MEMORANDUM

SUMMARY OF:

P960013/S068/A001 Tendril Leads Helix-Shaft Subassembly modification
P950022/S079/A001 Durata Leads Helix-Shaft Subassembly modification
St. Jude Medical

BACKGROUND

This supplement is requesting approval for minor design changes to the helix-shaft subassembly of market approved Tendril Models 1882, 1888, 1988, 2088 and Durata Models 7120Q, 7121Q, 7122Q, 7120, 7121, 7122, 7130, and 7131 leads for improved manufacturability and cost. On October 19, 2011, FDA communicated that this change could not be adequately reviewed in a "real-time" setting and requested additional information that has been included within this submission.

In **Amendment A001**, St. Jude responded to the FDA deficiency letter dated January 31, 2012. During the course of reviewing this amendment, follow-up questions were sent and responded to interactively.

INDICATIONS FOR USE

The indications for use, contraindications, warnings and precautions for the Tendril and Durata family of leads have not changed.

No modifications were made to the Tendril and Durata User's manuals. No new materials are used. The packaging and sterilization methods remain unchanged.

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

St Jude Medical is proposing a minor design change to the helix-shaft subassembly of the market approved Tendril and Durata family of leads for improved manufacturability and cost.

The Tendril and Durata family of leads are designed and manufactured by St. Jude Medical CRMD for long-term implantation. For the Tendril and Durata family of leads, SJM is proposing a slight modification to the interface of the helix to shaft incorporating a geometry that is used on other SJM market approved 1488 leads (Figure 1 and 2) as well as changing the shaft material from (b)(4) to (b)(4). Both (b)(4) and (b)(4) are approved blood/tissue contacting materials and have long standing use in the same application as in other market approved St Jude Medical leads.

All dimensions that affect the functional performance of the helix-shaft assembly of the lead are unchanged (Figure 4 and 5) and therefore there is no change to the functional performance of the helix-shaft assembly within the lead. SJM is proposing an (b)(4)

(b)(4). These modifications are not in response to any field issues.

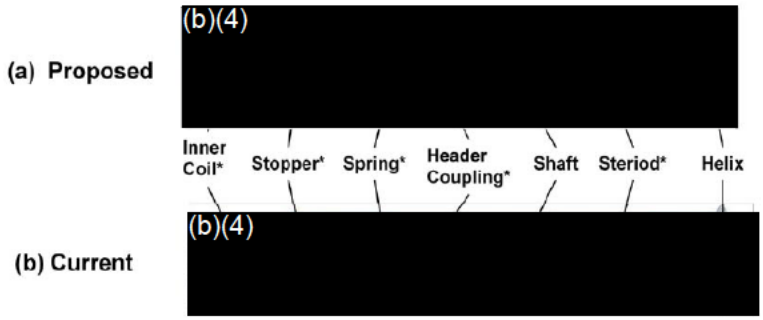

Figure 1: 1882/1888/1988/2088 Helix-Shaft assembly before and after modification. Note: a "*" indicates the component is identical between the proposed and current design.

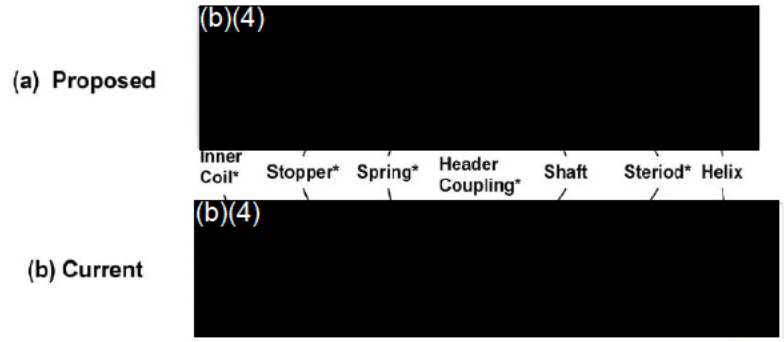

Figure 2: Durata Helix-Shaft assembly before and after modification. Note: a "*" indicates the component is identical between the proposed and current design.

The helix design is not new, nor is the material as it is used on the current market approved Model 1488 lead. Per the sponsor, the Tendril Model 1488 lead approved under P960013/S07 on March 7, 2000, has demonstrated a long history of proven reliability. The Model 1488 lead and the proposed helix design both incorporate a (b)(4). The product specification and welding requirements remain unchanged with the proposed helix-shaft design as demonstrated by the (b)(4) testing done in qualification testing. The shaft design is not new, nor is the material as it is used on the current market approved Model 1488 lead. As shown in Figure 3 below, (b)(4) is used in the same application in both the Model 1488 lead and the proposed assembly.

For both the Model 1488 assembly and proposed helix-shaft assembly, the connection design on the proximal end of the shaft includes an (b)(4). In addition, the connection on the distal end of the shaft includes an (b)(4).
The product specification and welding requirements remain unchanged with the proposed helix-shaft design.

1488 Helix-Shaft Assembly **Proposed Helix-Shaft Assembly**

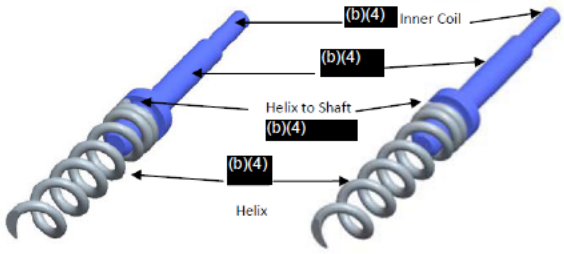

Figure 3: 1488 Helix-Shaft Assembly and Proposed Helix-Shaft Assembly

The interaction of the helix-shaft assembly with its adjacent components remains unchanged. As can be seen in Figure 4 and Figure 5, the assembly's (shaft and helix) outer and longitudinal dimensions remain identical to the current helix-shaft design. The helix extension/retraction specification has not changed. Helix extension/retraction testing was performed during qualification testing, and all samples passed the criteria.

