MEMORANDUM

SUMMARY OF:

P950029/S079
Updated flex circuit component and supplier
Sorin

BACKGROUND

Sorin is seeking approval for a modification to the flex circuit hybrid component as well as approval for an alternate supplier. This component is used in all Reply and Espirit Pacemakers.

The alternate component is functionally equivalent to the current one and the changes do not affect performance specifications of the devices. The purpose of the change is only to improve yield and reduce cost, not to address any complaints or field issues.

A Real Time Review Request was submitted for these changes on March 20, 2013. On April 18, 2013, Sorin received a rejection letter stating that the submission was not eligible for the RTR path because it requires a multidisciplinary review (engineering and QSR). Therefore these changes have been re-submitted as a 180-Day supplement.

The finished devices impacted by the changes are listed below:

Device Manufacturer	Device Family Name	Model	Type	PMA Supplement Ref.	Approval Date
Sorin	Reply/Esprit	SR	Single Chamber Pacemaker	P950029/S41	June 11th, 2009
Sorin	Reply/Esprit	DR	Dual Chamber Pacemaker	P950029/S41	June 11th, 2009

INDICATIONS FOR USE

The indications for use are not affected by the changes.

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

This PMA supplement is for a minor design modification to the pacemaker interconnection flex circuit component, and to request approval for a different supplier (b)(4) Trade Secret for this component. (b)(4) Trade Secret already supplies Sorin with a similar flex component for their ICD devices. After approval, the modified flex circuit component will be used in place of the current one. All device models affected by this change share the same internal electronic platform and overall assembly process.

Although the proposed change affects an electronic component of the assembled device (the flex circuit that ensures the electrical connection between the electronic hybrid module, the battery and the feedthrough components inside the device), the change involves a minor re-design of the flex pad. Per the sponsor, this change has no impact on the electrical connections

and therefore, no effect on the device's electrical performance, which remains unchanged from performance with the current component.

The following changes are proposed for the interconnection flex circuit:

1) An alternate flex supplier (b)(4) Trade Secret is introduced. (b)(4) Trade Secret is approved for ICD flex component manufacturing under P980049/S065 approved 10 April 2012.

2) The interconnection flex circuit pad (electronic hybrid module interface) is updated to reinforce the assembly. There is no change of layout and raw material.

3) The component control plans at supplier/incoming inspection levels are reinforced.
   a. At the supplier: (b)(4) Trade Secret
   b. At Sorin: (b)(4) Trade Secret

4) At Sorin, the (b)(4) Trade Secret

The flex circuit was part of the device approval (P950029/S041 June 2009). An updated revision of the flex was introduced in P950029/S069 (approved 30 July 2012) with an updated process assembly. Per the sponsor and since that change, manufacturing failures of the flex circuit have been noted at the in-process inspection (b)(4) Trade Secret An investigation determined that the induced component damage was occurring as a result of insufficient supplier capability to manufacture this flex circuit and flex interconnection (b)(4) Trade Secret

Per the sponsor, none of the devices impacted by the affected flex failures have been released or will be released.

The flex circuit was part of the device approval (P950029/S041 June 2009). An updated revision of the flex was introduced in P950029/S069 (approved 30 July 2012) with an updated assembly process. Per the sponsor and since that change, during manufacturing, flex circuit failures have been identified at in-process inspection (b)(4) Trade Secret resulting in reduced yield. An investigation has determined that the damage is being induced as a result of insufficient supplier capability to manufacture this flex circuit and to flex interconnection (b)(4) Trade Secret

RISK ANALYSIS

The sponsor states that a hazard analysis has been performed to assess the potential hazards associated with the changes in accordance with the company's risk management procedure MD013 which is included in the submission as attachment [3].

The sponsor provided the complete Hazard Analysis (AR357) in attachment [5] of the submission. Per the sponsor, the initial risk assessment (i.e., before mitigation) of the potential hazards related to the proposed change yielded a maximum risk level of I for which risk reduction is required, in accordance with MD013.

Reviewer Comment: The hazard analysis was reviewed and this information was found acceptable. The risk levels were found acceptable after the appropriate mitigations.

