



December 21, 2017

Boston Scientific Corporation  
Rachelle Register  
Principal Regulatory Affairs Specialist  
4100 Hamline Ave. North  
St. Paul, Minnesota 55112

Re: P150005/S014

Trade/Device Name: Blazer Open-Irrigated Ablation Catheter and  
IntellaNav Open-Irrigated Ablation Catheter

Filed: May 16, 2017

Amended: July 12, 2017

Product Code: OAD, OAE

Dear Rachelle Register:

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) supplement for the Blazer Open-Irrigated Ablation Catheter and IntellaNav Open-Irrigated Ablation Catheter for expanding the indication to include treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation. The Blazer and IntellaNav Open-Irrigated Ablation Catheters, when used with a compatible Radiofrequency Controller and Irrigation Pump, are indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, radiofrequency ablation of sustain or recurrent Type 1 Atrial Flutter in patients age 18 or older, and treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system. We are pleased to inform you that the PMA supplement is approved. You may continue commercial distribution of the device upon receipt of this letter.

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 three (3) years for the Blazer and IntellaNav Open-Irrigated Catheters.

Continued approval of the 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. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, <http://www.fda.gov/udi>.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA 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.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of each report, identified as "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

**OSB Lead PMA Post-Approval Study – Zero-AF PAS:** The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval.

The purpose of this study is to evaluate the short- (peri-procedural and one-year) and longer-term (through three years) safety and effectiveness of the Blazer Open-Irrigated catheter family for *de novo* atrial fibrillation ablation procedures. The study will be conducted within a prospective, multi-arm, sponsor-led registry. A minimum of 329 subjects will be enrolled at up to 50 centers (in the U.S., European Union, Asia, Middle East, and Africa), with at least half of those centers located in the U.S. No single center will account for more than 10 percent of study subjects. Subjects will be followed through three years.

The primary safety endpoint will be freedom from acute (i.e., within 7 days post-procedure) or chronic safety events at 12 months post-procedure. The primary safety hypothesis is that the safety endpoint event-free rate will be greater than the performance goal of 85% at 12 months post-procedure. The primary effectiveness endpoint will be freedom from procedure failure at

12-months post-procedure using a strict definition of failure (i.e., use of any anti-arrhythmic drugs (AADs) after the blanking period will be considered a mode of procedure failure). The secondary effectiveness endpoint will be freedom from procedure failure at 12 months using a less strict definition of failure (i.e., increased use or new type of AADs used after the blanking period will be considered a mode of procedure failure). The hypotheses for the primary effectiveness and secondary effectiveness endpoints are both that the 12-month failure-free rate will be greater than the performance goal of 50%. Additional endpoints will include: a descriptive evaluation of treatment failure at 24 and 36 months post-procedure, descriptive summaries of all reportable safety events through 36 months post-procedure, and an evaluation of the effectiveness of the training program via stratification of the primary safety and primary effectiveness outcomes by center experience. Subgroup analysis will also be provided for all endpoints stratified by age ( $\leq 60$  vs.  $> 60$  years of age), gender (male vs. female), and repeat procedures during the blanking period (subjects who had any repeat procedure within 90 days of index procedure vs. subject who had no repeat procedure during this period).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described above. Your PMA supplement should be clearly labeled as OSB Lead PMA Post-Approval Study Protocol as noted above and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Please be advised that the description of the Analysis Plan, interim (per agreed plan), and final study results will be published per protocol on the FDA Post Approval Study Webpage (<http://www.fda.gov/devicepostapproval>). Please also be advised that the results from this study 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.

For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" ([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2)).

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.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage <http://www.fda.gov/devicepostapproval>.

In addition, the results from any post approval study 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. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm>).

Before making any change affecting the safety or effectiveness of the PMA 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"

<http://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 <http://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 <http://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 <http://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 final labeling. Final 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 labeling is identical to the labeling approved in draft form. If the final 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 Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Tanya Farooque, PhD, at 301-796-7486 or [Tanya.Farooque@fda.hhs.gov](mailto:Tanya.Farooque@fda.hhs.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

for

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