Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

DATE: August 27, 2010

TO: File

CC: (b) (6) (Consultant Reviewer, Software)
Mitchell Shein (Branch Chief)

FROM: (b) (6) (Lead Reviewer)

SUBJECT: P980049 / S059 and P060027 / S026 180-Day PMA Supplement
Sorin – Revised Embedded Software (W2.8.4) and Programmer Software (2.22 UC1)

OVERALL RECOMMENDATION

Based on my review of the submission text, discussions with other FDA personnel, and interactions with the sponsor, **I recommend approval of the submission**.

Signature	*Date*	*Signature*	*Date*
(b) (6)		Mitchell Shein	
Scientific Reviewer		Branch Chief	
(Lead Reviewer)		(Management Oversight)	

PURPOSE OF SUBMISSION

The purpose of the submission is to request approval for the following software versions:

1. Revised embedded implant software (version W2.8.4) applicable to Paradym ICD / CRT-D devices operating with W2.8.2 embedded software, currently approved under P060027 / S011 (Paradym CRT-D model 8750) on October 27, 2009 and under P980049 / S050 (Paradym DR model 8550 and Paradym VR model 8250) on April 9, 2010.
2. Associated revised Smartview programmer software (version 2.22 UG1) compared to version 2.20 UG1 pending approval under bundled PMA supplement P980049 / S057. This programmer version is to be used on ELA's Orchestra or Orchestra Plus programmer hardware platform.

OVERVIEW OF CHANGE

These software modifications were previously reviewed and approved under G090064 / S006. This submission includes modifications necessary to correct anomalies related to the commercially available versions of the Paradym VR, DR, and CRT-D devices.

It is important to note that the present file does not introduce any change to the implantable device hardware, nor in Orchestra or Orchestra Plus hardware (electrical and mechanical components), nor in manufacturing processes. As stated by the sponsor, the reasons for making these software changes are the following:

Embedded Software

The Paradym embedded software (common to all Paradym ICD/CRT-D devices) has been revised from version W2.8.2 to W2.8.4 to correct a rare software anomaly affecting Paradym CRT-D SonR model 8770. The rare software anomaly only affects dual and triple-chamber Paradym devices (i.e., Paradym DR model 8550, Paradym CRT-D model 8750 and Paradym CRT-D SonR model 8770). The correction of the anomaly for the investigational device, Paradym CRT-D SonR model 8570, is out of the scope of the present file, which describes the software correction for commercially available devices. The software correction has already been submitted and approved for investigational devices under G090064 / S006.

This anomaly was observed on one (1) Paradym DR Model 8550 implanted in France, out of approximately devices implanted worldwide. The device involved in this report remains implanted; no injury or death has occurred as a result of the identified software anomaly. The in-depth investigation revealed that this software anomaly occurred under a rare and specific sequence of events (occurrence of less than 0.000137 per year per device), following which the device lost the ability to sense/pace and to deliver further therapy.

The in-depth investigation revealed that this software anomaly could only occur under a rare and specific sequence of events. First, the criteria to charge the shock capacitors (due to a ventricular arrhythmia) and the criteria to mode switch (due to an atrial arrhythmia) are met exactly at the same time. Second, the device delivers a shock (e.g. due to a sustained ventricular arrhythmia). In the unlikely event that these conditions occur, a software anomaly results in the protection circuit (which protects the device during the shock delivery) to not be automatically de-activated after the shock is delivered, resulting in the device to lose the ability to sense/pace and to deliver further therapy. This investigation was based on the analysis of the Holter episode of the device for which the anomaly occurred. It was reproduced internally on a prototype by forcing the charge and mode switch criteria to be triggered on the same cardiac cycle.

The revised embedded software that is the subject of the present submission will eliminate this risk. The company issued a Dear Doctor Letter on June 7, 2010, to inform its physicians about this rare software anomaly and to provide them with programming steps that eliminate any potential effect related to the anomaly, until the revised software is made available following FDA approval. The associated correction report was sent to the FDA Minneapolis district office on June 17, 2010, in accordance with the timeframe set forth in 21CFR 806.10(b).

