P060027/S053 and P980049/S085

Paradym RF: VR 9250, DR 9550, CRT-D 9750

Paradym: VR 8250, DR 8550, CRT-D 8750

Orchestra and Orchestra Plus

Smartview Remote Monitoring & Smartview Monitor PSTN & GPRS

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BACKGROUND/REASON FOR SUPPLEMENT

The subject 180 Day PMA/S was received on August 21, 2013, by the Sorin CRM USA, Inc., is requesting approval for:

(a). A new firmware (software inside the implantable device) patch, version 3.104.3, to be operated with implantable device with the hardware of the microprocessor (uP) V4B, MOSAIC RF, and Z170101 only.

(b). .A new firmware version 3.120.1, to be operated with implantable device with the hardware of the uP V4C and V4D, MOSAIC RF2, and Z170102 only.

(c). The application software packages for both programmer (Orchestra and Orchestra Plus) due to the modifications for the implantable device as stated in above.

(d). The software packages for the remote home monitoring which is due to the implantable device modifications as stated above.

FDA approved the firmware, version 3.104.2, to be operated with implantable device with the hardware of the uP V4B, MOSAIC RF, and Z170101 in the past, therefore. The firmware patch (Version 3.104.3) is the subject review for this PMA/S. The minor firmware patch is to remove some of the collection of the history data requirements.

The new firmware, version 3.120.1, to be operated with implantable device with the hardware of the uP V4C and V4D, MOSAIC RF2, and Z170102 are the major modifications for the implantable device in the subject PMA/S file. The hardware modifications impact the MV sensor, the RF communication with the programmer. The new firmware version and the modified hardware platform of the implantable device impact the programmer software packages and the home monitoring system.

INDICATIONS FOR USE

NOTE: The company claims, "the indications for use" are unaffected by the purposed changes in this PMA/S. The following is the Indications For Use Statements.

Paradym RF VR 9250 and DR 9550 models are indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to ventricular tachyarrhythmia.
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT)

Note: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies for this indication have not been studied.

Paradym RF CRT-D 9750 model is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening arrhythmias. The device is also indicated for the reduction of heart failure symptoms in medically optimized NYHA Functional Class III and IV patients with left ventricular ejection fraction of 35% or less, and QRS duration of 150 ms or longer.

DEVICE DESCRIPTIONS

The Paradym RF family includes one single chamber ICD (Paradym RF VR model 9250), one dual-chamber ICD (Paradym RF DR model 9550), and one* triple chamber CRT-D (Paradym RF CRT-D model 9750)

Paradym RF VR 9250 and DR 9550 devices are respectively single-chamber and dual-chamber implantable cardioverter defibrillators for the recognition and treatment of ventricular tachycardia and fibrillation.

Paradym RF CRT-D 9750 device is an implantable cardioverter defibrillator for the recognition and treatment of ventricular tachycardia and fibrillation with ventricular resynchronization.

Paradym RF VR 9250, DR 9550 and CRT-D 9750 are equipped with an accelerometer to allow adaptation of pacing to suit the patient's activity.

Paradym RF devices are equipped with radio-frequency (RF) wireless technology, enabling the automatic remote transmission of implant data to the physician through a home monitor called "Smartview monitor" and upon request only, in order to provide a comprehensive report to the physician about device functioning and patient cardiac status without the patient having to physically be in the clinic.

Paradym RF VR 9250, DR 9550 and CRT-D 9750 devices can be programmed with SORIN CRM's Orchestra and Orchestra Plus programmers using Paradym RF programmer software release v.2.02 or higher

According to the sponsor, these changes are mostly unrelated to each other (the reasons for change are detailed below) but are being submitted together in a single PMA supplement because they are being made concurrently and have been approved under the same PMA numbers.

For Paradym RF single chamber (VR 9250), dual chamber (DR 9550) and CRT-D 9750 models, Sorin is requesting approval for the following changes:

1. Updates to hardware (RF module update, TwinAce chip upgrade and improvement of belt).
2. Modification to Embedded (Device) Software to upgrade the software from W3.104.2 version to W3.120.1 version.
3. Modifications to the Paradym RF Programmer module software (Paradym RF 2.02).

Note: The term (b)(4) TS/CCI is the name given internally at Sorin CRM to designate the version of Paradym RF devices equipped with the subject changes. However, the product name Paradym RF remains unchanged.

According to the sponsor, changes to the programmer are limited to the associated device software module and have no impact on the programmer's operating software or hardware.

Reasons for Changes to Paradym RF:

- (b)(4) TS/CCI
  requirements
- to modify the platform (b)(4) TS/CCI
  (b)(4) TS/CCI   - upgrade of the chipset (TwinAce V4C/V4D & Mosaic RF V2) in order to solve a (b)(4) TS/CCI   sensor issue. The (b)(4) TS/CC sensor is (b)(4) TS/CCI in the approved version of the devices and will remain (b)(4) CCI in the (b)(4) TS/CCI version. The hardware correction of the (b)(4) TS/CC sensor management issue is being made to anticipate (b)(4) TS/CCI
  (b)(4) TS/CCI .
- to improve logistic chain by removing one component reference (b)(4) TS/CCI
  (b)(4) TS/CCI from the bill of materials and by improving the (b)(4) TS/CCI
  (b)(4) TS/CCI .
- to improve belt (flex circuit?) robustness – increase clip width to have a better distribution of the force during a mechanical shock on the flex surface.