COMPONENT VERIFICATION

The sponsor provided the following summary of the component risks, the risk control measure, the sample sizes used, the test plan and report, and the status.

UID	Hazardous situation	IRL	Risk Control Measure Implementation	N(c)		Plan - Report {Group}	Status
				Minimum	Selected		
C01	(b)(4) Trade Secret						
C02							
C03							
C04							
C05							
C06							

The sponsor stated that they use their internal sampling procedure, MD017 (attachment [4] of the submission) to determine the required sampling plan for bench testing.

Section 4.15 of procedure MD017 describes the risk-based approach used by the company to determine the required minimum sampling plan when no reference to a US-military or FDA-recognized standard is available. Based on the initial risk levels assessed, the corresponding minimum sampling plan N(c) for the bench tests to be performed is therefore (b)(4) Trade Secret N is the number of samples and c is the number of defects allowed.

Reviewer Comment: The component qualification test plan (PLAN1560) and report (REP2542) were reviewed and found acceptable. The component qualification test plan covers the supplier and design changes. It appears that the sponsor has completed the appropriate qualification testing with the appropriate sample sizes. For each group, all verification tests successfully passed.

MANUFACTURING

Process Qualification

The sponsor provided the following summary of the process risks, the risk control measure, the sample sizes used, the test plan and report, and the status.

UID	Hazardous situation	IRL	Risk Control Measure Implementation	N(c)		Plan - Report {Group}	Status
				Minimum	Selected		
P01	(b)(4) Trade Secret						
P02							
P03							

UID	Hazardous situation	IRL	Risk Control Measure Implementation	N(c)		Plan - Report {Group}	Status
				Minimum	Selected		
P04	(b)(4) Trade Secret						
P05							
P06							
P07							

UID	Hazardous situation	IRL	Risk Control Measure Implementation	N(c)		Plan - Report {Group}	Status
				Minimum	Selected		
P08	(b)(4) Trade Secret						
P09							
P10							
P11							

UID	Hazardous situation	IRL	Risk Control Measure Implementation	N(c)		Plan - Report {Group}	Status
				Minimum	Selected		
P12	(b)(4) Trade Secret						

Reviewer Comment: The process qualification plan (PLAN1559) and report (REP2541) were reviewed and found acceptable. The process qualification plan defines the necessary tests to validate the (b)(4) Trade Secret *It appears that the sponsor has completed the appropriate qualification testing with the appropriate sample sizes.*

The sponsor stated that during operator training, one device not enrolled in the OQ tests, showed (b)(4) Trade Secret

Reviewer Comment: The process improvement technical note (MISC1814) was reviewed and found acceptable. As a result of the identification of the root cause, a process was changed which is identified as change #4 in the DEVICE DESCRIPTION AND CHANGE DESCRIPTION section of this memo.

Purchasing Control

The purchasing control associated which the change to the (b)(4) Trade Secret flex component consists of:

- Performing verifications for each lot according to control plan at supplier level which is described in attachment [1] of the submission (SC0T773 "Component specification" section 3.10 "Control plan").
- Performing incoming inspection step at Sorin level which is described in attachment [2] of the submission (PC0T773 "Component incoming inspection" section 4.1 "Certificate of Conformance" and section 4.2 "Inspection report").

Reviewer Comment: The purchasing controls were reviewed and this information was found acceptable. It appears that the proper controls which consist of incoming inspection and verification are in place. In the component specification, the control plan was added in which key measurements are defined and verified. (b)(4) Trade Secret *is already approved to supply the ICD flex component (P980049/S065). Also, incoming inspection steps at Sorin have been added for the coverlay/soldermask positioning verification for the new flex circuit design.*

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Clinical
- Animal Testing
- EMC/EMI

- Biocompatibility
- Human Factors
- Packaging, sterilization, shelf-life
- Labeling
- Marketing
- Post Market

SUMMARY OF INTERACTIONS

--NONE--

CONCLUSION/RECOMMENDATION

The results of the non-clinical studies confirm that there are no new or increased risks associated with these changes. The component and process qualifications demonstrate that the proposed change is safe and effective and can be made without affecting final device operation.

I recommend that the sponsor receive an **APPROVAL** letter.