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: May 6, 2011

TO: The Record

THRU:
, PDLB/DCD/ODE/CDRH

Initials Date

FROM:

SUBJECT: P890003/S211, P900061/S098, P850051/S074, P820003/S104, P010031/S228, P010015/S107. P990001/S082, P980050/S057, P980035/S200, P980016/S273, P970012/S081, and P930022/S012

Medtronic Model 9986 Desktop/BOSS Version 2.4 for use on the Medtronic Model 2090 CareLink Programmer

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BACKGROUND

The 180-day PMA/S (subject file) was submitted by Medtronic (the company) dated January 4, 2011, requesting the approval for the above referenced PMA/S files for the Medtronic Model 9986 Desktop/BOSS Version 2.4 for use on the Medtronic Model 2090 CareLink Programmer.

After completed the review of this, a number deficiencies were generated, and e-mailed to the company, the company provided the responses via the e-mails and those e-mails were insert to the file as part the documentation. The detailed information of those e-mails are documented in the software/firmware sub-section of the Preclinical/Bench section of this review memo.

INDICATIONS FOR USE

The Model 2090 CareLink Programmer is indicated for use in the interrogation and programming of implantable medical devices.

Device Descriptions

The Model 2090 CareLink Programmer is a modified personal computer. Users select desired medical device applications by means of a graphical user interface (GUI) desktop. Communication with the implanted device (interrogation and programming) is achieved through RF telemetry.

Description of Technical Changes for Model 9986 SW v2.4

The Medtronic Model 2090 CareLink Programmer utilizes a Desktop/Baseline Operating Software System (BOSS), which is Model 9986. The purpose of this submission is to revise Model 9986, resulting in a new version hereafter referred to as Desktop 2.4. Desktop 2.4 supersedes Desktop v 2.3. This release will add the following set of capabilities (features) to the Desktop (BOSS):

- **Support for device application telemetry switching –** Telemetry switching allows a toggle between two already approved telemetries (B and C). This will allow devices with the associated device application an easier way to switch telemetry. Currently, the requirement is to go out of the application and back in to switch the telemetry type.

- **Save to PDF File enhancements –** Changes include the merging of multiple reports printed within a session to be merged to a single file and improve the file naming to include the patient name (when available) and device ID. Given the current nature of the print queue is to store and allow reprinting (resaving) of saved reports from previous sessions; the enhancement will ensure that reports from different patients are segregated into different PDF files.

- **Secure delete of protected health information (PHI) –** This feature provides a user-selectable option to purge reports with a multiple pass overwrite that ensures non-recoverability of PHI to protect patient privacy. User options include several delay times to allow the most recent reports to be retained and reports older than a specified number of days to be purged. Several other PHI reduction features will also be added, including: secure delete of temporary report files, secure delete when user manually deletes reports from the Desktop, and a user-selectable Delete PHI button, accessed by a new Programmer menu option, “Tools”.

- **Network troubleshooting enhancement –** This feature is targeted at Medtronic technical support and hospital/clinic IT staff that are responsible for establishing network connectivity between the 2090 and Paceart system. A single user selection launches a series of standard IP networking tools on the 2090 that provide information useful in determining why a network connection is not working. Results can be saved to media for printing or forwarding to technical support.

• **Support for additional printers –** Support for printing to the HP1006 and HP2035 printers will be added.

• **Input/Output Processor fix to address System Error –** Desktop 2.4 will deploy a LEM Input/Output firmware fix for an issue that can cause a System Error under specific conditions.

• **Unicode support in Find Patient window –**The Find Patient window must be updated to support display of Unicode-encoded strings for patient data that are read from the device. This enhancement will include software updates to use multibyte encoding (unicode) for the “find patient window” only. This will allow characters present in Asian languages, like Chinese and Japanese to be supported. The changes made are required to support planned translation efforts of the Desktop as well as Medtronic medical device software applications for both US and International devices. Although these changes are being made to the "global"
Desktop software application, there is no impact to the Desktop software application user interface that US customers see, nor is there impact to the US medical device software applications or how they interact with the Desktop software application.

• **Marker Channel Update –** This change adds space for additional marker channels associated with Reveal DX/XT. This change cannot be seen by the user until the Reveal DX/XT software is approved.

• **File Input/Output Processor robustness enhancements –** Update to address errors on programmer boot-up.

• **Miscellaneous Minor Bug Fixes –** The following is the list of the minor bug fixes that were addressed during Desktop 2.4:

Fixed call to asset management utility program: m_amscan.exe;

Correct date / time format;

Merge core file change to support Unicode report printing;

Fix issue on Aspen platform in which the onboard network fails to connect after using dialup;

Provide backward compatibility for older non-Unicode applications with shared data file;

Change print to PDF "media full" error message to “insufficient free space”;

Fix error in debug build only of SessionSync support executable, m_fxfer.exe;

Save/Restore trace report options file to fix inadvertent trace mode change in Brady apps when entering Marquis family apps;

Disable Parallel Port Printer Plug and Play;

Fix corruption in d:\ng\logs files;

Preserve Desktop Language preference before Entering Vitatron Desktop;

Fix issue with full Size Reports by restoring Windows print spool directory if necessary;

Update utility program, Hibernate.exe, to flush registry keys and prevent errors; and

Prevent side effects when patient name contains print job status word.

PRECLINICAL/BENCH

ANIMAL STUDIES: N/A

EMC/EMI: N/A

HARDWARE/COMPONENT TESTING: N/A

SOFTWARE/FIRMWARE:

The submitted the required software documents in the subject PMA/S. This includes the following software topics:

Software and Firmware Specification and Development Plan;

Software Project and Verification Plan
Software Requirements Specification (SRS)

Software and Firmware Verification;

Risk Management
Software Design/Implementation
Code Reviews
Unit / Integration Testing
Quality Assurance
Software Verification Test Development
Test Strategy Development
Software Verification Test Execution
Firmware Development and Verification Testing

Acquired Product Software Validation Plan and Report;
Software Release; and
Level of Concern.

In addition to the above, the PMA/S also contains the information associated to the known anomalies with the justifications.

After completed the review of the subject file, a number of the e-mails and teleconference calls were conducted to resolve the issues in the subject PMA/S file. Based on the e-mail from the company dated March 29, and April 6, 2011, a number of the issues were resolved, not all. Those issues includes the clarifications for SCRs, provide the detailed test report.

Based on the discussion between 4/6/2011 to 4/8/2011, one of the existed hardware anomaly, LEM I/O timing, still exist, and the software fix for the system error is to reduce the occurrences, not to resolve the root cause.

Based on e-mail from the company dated, April 19, 2010, the subject PMA/S is related to the P890003/S209, and the 510(k) file for the Reveal DX/XT. P890003/S209 is the application software for the Reveal DX/XT, and those two files require the approval of the subject file in order to operate.

CLINICAL DATA: N/A

CONCLUSION

On May 6, 2011, Medtronic notifies the reviewer of the subject file that, the 510(k) file for the Reveal DX/XT was SE by FDA. During the final check for the approval of the subject file, it is noticed that, the company omitted the information in the 890003/S209 which indicates the application software in related to the subject file. However, this omission can be due to the administrative error and is not directly related to the subject file.

Based on the information in the subject file, the company has provided appropriate data to demonstrate the subject device is safe and effective.

RECOMMENDATION – I recommend that the supplement be **Approval.**

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Date

Reviewer

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Date

PDLB