For SMARTVIEW Remote Monitoring System: Sorin is requesting approval of the following changes made to (b)(4) TS/CCI software modules used in the Smartview Remote Monitoring system:

1.
2. (b)(4) TS/CCI
3.

4. (b)(4) TS/CCI

The changes to the (b)(4) TS/CCI and (b)(4) TS/CCI (b)(4) TS/CCI e (for the Smartview Monitor) were made to introduce the capability to calibrate the 2.45 GHz ISM band channels' output power (b)(4) TS/CCI (management of component obsolescence).

The reasons for the changes made to the (b)(4) TS/CCI software were mainly:

- to support (b)(4) TS/CCI
- to support (b)(4) TS/CCI
  (b)(4) TS/CCI
- to introduce new features such as: lock out data by country, new fields in Patient Profile page, and introduction of the Health Professional Card (only available for France)
- to improve existing features such as: One-time PIT authorization ergonomic improvement, Password Reset workflow improvement
- to introduce bug fixes

What is not changing: Changes linked to the SMARTVIEW Remote Monitoring System are limited to software. According to the sponsor, no hardware changes are included in this submission.

According to the sponsor, none of the changes described herein affect the indications for use, the principles of operation, the diagnostics or therapies delivered and therefore, the existing clinical data continue to support all devices affected by the changes in this submission. Sorin claims to have verified and validated these changes through comprehensive pre-clinical testing as determined to be appropriate by the risk assessment processes and quality procedures.

The ICD communicates with the programmer or monitor in the MICS band. According to the sponsor, conducted and radiated output powers have not changed from the Paradym RF to the (b)(4) TS/CCI family. The ICD MICS antenna is a loop in the header.

Remote Monitoring System

The Paradym RF ICDs work with the Smartview remote monitoring system (RMS) to provide physicians access to data recorded by the implanted cardiac defibrillator while the patient is at home. At a specific time/date, data are sent wirelessly, using radio-frequency (RF) communication, from the implanted device to a Home Monitor located in the patient's home. Then the data is transferred to a central server that can be accessed by caregivers. The main purpose of this system is for the physician to be able to download implant data and create reports before a patient comes into the office for their visit.

The Remote Monitoring System consists of the following elements:

- HM – Home Monitor device. This is a small bedside system with a processor, an RF Transmitter/Receiver and a modem. The main functions of the HM are to connect to the implanted device over an RF connection, download raw implant data, package ICD raw binary data and transfer it to a central collection point. The HM will not be able to modify the implant programmed parameters or its firmware.
- BO – Back Office. The BO consists of a database server and a web server. It provides web services for a medical professional to be able to look at reports constructed (b)(4) TS/CCI . The BO also allows the user to set the time/date of a data collection request for the HM.
- (b)(4) TS/CCI . The (b)(4) TS/CCI composed of several custom software components. (b)(4) TS/CCI (b)(4) TS/CCI into a formatted report that is read by the physician.

According to the sponsor, the system does not alter the function of the implanted device and does not create diagnostic, decision support or alarm functions not already present in the implanted device for transmission to the dedicated Orchestra or Orchestra Plus programmers. There is no real-time, active, or online patient monitoring.

