, can be found in Appendix 2 of Amendment A003. There were no changes made to the Model 3330 Version 16.1 Programmer Software.

Reviewer Comment: The changes made by the sponsor for v1.1 were reviewed and found acceptable. The associated documentation provided by the sponsor was also reviewed and found acceptable. There are no further concerns.

The following areas were reviewed for Merlin PCS Programmer Model 3330 Software Version 16.1:

- 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

Reviewer Comment: No deficiencies were identified during the initial review of this documentation. The sponsor provided documentation was found acceptable and there were no further concerns.

CYBERSECURITY

The sponsor provided an Information Security Summary for the MerlinConduct Mobile Application system in Appendix 2 of the original submission. This document describes how the (b) (4) system complies with FDA Information Security guidelines (b) (4). (b) (4) is the internal name for the system that includes the MerlinConduct software application Model MC, which adds the capability to control the Merlin PCS Programmer software Model 3330 from an iPad over an encrypted short range point-to-point WiFi connection.

Review Comment: The document was reviewed and it appears that the sponsor has adequate measures in place for concerns in confidentiality, integrity, availability, and accountability. I also reviewed the system's method of connecting the iPad to the Wi-Fi connection and the implementation of the (b) (4) (b) (4) Trade Secret/CCI. I have no concerns with their implementation.

HARDWARE

The Model 3650 programmer hardware currently features a single user interface that is built-in to the programmer, as well as a VGA port that allows use of a wired monitor. A wireless user interface option is being added, through the use of the MerlinConduct mobile software application that simultaneously displays the same screen as the Merlin programmer on a mobile platform (Apple iPad).

There have been no modifications to the iPad hardware.

Regarding the Wi-Fi accessory for the programmer, the sponsor clarified the following via email:

- the off-the-shelf Wi-Fi accessory (^{(b)(4) Trade Secret/CC}) for the Merlin programmer was previously tested and submitted as disabled under P030054/S200. FDA approval of P030054/S200 was received on October 20, 2011.
- In the Model 3330 v16.1 programmer software, the use of ^{(b)(4) Trade Secret/CC} was simply enabled through the programmer software. No hardware modifications were made.

Review Comment: The clarification from the sponsor is adequate. Enabling of the Wi-Fi accessory is done by software only. Review of the usage and testing of the Wi-Fi accessory is handled through the EMC/wireless review.

LABELING

The Merlin PCS Help Manual was updated to include information for the new MerlinConduct feature. The redlined Merlin PCS Start-up Screen and Help Manuals in were located in Appendices 15 and 16 of the submission, respectively. Changes were also made to the Merlin PCS Hardware User Manual to add the enabled Wi-Fi card (see Appendix 17 of the original submission for the redlined manual and Appendix 18 of the original submission for the labels).

As a result of the EMC/Wireless review in **Amendment A003**, the sponsor updated the Merlin PCS User's Manual which was included in an email as part of an interactive review.

Review Comment: The labeling was also reviewed as a part of the clinical review. I also reviewed the labeling. The changes were due to the addition of the MerlinConduct feature and include information on how to setup the feature. There are no labeling specific deficiencies that were identified.

EMC/EMI/WIRELESS

The EMC reviewer reviewed the MerlinConduct Mobile Software Application for EMC and Wireless functionality. His original review identified deficiencies. He recommended that the sponsor perform full EMC and coexistence testing on their system which they did not provide in the submission.

In **Amendment A003**, the sponsor responded to these deficiencies. The EMC reviewer reviewed the responses to deficiencies #1 ~#3. During his review, the sponsor was asked to provide a test report that was not included in the submission. He found that the sponsor did not address all his concerns and there are two new questions for the sponsor. These questions were sent interactively to the sponsor. The sponsor provided a response on December 13, 2013 by email which was reviewed by the EMC reviewer. His review of this response found that the sponsor did not adequately address his concern. This remaining concern was listed as a deficiency to the sponsor.

In **Amendment A004**, the sponsor responded to the remaining deficiency. In their response, the sponsor did not originally include additional test data. However, a teleconference was held with the sponsor to discuss the response in detail. The sponsor clarified that the tests were performed within the calibrated field. However, after the teleconference, the sponsor discovered that there was a misunderstanding about the previous setup of the calibrated plane and therefore repeated the RF immunity test. The meeting minutes and additional test report were provided by the sponsor. The minutes and new test report were

reviewed by the EMC reviewer. He found that the sponsor has performed the tests as a complete system as requested and has no further concerns.

MANUFACTURING

There are no changes to the manufacturing of the Model 3650 Merlin PCS Programmer. Additionally, there were no modifications made to the iPad hardware.

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

OAI AND CORPORATE-WIDE-WARNING LETTER REVIEW

Per the Office of Compliance, this submission is recommended for approval as described in the GMP approval memo.

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Biocompatibility
 - Packaging/Sterilization
 - Shelf-Life
 - Post-market issues
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CONCLUSION/RECOMMENDATION

Based on the information in the submission, the sponsor response to the remaining deficiency has been found acceptable. There are no other deficiencies remaining. The sponsor has shown that the MerlinConduct Mobile Application is safe and effective at this time.

I recommend that the sponsor receive an **APPR - Approved** letter.