Programmer Software

The Smartview programmer software has been revised from 2.20 UG1 to 2.22 UG1 primarily to:

- Incorporate the revised Paradym embedded implant software as a patch, so that it gets automatically downloaded into already implanted Paradym devices at the next patient follow up visit (therefore correcting the anomaly). Upon FDA approval of the present IDE supplement, the company will promptly upgrade its US programmers with the Smartview 2.22 UG1 version.
- Correct seven (7) minor programmer software anomalies previously unresolved, pursuant to ELA's commitment from its response to the October 1, 2009, FDA Approvable Letter for P060027/S011 (Paradym CRT-D model 8750).

Summary

The new implant and programmer software versions have been respectively created based on previous versions of the implant software version W2.8.2and Smartview 2.20 UG1 programmer software version.

Please note that the firmware and programmer software in the present submission is very similar to the firmware and programmer software reviewed under G090064 /S006 based on the following information:

- The implant software version proposed in the present IDE supplement is the exact same as the implant software version proposed in P060027/S026 and P980049/S049.
- The programming software version proposed in the present IDE supplement includes the exact same modules as the ones proposed in the programmer software version proposed in PMA Supplement P060027/S026 and P980049/S049. The only difference between both releases (i.e. Smartview 2.22 UG1 and Smartview 2.22 UC1) is that Smartview 2.22 UC1 has been repackaged to allow the interrogation and programming of investigational devices.

CONSULTANT REVIEW – SOFTWARE

reviewed the relevant sections of the submission related to the revised embedded implant software and programmer software. His review memo is provided as **Attachment 2**. I concur with his recommendations and do not have any other concerns.

INTERACTIONS WITH OTHER FDA PERSONNEL AND SPONSOR

The primary contact for the sponsor is Claudia Manikam (763-519-9408, Claudia.Manikam@sorin.com).

July 28, 2010

I requested a software consult from .

August 10, 2010

(b) (6) was previously assigned the PMA-S related to this identical change for the company's commercially available devices. This change is intended to correct a problem in the field. Therefore, the company would like FDA to review the submission as soon as possible. Due to his busy schedule, (b) (6) hasn't been able to review the file so far. Therefore, the PMA-S file was reassigned to me.

I contacted the sponsor and asked them to compare and contrast the changes in the IDE supplement and PMA supplement.

August 11, 2010

The sponsor provided the requested clarifications regarding the IDE supplement and PMA supplement (**Attachment 1**).

August 14, 2010

(b) (6) provided a written review of the software changes with a recommendation for approval (**Attachment 2**).

ATTACHMENTS

1. Comparison of IDE supplement and PMA supplements
2. Software Consult Memo from (b) (6)

Attachment 1

From: Orellou, Marc [Marc.Orellou@sorin.com]
Sent: Wednesday, August 11, 2010 6:12 AM
To:
Cc: Manikam, Claudia
Subject: RE: P980049/S059 and P060027/S026

Attachments: P980049_S059B_180D_Paradym_ESW284&SV2.22UG1_1Q-ODE-10Aug10_11Aug10.doc

H ,
Please find attached a short document that answers your question. Please let me know if you have any other question as you get into the details of the files.
As I told yesterday (and previously), these two submissions are mitigating a software issue present in the field (Dear Doctor Letter sent to our physicians last June and communicated to FDA Minneapolis district office as a correction report), so it is really important for Sorin to work with FDA to expedite the review as much as possible (our commitment to our customers in the DDL was to try to get the revised software approved throughout the summer).
So far we've been successfully working with the competent authorities from all the other countries affected by this anomaly to expedite the approval of similar revised software versions, so I'm really hoping we can do the same with FDA.
Thanks,
Marc.

Marc Orellou
Regulatory Affairs Manager
Sorin CRM
Tel: +33 1-46-01-33-11
Cell:+33 6-15-57-17-20
Email: marc.orellou@sorin.com

From: Manikam, Claudia
Sent: Wednesday, August 11, 2010 5:39 AM
To: (b) (6)
Cc: Orellou, Marc
Subject: RE: P980049/S059 and P060027/S026
Importance: High

Dear Mr (b) (6) and Marc,
My sincere apologies for not getting back to you on this earlier today. I have been out of the office since yesterday with every intention to check my emails every day while I am out this week, due to a family death. As such, if you do not mind, I would like to forward this to my boss.
Hi Marc, as shown below, Mr (b) (6) is now reviewing this file in addition to the IDE. I think that makes sense as well. Would you kindly have a look at his request below and respond while I am gone? If you could both keep me in cc, I would appreciate – I would like to continue being "present" albeit at night so it seems.
Thank you,
Claudia

From: (b) (6)
Sent: Tuesday, August 10, 2010 12:06 PM
To: Manikam, Claudia
Subject: P980049/S059 and P060027/S026

Claudia,

I understand that these submissions are related to the IDE supplement that I am currently reviewing (G090064-S006). As a result, these files have been transferred to me. I expect to have some feedback later this week

regarding the IDE supplement. In preparation for my review of the PMA supplements, can you outline the differences between the IDE and PMA submissions? Any additional information that you can provide will help expedite my review of the files.