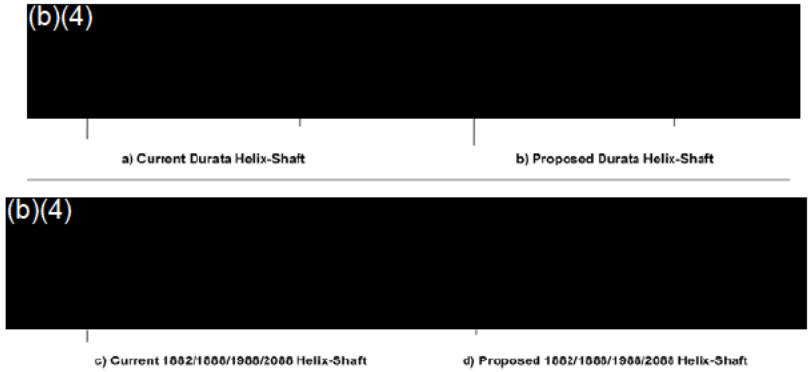

Figure 4: Diametric Comparison for the Current and Proposed Helix-Shaft Assembly (all displayed dimensions are in millimeters).

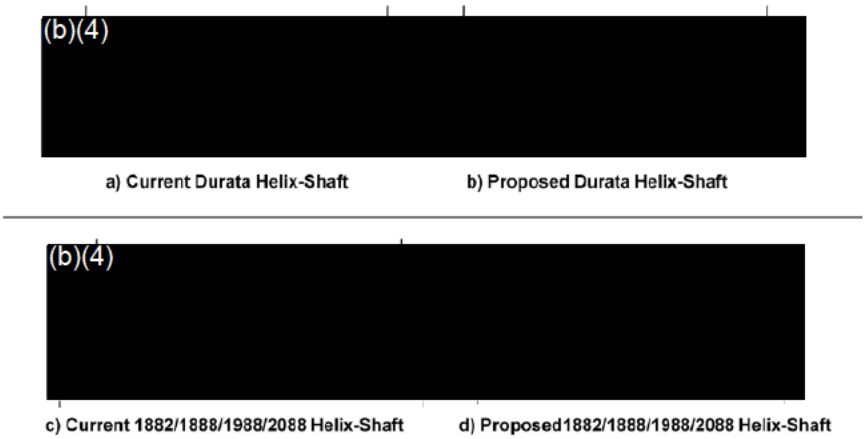

Figure 5: Longitudinal Comparison for the Current and Proposed Helix-Shaft Assembly

All dimensions that affect the functional performance of the helix shaft assembly of the lead are unchanged. The product specifications are unchanged. All samples satisfied all the test requirements specified in the qualification test plan.

In her original review memo dated Jan 19, 2012, the Mechanical Reviewer reviewed the proposed design changes and identified a major deficiency which requested historical performance data for the Model 1488 helix design.

In **Amendment A001**, the sponsor responded to the deficiency. The response was reviewed by the Mechanical Reviewer. During the course of the review, additional questions were interactively discussed. The reviewer found the responses acceptable.

RISK ANALYSIS

The Risk Management Reports summarizes the product and process risk assessment activities associated with the Tendril and Durata family of leads. The Risk Management Report for Tendril lead 1882/1888 is provided in Appendix 1a of the submission and Tendril lead 1988/2088 is provided in Appendix 1b of the submission. The Risk Management Report for Durata leads is provided in Appendix 2 of the submission.

For all three Risk Management Reports, the proposed changes were evaluated for impact to overall risk and no significant change in risk was identified. There were no new hazards identified with any of the mitigations proposed.

This information was reviewed and found acceptable by both the Mechanical Reviewer and myself.

BENCH TESTING

(b)(4)

(b)(4)

In **Amendment A001**, the sponsor responded to the multi-part deficiency. The response was reviewed by the Mechanical Reviewer. During the course of the review, additional questions were interactively discussed. The reviewer found the responses acceptable.

POST MARKET

A discussion was held on January 27, 2012 with Erin Cutts, Kelly Bauer, Diane Dwyer, and Dharmesh Patel to review Post Market signals related to the Tendril and Durata family of leads.
(b)(4)
(b)(4) (b)(4)

This information will be reviewed when provided by the sponsor. Based on the results, further investigation may be necessary.

In **Amendment A001**, the sponsor responded to the deficiency. The response was reviewed by the Mechanical Reviewer. During the course of the review, additional questions were interactively discussed. The reviewer found the responses acceptable and no further investigation is necessary. (b)(4)

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Clinical
- Animal Testing
- EMC/EMI
- Biocompatibility
- Manufacturing
- Human Factors
- Packaging, sterilization, shelf-life
- Labeling
- Marketing

SUMMARY OF INTERACTIONS

Original:
NONE – No additional contact with the sponsor was necessary.

Amendment A001:
8/1/12: Additional questions sent to sponsor
8/30/12: Final response from sponsor to additional questions

CONCLUSION/RECOMMENDATION

Based on the additional information provided in **Amendment A001** and the interactive discussion, the remaining concerns are now resolved. The sponsor has shown that the helix shaft subassembly change is safe and effective at this time.

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