



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 24, 2014

Jennifer Zwiefelhofer
Director, Regulatory Affairs
St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117

Re: P130026
TactiCath Quartz® Catheter and TactiSysQuartz® Equipment
Filed: November 29, 2013
Amended: December 16, 2013; December 20, 2013; January 01, 2014; January 23,
2014; January 24, 2014; February 3, 2014; February 6, 2014; February 21,
2014; March 18, 2014; April 1, 2014; April 3, 2014; April 9, 2014; July 22,
2014; August 20, 2014
Procode: OAE

Dear Ms. Zwiefelhofer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the TactiCath Quartz® Catheter and TactiSysQuartz® Equipment. This device is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible radiofrequency generator and three-dimensional mapping system. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 2 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

As a condition of approval you have agreed to conduct a post approval study for the TactiCath Quartz® Catheter. In addition to the Annual Report requirements, you must provide post-approval study (PAS) reports in accordance with the approved PAS protocol (received August 20, 2014, Version A). Two (2) copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. An overview of the PAS protocol Version A received on August 20, 2014 follows:

- TactiCath Quartz PAS Study: The PAS study will confirm that chronic performance of the TactiCath Quartz catheter with the modified force measurement sensor is acceptable and consistent with the TactiCath Set catheter with the old force measurement sensor. This will be a prospective, non-randomized, multicenter, study to evaluate the safety and effectiveness of the TactiCath Quartz Percutaneous Ablation Catheter for the treatment of symptomatic paroxysmal atrial fibrillation using contact force assisted irrigated radiofrequency ablation.
 - a. The primary safety endpoint will assess if the rate of device or procedure related serious adverse events occurring within 7 days of the index procedure or hospital discharge, whichever is later, is lower than a performance goal of 16.2% with 95% power and 0.05 alpha.
 - b. The primary effectiveness endpoint will assess if the rate of subjects free from symptomatic paroxysmal atrial fibrillation (PAF), atrial flutter (AFL), and atrial tachycardia (AT) lasting longer than 30 seconds through 9 months of follow-up (after a 3- month blanking period) is higher than a performance goal of 54.9% with 80% power and 0.05 alpha. Procedural failure is defined by the occurrence of any of the following events:
 - Documentation of recurrence of AF/AFL/AT episodes during the 9-month observational period lasting longer than 30 seconds
 - Repeat ablation following the blanking period
 - Use of a new antiarrhythmic drug (AAD) following the blanking period (use of a previously ineffective drug does not constitute treatment failure)

- c. Patients will be evaluated at pre discharge, at 7 days, at 3, 6, and 12 months post index procedure and then yearly thereafter through 5 years. A total of 175 patients will be enrolled in up to 35 U.S. sites through 12 months.

Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. Additionally, please be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

(www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on

the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Deborah Castillo at (301) 796 - 4908.

Sincerely yours,


Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health