Thanks,

Interdisciplinary Scientist / Scientific Reviewer
Food & Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Email
Office Phone

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0 Introduction

ELA submitted a 180-Day PMA supplement (P980049/S059 and P060027/S026) on June 26, 2010, and an IDE supplement (G090064/S006) on July 21, 2010 to request approval for a revised implant software version to its Paradym ICD/CRT-D family (W2.8.4) and associated revised programmer software versions (Smartview 2.22UG1 for commercial devices, and Smartview 2.22UC1 for investigational devices).

On August 10, 2010, ELA received one question from FDA reviewer ( ) via email. The purpose of this document is to provide an answer to the FDA question.

1 Differences between Bundled P980049/S059 P060027/S026 and G090064/S006 submissions

1.1 FDA's question

I understand that these submissions are related to the IDE supplement that I am currently reviewing (G090064-S006). As a result, these files have been transferred to me. I expect to have some feedback later this week regarding the IDE supplement. In preparation for my review of the PMA supplements, can you outline the differences between the IDE and PMA submissions?

1.2 ELA's answer

1.2.1 Implant software

First, it is important to understand that the purpose for the company to submit these PMA and IDE supplements is the same, i.e., to correct a rare implant software anomaly affecting dual-chamber Paradym DR model 8550 (approved under P980049/S050) and triple-chamber Paradym CRT-D model 8750 (approved under P060027/S011) and Paradym CRT-D SonR model 8770 (approved under G090064). Single-chamber Paradym VR model 8250 (approved under P980049/S050) is not affected by this anomaly.

It is also important to understand that all Paradym models (from the most complex to the least: CRT-D SonR model 8770, CRT-D model 8750, DR model 8550 and VR model 8250) share the same implant software by design, the specific feature/programming differences between each model and for each region of the world being managed through software lock-outs at the programmer level.

As a consequence, the proposed revised embedded software, W2.8.4, is the <u>same</u> for bundled PMA supplement P980049/S059 and P060027/S026 and IDE supplement G090064/S006. Section 2 of the main document (entitled Paradym Implant Software Validation) of both submissions and associated attachments [01] through [07] are therefore the same, the only exception being for section 2.12 of the main document (Implant software errata sheet) because such errata sheet is only made available for commercial devices.

1.2.2 Programmer software

From a programmer software standpoint, the Smartview versions are necessarily different between the PMA supplement (Smartview 2.22U**<u>G</u>**1, 'U' standing for United States and 'G' standing for general version, i.e. commercial) and the IDE supplement (Smartview 2.22U**<u>C</u>**1, 'C' standing for clinical version), because only the IDE software version must recognize investigational devices Paradym CRT-D SonR 8770 to allow them being interrogated and programmed during the course of the Clepsydra clinical investigation.

The key difference between the programmer versions of the PMA supplement and the IDE supplement is therefore the capability for Smartview 2.22UC1 to interrogate/program not only commercially approved Sorin devices (Paradym VR/DR/CRT, Ovatio VR/DR/CRT, Reply SR/DR, etc), but also investigational device Paradym CRT SonR model 8770, while Smartview 2.22UG1 can only recognize commercially approved Sorin devices.

All the lower-level programming modules contained in the Smartview application software are the same, as highlighted in the table provided in section 3.2.1, page 16 of 33 of the main document of the IDE supplement. See also section 1.2.3 below.

From a submission standpoint, the main document structure of the programmer software sections (corresponding to section 3) for both PMA and IDE supplements are similar (i.e., similar section 3 layouts for both submissions down to heading level 2), but the lower-level sections (heading level 3) are different because the programmer software versions used as predicate for comparison are different:

- The most recently approved commercial Smartview version, 2.20UG1, approved on June 28, 2010[i] under P980049/S057, was used as a starting point to introduce changes made in 2.22UG1 version.
- On the other hand, the most recently approved clinical Smartview version, 2.14UC1, approved on October 28, 2009 under G090064, was used as a starting point to introduce changes made in 2.22UC1 version.

