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: 14 Jan 2011

From: (b)(5), Biomedical Engineer, FDA/CDRH/ODE/DCD/PDLB

Subject: P950022/S069/A001
St Jude Medical
Durata family of defibrillation leads

Contact: Geena George, Regulatory Affairs, St Jude Medical CRMD

To: The Record

Recommendation: **APPROVAL**

(b)(5), Lead Reviewer, PDLB Date

(b)(5), PDLB Date

SUMMARY

This PMA supplement was submitted to gain approval for the following changes to the St Jude Medical's Durata family of defibrillation leads: suture sleeve design change, introduction of new suture sleeve accessory kit for redesigned suture sleeve, reduction in FastPass coating length, and design modification to IS-1 crimp connection. Initially, FDA presented 7 major and 3 minor deficiency concerns in a letter dated July 30, 2010. The firm responded to those concerns in P950022/S069/A001.

The firm's responses adequately address FDA's initial concerns as documented in the Engineering Consultant review memo. The firm has provided comparative bench testing demonstrating their proposed IS-1 connector crimp design has improved performance relative to the current design, specifically with respect to the failure mode observed in the field. They also clarify that the proposed suture sleeve and accessory kit are intended only as replacements of the suture sleeve included in the lead package, therefore concerns of testing a lead fixed at multiple points is no longer an issue. And lastly, the reduction in FastPass coating was discussed with Dr. (b)(5); he and I have no outstanding concerns about the requested change since (1) that change is within the lengths of single coil models, (2) the reduction is relatively small ((b)(4)" proximally) and (3) the testing provided is as good as can be expected with respect to assessing clinically relevant performance criteria in a bench

setting. Minor labeling concerns were addressed interactively and final labeling will be submitted to FDA upon receipt of an Approval Order for the supplement.

No concerns remain with this submission, and I recommend approval.

Indications For Use

The Durata defibrillation leads are intended to be used with compatible pulse generators to provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart. The sponsor indicates that no changes have been made to the indications for use for the Durata leads as a result of the requested changes.

> *LEAD REVIEWER COMMENTS: The changes described in this submission would not affect either the indications or contraindications for use, and, therefore, I have no concerns about this section of the review.*

Device Description

The Durata family of defibrillation leads includes active and passive fixation models with bipolar or integrated sensing configurations and dual or single coil designs. All involved models are listed on pages 65 to 67 of the submission. Although some of the subject changes were verified in the Riata models, SJM plans to discontinue those families in 2010 and, therefore, is only requesting approval of the changes in the Durata models.

Detailed Description of Changes

Change #1: Suture Sleeve Modifications.

Modification	Reason for Change
1. Increased width of nubs and positioned nubs under center groove	To optimize the effect of the tie-down force exerted by the suture
2. Wider groove for tie-down	To allow additional tie-downs within the same groove (if desired by the physician)
3. Longer leading edge with decreased radius	To facilitate suture sleeve placement into the vein or facia during tie down as an improvement for ease of implant.

No change have been made to the materials or manufacturing processes. The change was made in response to user feedback. One MDR has been filed relating to suture sleeve complaints. These changes are intended to ease the implant procedure by requiring less tie-down effort from the physician while maintaining the desired slip force. The current design and proposed design are illustrated on page 3 of the submission. The firm requests approval for the illustrated suture sleeve in addition to a new 7Fr suture sleeve accessory kit (Model DS0A001) which will contain a slit version of the same modified suture sleeve design.

Change #2: Reduction in PVP (Fast Pass) Coated Length

Currently, the PVP coated region on dual shock Durata leads extends (b)(4) inches proximal from the SVC shock coil. The firm requests to shorten this distance to (b)(4) inches from the shock coil. The firm indicates that this change would maintain a coated length within the existing range of coated lengths present in SJM single shock lead models.

Change #3: IS-1 Connector Design Modifications

This change is made to decrease the effects of flex fatigue. Ten MDRs associated with flex fatigue of the IS-1 connector had been identified and reported for the Durata leads. The existing crimp process will still be used, but the crimp core length will be reduced and view holes will be added to ensure the outer coil and crimp core are fully inserted prior to crimping.

Modification	Reason for Change
1. Reduction of the crimp core length, from (b)(4) " to (b)(4) ".	The reduction in crimp core length better allows for internal flexural bending of the IS-1 coil, reducing stresses that may lead to flex fatigue.
2. Addition of view holes on the connector ring	This change will aid visual inspection that the outer coil and crimp core have been fully inserted into the connector ring, prior to crimping.

These changes are illustrated on page 6 of the submission.

Preclinical/Bench Evidence

The firm supports the approval of the three described modifications with Verification Testing documented in Appendices of the original submission that included suture sleeve qualification testing (Appendix 2), suture sleeve accessory kit testing (Appendix 3), PVP coated length handling test (Appendix 4), and connector qualification testing (Appendix 5).

