October 27, 2023

Boston Scientific Corporation
Amy Reilly
Regulatory Affairs Specialist
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Re: K233207
Trade/Device Name: Polaris X™ Unidirectional Steerable Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: September 28, 2023
Received: September 28, 2023

Dear Amy Reilly:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233207

Device Name
Polaris X™ Unidirectional Steerable Diagnostic Catheter

Indications for Use *(Describe)*
The Polaris X catheter is indicated for use to diagnose cardiac arrhythmia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for Polaris X™ Unidirectional Steerable Diagnostic Catheter

1. Submitter

Boston Scientific Corporation
Electrophysiology Division
4100 Hamline Ave North
St. Paul, MN 55112

Contact:
Amy Reilly
Regulatory Affairs Specialist
Phone: 651-582-4805
E-mail: amy.reilly@bsci.com

Date Prepared: 28 September 2023

2. Device

Name of Device: Polaris X™ Unidirectional Steerable Diagnostic Catheter
Common or Usual Name: Polaris X Diagnostic Catheter
Classification Name: Electrode recording catheter or electrode recording probe (21 CFR 870.1220)
Regulatory Class: II
Product Code: DRF

3. Predicate Device

Polaris X™ Unidirectional Steerable Diagnostic Catheter, K211494
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

4. Device Description

The Polaris X Unidirectional Steerable Diagnostic Catheter is a sterile, single use, unidirectional, steerable, diagnostic catheter intended for temporary use in electrophysiological studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

The catheter consists of a distal electrode segment, a shaft and a handle. The distal electrode segment consists of 10 electrodes (decapolar); 1 tip electrode that is 2 mm in length and 9 ring electrodes in a variety of electrode spacings, as detailed in **Table 1**. The distal electrode segment is capable of forming a 270° standard curve configuration.

Table 1: Polaris X Catheter UPNs and Technical Descriptions

UPN	Tip Length	Tip Size	Shaft Size	Number of Electrodes	Electrode Spacing	Useable Shaft Length	Curve Style
M004 7000D 0	2 mm	6F	6F	10	2.5 mm	105 cm	270° Standard
M004 7001D 0					5 mm		
M004 7003D 0					2.5/5/2.5 mm		
M004 7004D 0					2/8/2 mm		
M004 7005D 0					2/10/2 mm		

The shaft of the Polaris X catheter has a 6 French (F) outer diameter and a useable length of 105 cm. The proximal end of the shaft is connected to a handle, which contains a patented thumb-slide steering control that actuates the curve.

This catheter is compatible with most commercially available recording and mapping systems and connects to these systems via a cable, which is available separately.

5. Intended Use/Indications for Use

Intended Use: The Polaris X catheter is intended for temporary use in electrophysiological studies for intracardiac stimulation (pacing) and/or recording of electrical potentials. The device is intended for use in adult (not pediatric) patients, with the exclusion of pregnant and/or nursing patients.

Indications for Use: The Polaris X catheter is indicated for use to diagnose cardiac arrhythmia.

6. Comparison of Technological Characteristics with the Predicate Device

The Polaris X Unidirectional Steerable Diagnostic Catheter incorporates identical design, packaging, fundamental technology, manufacturing processes, and sterilization process as those featured in the predicate device. The updates to the intended use were for clarification purposes.

7. Substantial Equivalence

The proposed labeling modifications of the Polaris X catheter do not impact the device's substantial equivalence to the previously cleared version of this device. The device is as safe, as effective and performs as well as the predicate device. The intent of the indications for use and

intended use, classification, product functions, materials, configuration, and sterility are substantially equivalent to the predicate device.

8. Performance Data

Not applicable for Special 510(k).

9. Conclusion

The subject Polaris X Unidirectional Steerable Diagnostic Catheter is substantially equivalent in indications for use, design, product function, materials, and sterility to the predicate Polaris X Unidirectional Steerable Diagnostic Catheter. Therefore, Boston Scientific believes the proposed Polaris X catheter is as safe and effective as its predicate device.