As a consequence, because 2.14UC1 is an older version than 2.20UG1, in section 3 of the submissions, more changes are described in the IDE supplement (comparison between 2.22UC1 versus 2.14UC1) than in the PMA supplement (comparison between 2.22UG1 versus 2.20UG1).

However, from an attachment standpoint, it is important to note that only attachments [08] through [12] corresponding to Smartview packaging software tests differ between the two submissions, the other attachments [13] through [23] for lower-level Smartview programming module software tests being identical because as stated above the modules are the same.

1.2.3 Summary comparison table

As a conclusion, the table next page summarizes the differences between the two submissions.

[i] Please note that at the time the PMA and IDE supplements were submitted, the official FDA Approval Letter for Smartview 2.20UG1 (P980049/S057) had not yet been received by the company. However, informal discussion between Sorin and FDA allowed the company to assume that this approval was forthcoming, and therefore to use 2.20UG1 as a predicate Smartview version.

	P980049/S059 P060027/S016	G090064/S006	Corresponding Main Doc Section	Comment on Main Doc differences	Corresponding Attachments	Comment on Attachment differences
Paradym implant software (common to all clinical and commercial Paradym devices)	W.2.8.4	W.2.8.4	Section 2	No difference except Section 2.12 (errata sheet only for commercial devices)	[01] thru [07]	No difference
Smartview programmer (common to both Orchestra and Orchestra Plus programmer HW)	2.22UG1	2.22UC1	Section 3 More specifically: Section 3.2.1	Section layout similar Differences due to the fact the predicate Smartview version used for comparison purpose is different (2.20UG1 for 2.22UG1 and 2.14UC1 for 2.22UC1)	Smartview packaging tests [08] thru [12]	Different attachments (different Smartview versions)
Previously approved Smartview version (predicate)	2.20UG1	2.14UC1				
Can interrogate commercial Paradym devices?	YES	YES				
Can interrogate clinical Paradym CRT-D SonR devices?	NO	YES				
Can interrogate commercial Ovatio devices?	YES	YES				
Can interrogate commercial Reply/Esprit devices?	YES	YES				
Paradym programming module within Smartview (used to interrogate all Paradym devices)	2.08	2.08	Section 3.2.2	Differences due to the fact the predicate Smartview version used for comparison purpose is different (2.20UG1 for 2.22UG1 and 2.14UC1 for 2.22UC1)	[13] thru [18]	No difference
Manager module within Smartview (used to initialize communication between implant and programmer)	3.11	3.11	Section 3.2.3		[19] thru [23]	No difference
Ovatio programming module within Smartview (used to interrogate all Ovatio devices)	1.11	1.11	IDE Sup only: Section 3.2.4		N/A (modules already approved in predicate Smartview version 2.20UG1)	No difference
Reply programming module within Smartview (used to interrogate all Reply and Esprit devices)	1.09	1.09	IDE Sup only: Section 3.2.5			
Paceart module within Smartview (used to convert ELA Medical's patients' data into Paceart database)	1.09	1.09	IDE Sup only: Section 3.2.6			
HSO module within Smartview (used to manage secure access to the implant)	2.82	2.82	IDE Sup only: Section 3.2.7			

Attachment 2

From:
Sent: Saturday, August 14, 2010 2:00 AM
To:
Subject: P980049 S059 ELA Medical Paradym Implant and Programmer Software APPROVAL

Attachments: P980049 S059 ELA Medical Paradym Implant and Programmer Software APP 10 08 13.doc

Please find attached my software review of the submission supra, recommending APPROVAL.

MEMO OF

SOFTWARE REVIEW

of a MAJOR Level Of Concern device

PMA: P980049/S059

DATE: 11/10/09

FROM: Senior Biomedical and Software Engineer OSEL-DESE 301-796-2588

TO: ODE/DCD/PDLB Bldg 66 1250 301-796-6364

SUBJECT: Software review of bug fix to SORIN/ELA Medical's Paradym ICD/CRT-D Models 8750, 8550 and 8250, and associated Smartview programmer Software used on ELA's Orchestra and Orchestra Plus. ELA:

Succinct Conclusion: APPROVE

The information contained within this submission is sufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, this submission be approved.

SUMMARY:

The firm has identified a serious bug in their software, discovered initially in an incident in France. This submission requests approval to 1) fix the bug and 2) modify the programmer software to allow the programmer to upload the appropriately modified software into the implant.

