September 29, 2023

Boston Scientific Corporation
Laura Wotta
Regulatory Affairs Specialist
4100 Hamline Ave North
St. Paul, Minnesota 55112-5798

Re: K232651
Trade/Device Name: BLAZER™ Dx-20 Bidirectional 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 31, 2023
Received: August 31, 2023

Dear Laura Wotta:

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,

Marco Cannella -S

for
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)*
K232651

Device Name
BLAZER™ Dx-20 Bidirectional Steerable Diagnostic Catheter

Indications for Use *(Describe)*
The Blazer Dx-20 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.

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Marlborough, MA 01752
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510(k) Summary for BLAZER™ Dx-20 Bidirectional Steerable Diagnostic Catheter

1. Submitter

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

Contact:
Laura Wotta
Regulatory Affairs Specialist
Phone: 651-581-2151
E-mail: laura.wotta@bsci.com

Date Prepared: August 31, 2023

2. Device

Trade Name: BLAZER™ Dx-20 Bidirectional Steerable Diagnostic Catheter
Common Name: Blazer Dx-20 Diagnostic Catheter
Classification Name: Electrode Recording Catheter or Electrode Recording Probe
Product Code: DRF
Device Class and Panel: Class II, Cardiovascular
Classification Regulation: 21 CFR Part 870.1220

3. Predicate Device

Trade Name: BLAZER™ Dx-20 Bidirectional Steerable Diagnostic Catheter
Manufacturer: Boston Scientific Corporation
Clearance Number: K211375
Common Name: Blazer Dx-20 Diagnostic Catheter
Classification Name: Electrode Recording Catheter or Electrode Recording Probe
Product Code: DRF
Device Class and Panel: Class II, Cardiovascular
Classification Regulation: 21 CFR Part 870.1220

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4. Device Description

The Blazer Dx-20 Bidirectional Steerable Diagnostic Catheter is a sterile, single use, steerable, diagnostic catheter intended for temporary use in electrophysiological studies for intracardiac stimulation (pacing) and/or recording of electrical potentials. The catheter is provided in two different bidirectional curve configurations, Medium (25 mm diameter) and Super Large (56 mm diameter), to assist the physician in reaching the desired anatomical location.

The distal electrode segment of the catheter contains an electrode tip and 19 electrode rings which are designed to carry electrical signals for endocardial stimulation (pacing) and/or recording. The electrode rings are placed on the distal segment of the catheter in various electrode spacing configurations, as described in Table 1. A 7F torqueable shaft connects the distal electrode segment to an ergonomically designed cylindrical handle.

The catheter handle contains both a steering knob and tension control knob. The degree of tip deflection of the catheter is controlled by the steering knob. The adjustable tension control knob can be tightened to hold the tip in the desired position

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

Table 1: Blazer Dx-20 Catheter UPNs and Technical Descriptions

UPN	Tip Size / Shaft Size	Number of Electrodes	Useable Shaft Length	Curve Style	Electrode Spacing
M00420SL2220	7F / 7F	20	100 cm	Super Large	2/2/2 mm
M00420SL2520					2/5/2 mm
M00420SL2820					2/8/2 mm
M00420SL5550					5/5/5 mm
M00420SL21020					2/10/2 mm
M00420SL28600					2/8/2/8/2/8/2/8/2/60/ 2/8/2/8/2/8/2/8/2 mm
M00420SL220250					2/20/2/2/2/2/2/2/2/2/ 2/2/2/25/2/25/2/25/2 mm
M00420M2220			109 cm	Medium	2/2/2 mm
M00420M2520					2/5/2 mm
M00420M210350					2/10/2/10/2/10/2/10/2/35/ 2/10/2/10/2/10/2/10/2 mm
M00420M54050					5/5/5/5/5/5/5/5/5/40/ 5/5/5/5/5/5/5/5/5 mm
M00420M255050					2/5/2/5/2/5/2/5/2/50/ 5/5/5/5/5/5/5/5/5 mm
M00420M28400					2/8/2/8/2/8/2/8/2/40/ 2/8/2/8/2/8/2/8/2 mm

5. Indications for Use/Intended Use

The Blazer Dx-20 Catheter is indicated for use to diagnose cardiac arrhythmia (**Indications for Use**).

The Blazer Dx-20 Catheter is intended for temporary use in electrophysiology 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 (**Intended Use**).

6. Technological Characteristics

The Blazer Dx-20 catheter incorporates the 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 Blazer Dx-20 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 indications for use, intended use, classification, product functions, materials, configuration, and sterility are substantially equivalent to the predicate device.

8. Performance Data

Not applicable for this Special 510(k).

8. Conclusion

The proposed Blazer Dx-20 catheter is equivalent in indications for use, intended use, classification, product functions, materials, configuration, and sterility to the predicate device, the Blazer Dx-20 catheter. Therefore, Boston Scientific believes the proposed Blazer Dx-20 catheter to be substantially equivalent to the predicate Blazer Dx-20 catheter.