LEAD REVIEWER COMMENTS: (b)(5) *provided the engineering review for the submission. She documented a thorough review of the original testing provided in P950022/S069 and submitted separately in response to FDA's major deficiency letter. Her comments from memos dated 19 July 2010 and 14 Jan 2011 are summarized below:*

Suture Sleeve Changes:

The proposed changes appeared acceptable from an engineering perspective. As the firm indicated, the new location of the nubs should help more efficiently transfer the force of the sutures to the lead and decrease the tie-down force required from physicians. The new location also increases the Moment of Inertia at the grooves. All specimen passed acceptance criteria in the testing conducted and no concerns were found with the unslit sleeve.

The firm also requested to market a slit version of the suture sleeve. Initially FDA understood that the slit version was for use when a physician wants to use two sleeves on the lead body. The presence of two sleeves presented concerns from an engineering and flex fatigue perspective: the distance between the two suture sleeves may affect the relative motion of lead body between them and, therefore, the flex fatigue performance. The firm was asked (1) to clarify when the slit suture sleeve was intended to be used and (2) if the intended use included multiple sleeves on the lead at one time, to conduct additional fatigue testing to assess the lead's mechanical performance in such a situation. In A001, the sponsor clarified that only one sleeve should be on the lead at any time. Revised labeling incorporating a warning to the user of the potentially negative impact on lead fatigue performance if more than one sleeve was placed on the lead at any given time was also provided. The firm's response was deemed appropriate and no concerns remain.

PVP Coated Length Change:

The bench testing provided to support the decrease in FastPass coating was initially concerning largely due to the lack of supporting rationale regarding the degree to which the test fixture and protocol provide clinically relevant assessments of handling performance. The firm provided supporting rationale in A001 which was discussed with Dr. (b)(5) *. He indicated reservations with the ability of a bench test to adequately assess clinical handling performance at all, but, that being said, he did not have large concerns with the proposed reduction in coating due to (1) the relatively small length change and (2) the fact that the proposed length is within that approved for other single coil models. Based on my discussions with him, I have no further concerns with the proposed change to decrease the FastPass length.*

Connector Crimp Change

The proposed changes initially presented some engineering concerns regarding (1) potential impact on crimp strength, (2) potential stress concentration introduction by viewing holes, and (3) lack of comparative testing to confirm the proposed design adequately addresses the observed field performance issues. In A001, the firm addresses each of these concerns adequately:

(1) Crimp strength testing was conducted demonstrating statistically significant fixation strengths of the proposed and current designs.
(2) An engineering justification was presented that specifically detailed the loading at the viewing holes and referenced the relevant results of flex fatigue testing.
(3) Comparative testing was conducted to confirm both the suspected root cause of failures seen in the current design and superior performance of the proposed design.

No concerns remain from an engineering perspective with the proposed connector crimp change.

Packaging

On page 8 of the submission, the firm indicates that the packaging process, package material, and package integrity of the leads have not changed as a result of the proposed modifications. The leads will be packaged in the same packaging configuration as market-approved Durata leads: a double aseptic package composed of Polyethylene Terephthalate Glycol polyester (PETG) with a Tyvek lid.

LEAD REVIEWER COMMENTS: The proposed lead packaging is identical to the market-approved lead packaging. The proposed modifications would not affect the ability of the already approved packaging to provide an acceptable protective sterile barrier from environmental stresses and transport; therefore, I have no concerns about the packaging of the subject leads.

The suture sleeve accessory kits will be packaged and labeled by (b)(4), an established and approved packaging vendor for the firm. The packaging is based on the packaging of the market-approved suture sleeve kit model SS-1056 approved under P030053/S018 in 2006: a double Mylar-Tyvek pouch configuration.

LEAD REVIEWER COMMENTS: In the major deficiency letter sent 30 July 2010, FDA requested a detailed comparison of the accessory kit packaging for the predecessor SS-1056 and the subject kit. That information was provided in A001 and reviewed by (b)(5), the engineering consulting reviewer. As documented in her memo dated 14 Jan 2011, the only difference is the size of the outer pouch (from (b)(4)" by (b)(4)" to (b)(4)" by (b)(4),"). This larger pouch and modified configuration was cleared under K090163 for use with a stylet package. Since the proposed packaging has already been evaluated, no concerns remain. The differences between the proposed suture sleeve accessory kit and the market-approved SS 1056 kit and 4090 stylet kit would not impact the ability of the packaging to function as intended.

Shelf Life

The firm requests a 3 year shelf life for the Durata leads. All steroid-eluting St Jude Medical leads have been approved for this shelf life under P960030/S009, P960013/S012, and P950022/S015.

LEAD REVIEWER COMMENTS: The differences between the proposed lead and its market released predecessor would not affect the 3 year shelf life. Therefore, I have no concerns about approving the lead shelf life requested by the firm.

