September 14, 2021

Boston Scientific Corporation
Donall Hosna
Regulatory Affairs Senior Manager
4100 Hamline Ave North
St. Paul, Minnesota 55112

Re: K211494
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: August 10, 2021
Received: August 11, 2021

Dear Donall Hosna:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Deoras
Assistant Director (Acting)
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)*
K211494

Device Name
Polaris X™ Unidirectional Steerable Diagnostic Catheter

Indications for Use *(Describe)*
The catheter is intended for temporary use in electrophysiological studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

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

K211494, Polaris X Unidirectional Steerable Diagnostic Catheter

I. Submitter

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

Contact:
Donall Hosna, MS
Regulatory Affairs Senior Manager
Phone: 651-582-6323
E-mail: donall.hosna@bsci.com

Date Prepared: August 9, 2021

II. 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

III. Predicate Device

Polaris X™ Unidirectional Steerable Diagnostic Catheter, K003452
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. 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° staK21ndard 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.

V. Indications for Use

The catheter is intended for temporary use in electrophysiological studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

VI. Comparison of Technological Characteristics with the Predicate Device

The Polaris X Unidirectional Steerable Diagnostic Catheter incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device. An adhesive material change is the primary technological difference between the subject and predicate devices.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biological testing was performed per Good Laboratory Practices (21 CFR, Part 58) with appropriate consideration of ISO 10993-1: 2018 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process and FDA Guidance Use of International Standard ISO 10993-1 (June 16, 2016) for devices categorized as externally communicating, limited contact, circulating blood contacting. The battery of testing included:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogen Testing
- Genotoxicity, Bacterial Reverse Mutation Study
- Genotoxicity, Mouse Lymphoma
- Thrombogenicity, Partial Thromboplastin Time
- Hemolysis, Direct Contact
- Hemolysis, Extract Method
- Platelet and Leukocyte Count
- Complement Activation, SC5b-9

Ethylene Oxide Residual Testing

Ethylene oxide residual testing was conducted to verify acceptable residual limits per ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.

Bacterial Endotoxin and Bioburden Testing

Bacterial endotoxin testing, per ANSI/AAMI ST72, Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing, and bioburden testing, per ISO 11737-1, Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products, were performed to confirm endotoxin and bioburden levels of the catheter were not adversely affected.

Design Verification Testing

Product specifications tested were:

- Reliability Cycle: Mechanical Integrity after Introduction / Withdrawal
- Reliability Cycle: Mechanical Integrity after Steering Lifecycle
- Twisting

VIII. 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. The performance data, including biocompatibility, sterilization and design verification testing supports that the subject catheter is as safe and effective as its predicate device.