April 25, 2023

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

Re: K230503
Trade/Device Name: Blazer™ Dx-20 Catheter Cable, Polaris X™ Catheter Cable
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: February 23, 2023
Received: February 24, 2023

Dear Stephanie Andre:

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 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)*
K230503

Device Name
Blazer™ Dx-20 Catheter Cable
Polaris X™ Catheter Cable

Indications for Use *(Describe)*
Blazer Dx-20 Catheter Cable:
The BSC Cables are intended to be used with the BSC Cardiac Diagnostic Catheters during an electrophysiology procedure for intracardiac stimulation (pacing) and/or recording of electrical potentials.

Polaris X Catheter Cable:
The BSC Cables are intended to be used with the BSC Cardiac Diagnostic Catheters during an electrophysiology procedure 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.

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510(k) Summary for Blazer Dx-20 Cable and Polaris X Cable
K230503

I. Submitter

Boston Scientific Corporation
Electrophysiology Division
4100 Hamline Ave North
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Contact:
Stephanie Andre
Principal Regulatory Affairs Associate
Phone: 651-582-5544
E-mail: stephanie.andre@bsci.com

Date Prepared: February 23, 2023

II. Device

Name of Device:	Blazer™ Dx-20 Catheter Cable Polaris X™ Catheter Cable
Common or Usual Name:	Blazer Dx-20 Cable Polaris X Cable
Classification Name:	Electrode recording catheter or electrode recording probe (21 CFR 870.1220)
Regulatory Class:	II
Product Code:	DRF

III. Predicate Device

Subject Device	Predicate Device	Predicate 510(k)
Blazer™ Dx-20 Catheter Cable	Blazer™ Dx-20 Catheter Cable	K081576
Polaris X™ Catheter Cable	Electrophysiology Cable	K924163

The predicate cables have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

Blazer™ Dx-20 Cable:

The subject Blazer Dx-20 Catheter cable (sold separately) is used with the Blazer Dx-20 Bidirectional Duodecapolar Catheter during an electrophysiology procedure. The Blazer Dx-20

Catheter Cable provides an electrical connection between the Blazer Dx-20 Diagnostic Catheter and the Electrophysiology (EP) Recording System. The cable has one connector that directly connects to the diagnostic catheter and multiple connection points that connect to an EP Recording System.

The main trunk consists of a jacketed 20-conductor cable that is split into individual leads by means of an over-molded splitter yoke. The proximal end of the cable has 20 universal 2 mm shrouded male pins that are typical to electrophysiology recording and stimulation systems. The Blazer Dx-20 cable is provided sterile using an EO sterilization process. The cable is reusable and can be reprocessed (i.e. re-sterilized) up to 10 times using either EO or STERRAD™ sterilization methods. The Blazer Dx-20 cable is to be used in a fully-equipped electrophysiology lab by physicians thoroughly trained in invasive cardiac mapping and ablation procedures.

Polaris X™ Cable:

The subject Polaris X Catheter Cable (sold separately) is used with the Polaris X Steerable Decapolar Mapping Catheters during an electrophysiology procedure. The Polaris X cable provides an electrical connection between the Polaris X Catheter and the Electrophysiology (EP) Recording System. The cable has one connector that directly connects to the diagnostic catheter and multiple connection points that connect to an EP Recording System.

The main trunk consists of a jacketed 10-conductor cable that is split into individual leads by means of an over-molded splitter yoke. The proximal end of the cable has 10 universal 2 mm shrouded male pins that are typical to electrophysiology recording and stimulation systems. The Polaris X cable is provided sterile using an EO sterilization process. The cable is reusable and can be reprocessed (i.e. re-sterilized) up to 10 times using EO sterilization method. The Polaris X cable is to be used in a fully-equipped electrophysiology lab by physicians thoroughly trained in invasive cardiac mapping and ablation procedures.

UPN and Technical Description

Each cable has a single configuration. The UPN and general technical specifications of the Blazer Dx-20 and Polaris X cables are provided in **Table 1**.

Table 1: Electrophysiology Cable Descriptions and UPNs

UPN	Product Description	Length	Number of Contacts	Reprocessing Method	Jacket Color
M00420S0	Blazer Dx-20 Catheter Cable	5 ft	20	EO STERRAD	Grey
M0045454S0	Polaris X Catheter Cable	5 ft	10	EO	Black

V. Intended Use

The BSC cables are intended to be used with the BSC cardiac diagnostic catheters during an electrophysiology procedure for intracardiac stimulation (pacing) and/or recording of electrical potentials.

VI. Comparison of Technological Characteristics with the Predicate Device

The Blazer Dx-20 Cable and Polaris X Cable incorporate substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices. The non-patient contacting material changes are the primary technological differences between the subject and predicate devices.

VII. Performance Data

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

Bioburden Testing

Bioburden testing, per ISO 11737-1, Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products, was performed to confirm bioburden levels of the cables were not adversely affected.

Reusable Device Testing

The subject Blazer Dx-20 and Polaris X cables underwent 10x manual cleaning and resterilization qualification. The cables were subjected to 2X EO sterilization in qualified EO cycles and then 10X manual cleaning and resterilization cycles using either EO or STERRAD methods, as described in the Blazer Dx-20 and Polaris X cable IFUs, to confirm the cable design meets its pre-determined design input specifications.

Design Verification Testing

Design verification testing was performed on a subset of product specifications to provide objective evidence that after 2X EO sterilization cycles, distribution challenge, climatic conditioning, and 10X manual cleaning and resterilization cycles, the Blazer Dx-20 and Polaris X cables meet the design input specifications in accordance with the applicable product specifications.

VIII. Conclusion

The subject Blazer Dx-20 Catheter Cable and Polaris X Catheter Cable are substantially equivalent in indications for use, design, product function, materials, and sterility to the predicate Blazer Dx-20 Catheter Cable and predicate Electrophysiology Cable, respectively. The performance data, including sterilization, and design verification testing supports that the subject catheters are substantially equivalent to their respective predicate devices.