Initially, no specific request or supporting testing/rationale for the shelf life of the suture sleeve accessory kit were provided. In A001 the firm requested a 3 year shelf life and supported this request by noting that the predecessor SS-1056 accessory kit and 4090 stylet package (both of which have similar packaging compared to the subject kit) are market-approved for a 3 year shelf life. (b)(5) provided a review of these issues in her engineering review memo dated 14 Jan 2011 and indicated no concerns with the firm's approach.

Sterilization

The firm indicates on page 8 of the submission that the suture sleeve kit will be sterilized by an approved sterilization vendor, (b)(4). This method is identical to that of the market-approved Suture Sleeve Accessory Kit SS-1056 as indicated on page 49 of the submission. A discussion of the sterilization procedures to be used on the Durata leads package with the proposed unslit suture sleeves was not provided.

LEAD REVIEWER COMMENTS: Initial concerns regarding the documentation of sterilization validation activities for the new accessory kit and details of the sterilization process for the leads package were communicated in the 30 July 2010 deficiency letter. In their response to that letter (A001), the firm indicated no changes to the sterilization process for the lead package have been made and that appropriate sterilization validation activities (including bioburden, (b)(4), etc) have been conducted on the new accessory kit as documented in the product adoption memo. No concerns with sterilization remain since (1) no changes have been made to the lead sterilization process and the changes proposed would not affect the acceptability of the approved process and (2) appropriate validation activities have been conducted and documented for the new accessory kit.

Biocompatibility

The firm indicates on page 7 of the submission that no new materials with blood/tissue contact have been introduced as a result of the proposed modifications.

LEAD REVIEWER COMMENTS: Since no new materials or manufacturing processes are being introduced with the implementation of the described changes, I have no concerns about the biocompatibility of the subject device and accessory.

Clinical Data

No clinical data was provided to support approval of this submission.

LEAD REVIEWER COMMENTS: The proposed modifications are such that appropriate evaluation can be made with a risk assessment and in a bench testing environment. I have no concerns about the absence of clinical data to support the requested changes.

Labeling

On page 8, the firm indicates that no changes have been made to the intended use, contraindications, warnings or precautions for the Durata family of defibrillation leads as a result of the proposed modifications. The suture sleeve kit will require a new label as a result of the new model number: DS0A001. The draft label is provided in Appendix 6.

LEAD REVIEWER COMMENTS: Two initial concerns were communicated to the firm regarding the provided labeling. First, the firm proposed to label the new suture sleeve kit as compatible with "7 Fr" leads instead of specifically calling out the lead families with which the sleeve was safe to use. Second, the firm did not clearly indicate in their specification sheet for the lead if the accessories compatible with the product were provided in the lead package or

had to be obtained separately. FDA was concerned that physicians would be confused about where to locate a tool when needed if some were included in the lead package and some were not. In A001 and subsequent interactive email and telephone conversations, the firm adequately addressed both of these concerns: (1) labeling will be modified to indicate exactly the lead families with which the suture sleeve can be safely used and (2) the firm clarified that all accessories are provided both in the lead package and separately. No concerns remain; the firm will submit final labeling upon receipt of the Approval Order for this submission.

Risk Management

The firm provides an updated risk analysis that includes the design modifications detailed in the submission. The changes to the Risk Management Report are provided in Appendix 1. On page 20 of the submission (within Appendix 1), the firm lists the new features, enhancements, and methods that are evaluated in the Risk Management report. In this list they include the reduction of the crimp core length and the addition of the view holes. They also list "Addition of tab and reduction of thickness on serial number label for Durata," and "Usage of (b)(4) for outer coil of IS-1 connector on Durata." The firm indicates that no new risks were identified for the evaluated design changes.

LEAD REVIEWER COMMENTS: Initial concerns were identified with the provided risk assessment: the link between the changes requested and the updates made to the risk assessment were unclear. The firm did not clearly indicate all changes being requested were assessed for their impact of safety and effectiveness of the subject devices. In A001, the firm addresses this concern, clearly stating that all changes were assessed and no new risks or changes to current risk profile were identified. Separately, the firm clarified that they were requesting approval for two changes not detailed previously in the submission (although minor in nature). The firm's responses adequately address FDA's initial concerns- the firm has appropriately documented its review of the risks associated with the subject changes and determined no new risks are applicable.

Manufacturing

The Durata lead family will be manufactured at the St Jude Medical (b)(4), and (b)(4) facilities, all of which are FDA-approved.

The manufacturing sites listed are already being used for production of the market-approved Durata leads and accessories. The proposed modifications and new suture sleeve kit would not affect the ability of the cited facilities to manufacture the devices using approved protocols and in compliance with FDA Quality System Regulation 21 CFR 820, and I have no concerns about the production of the subject leads and accessories.