The Home Monitor (HM) is "paired" with a single ICD and initiates the communication with it through RF communication, usually in the patient's bedroom. After establishing the communication with the ICD, and in case of follow-up, the HM collects ICD clinical data (ICD memory, programmed parameters.(b)(4) TS/CCI . The HM then exchanges this information with the (b)(4) TS/CCI (schedules provisioned by the physician, configuration). The BOC sends a processing request to the (b)(4) TS/CCI retrieves the resulting outputs.
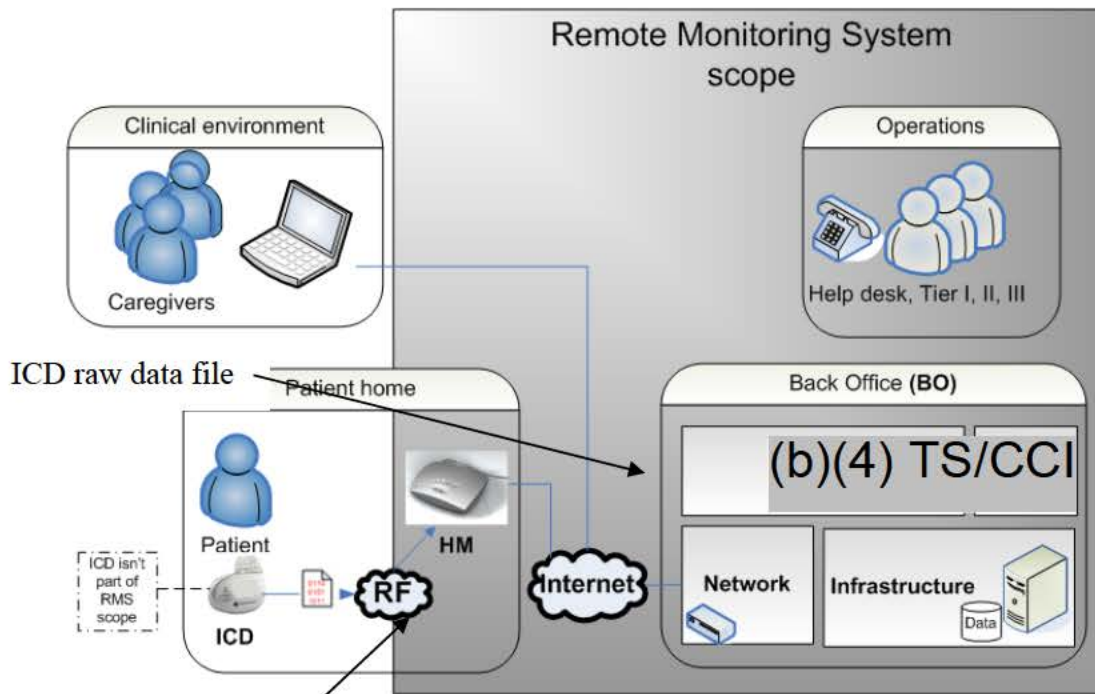
Figure 1 – Remote Monitoring System overview

The data received from the implant is stored in the HM in non-volatile (flash) memory until it has been successfully verified and transmitted to the BO.

The connection between the HM and the implant is achieved through RF wireless telemetry while the connection to the server is performed by the following connection options:

- PSTN modem when it is connected to BO through the telephone line
- GPRS modem when it is connected to BO through the mobile cellular telephone network.

RF communications between the HM and the implant consists of the following:

- A unidirectional link from the HM to the implant in the ISM band (2.45 GHz) to wake up the implant
- A bidirectional link between the HM and the implant in the MICS band (402-405 MHz) for patient data transmission
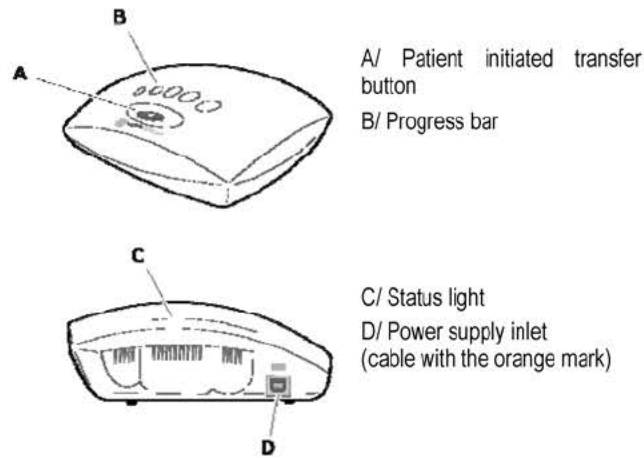
A/ Patient initiated transfer button

B/ Progress bar

C/ Status light

D/ Power supply inlet (cable with the orange mark)

Figure 2 – The Smartview Monitor

All alerts are categorized as "critical" or "significant. After a particular alert is sent, it is inhibited from re-sending for a fixed number of days. Each alert has a specified maximum number of occurrences. An alert can be configured to be reminded (a new instance issued) a few days after the event occurrence. The purpose of this is to make sure that very critical alerts are not missed.

DEVICE TESTING/REVIEW

The subject file contains lots information for the system, hardware, software, manufacture, labeling, and the company's process. The subject file does NOT seek the approval of the (b)(4) TS/CCI sensor feature, and the company is not to seek the approval of the real time RF communication as well. (b)(4) TS/CCI

A number of the deficiencies were generated, and the FDA letter was issued to the company. The company submitted the responses to FDA deficiencies as PMA/S Amendment 01 (dated January 15, 2014). Based on the information in the PMA/S Amendment 01, a conference call was held on February 24, 2014 for additional information to resolve all the issues in the subject file.

The subject file contains the information for the system, which includes the environmental testing such EMI/EMC, the complete requirements (specifications), the risk assessments such as the hazard analysis, the trace matrix, and the company's development processes.

The subject file contains the information for the software (and the firmware), which includes the requirements (specifications), the documents for the design, the development of the software (firmware), the test reports, the software (firmware) information with respect the anomalies, version history, and the company's process for the software (firmware).

The subject file contains the information for the manufacture and quality system information, the complete labeling, and other required information for PMA review process.

BIOCOMPATIBILITY: N/A

ANIMAL STUDY: N/A

CLINICAL DATA: N/A

LABELING:

The company provided the draft version of the labeling in the subject PMA/S, therefore, this is acceptable.

CONCLUSION

.Based on the information in the subject file with the past FDA approval actions, I recommend the approval for the subject PMA/S file.