Specifically, the currently implant software version W2.8.2 will be modified, and identified as versions W2.8.4. W2.8.2 is used in the Paradym ICD/CRT-D devices approved under P060027/S011 (Paradym CRT-D model 8750) on October 27, 2009, and under P980049/S050 (Paradym DR model 8550) on April 9, 2010. In addition, the current version 2.20 UG1 Smartview programmer software used on ELA's Orchestra and Orchestra Plus programmer will be modified and identified as version 2.22 UG1.

The software anomaly, a loss of pacing/sensing and ability to deliver therapies to treat an arrhythmia, was observed on a Paradym DR Model 8550 implanted in France, and remains implanted; no injury or death occurred as a result of the identified software anomaly.

The anomaly can occur when the criteria to charge the shock capacitors (due to a ventricular arrhythmia) and the criteria to mode switch (due to an atrial arrhythmia) are met exactly at the same time and the device delivers a shock (e.g. due to a sustained ventricular arrhythmia). When this occurs the software anomaly results in the protection circuit (which protects the device during the shock delivery) to not be automatically de-activated after the shock is delivered, resulting in the device to lose the ability to sense/pace and to deliver further therapy.

The software solution was to add a functional requirement to inhibit the Mode Switch algorithm during the cardiac cycle when the shock is delivered. The firm states that this requirement will fully address the software bug.

The firm sent a Dear Doctor Letter on June 7, 2010, to inform its physicians about this rare software anomaly and to provide them with programming workarounds that eliminate any potential effect related to the anomaly, until the revised software is made available. The associated correction report was sent to the FDA Minneapolis district office on June 17, 2010, in accordance with the timeframe set forth in 21CFR 806.10(b).

In addition to this main bug fix, the firm is correcting seven minor programmer software anomalies previously unresolved, pursuant to ELA's agreement in its response to the October 1, 2009, FDA Approvable Letter for P060027/S011 (Paradym CRT model 8750).

No hardware changes are made.

This device is used in the clinical study in G090064/S006 wherein the firm is requesting approval in that submission to make the software changes described supra. This software review encompasses files from both submissions.

Software Controlled Aspects of the Device

All components of the device are controlled/monitored by software, which is responsible for the functionality, user interface, safety checks and performance accuracy.

SOFTWARE REVIEW

When a firm wishes to update/enhance a device for which a submission has been previously cleared/approved from a software standpoint, only the following update information is needed.

1. **Updated Level of Concern: Acceptable**
   In Section 2.1 entitled Level of Concern, the firm confirmed that their Level Of Concern remains MAJOR. This is acceptable.

2. **Updated Software Description: Acceptable**
   In Section 2.2 entitled Paradym Software Description, **t**he firm provided an acceptable updated description of the modification made to the software.

3. **Updated Device (including software) Hazard Analysis: Acceptable**
   In Section 2.3 entitled Device Hazard Analysis, the firm provided an acceptable updated analysis of the hazards

presented by this device, and concluded that no new hazards were created. This is acceptable.

4. Updated Software Requirements Specifications (SRS): Acceptable
In Section 2.4 entitled Software requirements specifications and in Attachment 1 with the same title, the firm provided acceptable updated software requirement specifications, which documented the updated functional, performance and interface requirements.

7. Updated Traceability: Acceptable
In Section 2.7 entitled Traceability Analysis, the firm provided acceptable updated traceability, which provided the links between the requirements, validation and testing.

9. Updated Verification and Validation Documentation: Acceptable
In Section 2.9 entitled Verification and Validation documentation,, the firm provided an acceptable updated description of their Verification and Validation activities for the updates.

10. Updated Revision Level History: Acceptable
In Attachments 1 and 5, the firm provided acceptable updated revision history logs, which provides the history of software revisions generated during the course of product development.

13. Updated Compliance With Previously Reviewed Software Process: Acceptable
Although not explicitly stated, it is clear from the documentation that the firm is following the software process previously reviewed in a prior submission. This is acceptable.

RECOMMENDATION: APPROVAL

The firm has provided acceptable documentation demonstrating that they have developed the software for this device under an appropriate software development program; that they have performed a hazard analysis from both the patient's and user's standpoint, and addressed those hazards; and carried out an appropriate validation process. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way. It is recommended that from a software standpoint this submission be approved.