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: March 29, 2010

From: Erin Cutts, Biomedical Engineer, FDA/CDRH/ODE/DCD/PDLB

Subject: P960013/S054
St Jude Medical
Tendril STS Model 1988TC Pacing Lead

Contact: Beena Flynn, Regulatory Affairs, St Jude Medical, CRMD

To: The Record

Recommendation: **Approval**

Erin Cutts, Lead Reviewer, PDLB Date

Mitchell Shein, Chief, PDLB Date

Background/ Reason for Supplement

This PMA supplement was submitted to gain approval for a new pacing lead, the Tendril STS Model 1988TC. This model is identical to the market-approved Tendril STS Model 2088TC except that Fast Pass coating is incorporated on the lead body of the market-approved lead, but will be present on the new model. The insulation of both leads is a proprietary hybrid material called (b)(4) The firm believes that this material acceptably reduces the frictional resistance encountered during implantation, making the Fast Pass coating unnecessary.

Review Team

Engineering: Erin Cutts, FDA/CDRH/ODE/DCD/PDLB
Clinical: Brian Lewis, MD, FDA/CDRH/ODE/DCD/PDLB

Indications For Use

The St Jude Medical Tendril STS Model 1988TC lead is intended for chronic pacing and sensing in the right ventricle and right atrium when used in conjunction with a compatible pulse generator.

Device Description

The Model 1988TC lead is a device/drug combination product made up of two regulated components: (1) a device (the Model 1988TC lead) and (2) a drug component (320 to 760 µg dexamethasone sodium phosphate (DSP) per lead located in a Monolithic Controlled Release Device (MCRD)). The active fixation lead contains an IS-1 bipolar connector and is intended to be used with a stylet and a 6 French introducer.

Preclinical/Bench

The firm provides documentation of functional/mechanical testing and in-vivo physician handling data to support approval of the new lead model without Fast Pass coating.

Verification Testing

The engineering review was performed by CDRH/ODE reviewer Erin Cutts and documented in a review memo dated 12 February 2010. The firm provided the protocol and results for all verification tests. The tests were performed using the Model 2088TC lead and were identical to those used to support approval of the Model 2088TC in P960013/S046.

Engineering reviewer comments:
The provided verification test protocols and results are appropriate and acceptable to support approval of the new lead. The only difference between the Model 1988TC and 2088TC leads is the presence of Fast Pass coating on the lead body. An initial concern about the use of testing on Model 2088TC lead to support approval for Model 1988TC lead was addressed via email (attached). Based on this correspondence and a review of the test protocol, the engineering reviewer believes the presence or absence of coating should not affect results of the tests conducted; therefore, test results of the Model 2088TC are appropriately cited to support approval of the Model 1988TC lead, and no additional testing is needed to demonstrate performance of the lead without Fast Pass coating. The test results support approval of the Tendril STS Model 1988TC lead, and no concerns remain.

Physician Handling Assessment

The clinical review was performed by Dr. (b)(6) and documented in a review memo dated 15 January 2010. The firm provided data from a non-GLP animal study to document acceptable handling performance of the new lead without Fast Pass coating. Two acute studies were performed by two different physicians in two separate porcine models. In each study, the physician was asked to rate the ease of insertion of different leads. Two leads were tested together to mimic the clinical scenario of having one lead in place during implantation while a second is inserted. Positive and negative controls were established using two low friction leads and two high friction leads, respectively. Results indicated the acceptance criterion of a rating of at least 3 (indicating similar handleability to the positive control) was met in both studies.

Clinical reviewer comments:
The provided testing is appropriate and demonstrates acceptable handling performance. The proposed rating scale appears reasonable. The results, however, were not entirely clear and the following concerns should be communicated to the firm. Compared to the prior model (Model 2088TC), the new Model 1988TC without Fast Pass coating demonstrated increased friction- the current model underperformed relative to the prior model when both physicians were asked to assess performance. Also, the prior model, the logical comparator, was not used as the positive control. Instead, two models with silicone insulation and Fast Pass coating served this purpose. In addition, the negative control, silicone against silicone, is not a market-approved lead design. The clinical reviewer believes interactive discussion between FDA and the firm may appropriately address these concerns.

Lead reviewer comments:
The clinical reviewer's concerns were communicated to the firm via email. Based on the firm's initial response and further internal discussions within FDA, the review team decided that the firm's documentation demonstrated adequate performance of the new Model 1988TC lead without Fast Pass coating. While handling performance was not as good as the predecessor, the supporting evidence did indicate that performance was acceptable relative to other market-approved leads. FDA communicated to the firm its concerns about user awareness and understanding of the differences in lead handling performance between the predecessor and the new model. Afterwards, FDA and the firm worked interactively to develop labeling wording that clearly informs the user of these differences. The final redlined labeling is included after the lead review memo as is the email conversation to which it was attached. FDA has no further concerns and believes the new labeling adequately informs the user of the handling performance of the new lead.

Packaging and Shelf Life

A three year shelf life was approved for all Tendril lead families on 22 January 2003 under P960030/S009, P960013/S012, and P950022/S015. The firm believes the Model 1988TC lead should also have a 3 year shelf life based on this prior approval.

Lead reviewer comments:
The new lead is of the same materials and similar design compared to the predecessor and other Tendril leads; therefore, it presents a similar if not identical sterilization challenge, and FDA believes the three year shelf life previously approved for related models is appropriate for the new lead as well.

Clinical Data

The device's functionality and performance should not change with the removal of Fast Pass coating. Therefore, no clinical data was required to support approval of this supplement.

Summary of interactive Review/correspondence

02 February 2010
Email sent to firm with initial questions regarding verification test specimen and handling performance.

08 February 2010
Email response provided by firm.

16 February 2010
Email sent to firm indicating submission is approvable with the exception of the labeling. Specific labeling concerns were presented for the firm to address prior to approval being granted.

26 February 2010
Email provided by firm with revised labeling to address labeling concerns

23 March 2010
Email sent to firm with revisions to labeling from clinical reviewer; phone conversation held between lead reviewer and firm to discuss FDA's revisions

24 March 2010
Email provided by firm with final revision of labeling

25 March 2010
Email confirmation provided by clinical reviewer for final revision of labeling

Conclusion

The firm has provided acceptable documentation of mechanical/functional performance and physician handling performance of the new lead. Based on the similarity in design and construction, verification testing of the predecessor lead was determined by FDA to adequately demonstrate the mechanical and electrical performance of the new Tendril STS Model1988TC. Simulated in vivo physician assessments demonstrated that handling performance of the new lead, while not rated as highly as that of the predecessor, is acceptable. Revised labeling constructed interactively between FDA and the firm clearly informs the user of the differences between the predecessor Model 2088TC lead and the new Model 1988TC lead.