November 1, 2024

Boston Scientific Corporation
Melissa Schneider
Senior Regulatory Affairs Specialis
4100 Hamline Ave North
St Paul, Minnesota 55112

Re: K240366
Trade/Device Name: EP•XT™ Unidirectional Steerable Diagnostic Catheter; Dynamic Tip™ Unidirectional Steerable Diagnostic Catheter; Dynamic XT™ 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: February 5, 2024
Received: February 6, 2024

Dear Melissa Schneider:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240366

Device Name
EP•XT™ Unidirectional Steerable Diagnostic Catheter; Dynamic Tip™ Unidirectional Steerable Diagnostic Catheter; Dynamic XT™ Unidirectional Steerable Diagnostic Catheter

Indications for Use *(Describe)*
EP•XT, Dynamic Tip, and Dynamic XT Unidirectional Steerable Diagnostic Catheters are 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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510(k) Summary for EP•XT, Dynamic Tip, and Dynamic XT Unidirectional Steerable Diagnostic Catheters

1. Submitter

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

Contact:
Melissa Schneider
Regulatory Affairs Specialist
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E-mail: melissa.schneider@bsci.com

Date Prepared: October 31, 2024

2. Device

Name of Devices:
EP•XT™ Unidirectional Steerable Diagnostic Catheter;
DYNAMIC TIP™ Unidirectional Steerable Diagnostic Catheter;
DYNAMIC XT™ Unidirectional Steerable Diagnostic Catheter

Common Name: Dynamic Unidirectional Steerable 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

Subject Device	Predicate Device	Predicate 510(k)
EP•XT Steerable Diagnostic Catheter	Bard® Steerable Catheter	K921872
Dynamic Tip Steerable Diagnostic Catheter	Bard® Dynamic Tip Catheter	K912213
Dynamic XT Steerable Diagnostic Catheter	Bard® Steerable Catheter	K921872

4. Device Description

The unidirectional steerable diagnostic catheters acquire electrical signals from the cardiac tissue, which are transmitted via the electrode wiring through the connector and cable to an amplifier, where the signals are displayed on an EP recording system for the physician to view and interpret in diagnosing cardiac arrhythmias. The physician inserts the diagnostic catheter(s) percutaneously via either the anterior approach using the internal jugular vein or the subclavian vein or via the femoral vein or for a retrograde approach, via the femoral artery. In some cases, the radial artery may be used to access the targeted cardiac chamber. Using fluoroscopic guidance, the physician then navigates the diagnostic catheter to the target site using the catheter steering mechanism as confirmed by the intracardiac electrograms and/or pacing threshold, confirming electrode to endocardium interface.

The steerable diagnostic electrode catheters are radiopaque, flexible, insulated catheters with a polymer shaft, each having a mechanical operating mechanism. In each catheter the polymer shaft connects to the catheter handle whereby the curve or loop is actuated by a single pull cable. The EP•XT Catheter has a white rotating handle mechanism which provides curve actuation of the distal tip. The Dynamic Tip and Dynamic XT Catheters have a plunger mechanism, which, when moved forward or back, results in curvature of the distal tip.

The EP•XT, Dynamic Tip, and Dynamic XT Catheters are offered pre-packaged sterile and are a single use product not to be reused, reprocessed, or resterilized. The method of sterilization is ethylene oxide (EO).

5. Intended Use & Indications for Use

Intended Use

EP•XT, Dynamic Tip, and Dynamic XT Unidirectional Steerable Diagnostic Catheters are intended for temporary intracardiac sensing, recording, stimulation, and temporary pacing during the evaluation or cardiac arrhythmias. The device is intended for use in adult (not pediatric) patients, with the exclusion of pregnant and/or nursing patients.

Indications for Use

EP•XT, Dynamic Tip, and Dynamic XT Unidirectional Steerable Diagnostic Catheters are indicated for use to diagnose cardiac arrhythmia.

6. Comparison of Technological Characteristics with the Predicate Device

The catheters incorporate substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device.

7. 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 devices were not adversely affected.

Design Verification Testing

Design verification testing was performed on the EP•XT, Dynamic Tip, and Dynamic XT Catheters to demonstrate that the devices, as manufactured, packaged and 2x EO sterilized, adhere to the requirements set forth in accordance with the applicable product specifications.

Testing was conducted at baseline (T=0) and 37 months (1125 days) accelerated aging to support the labeled shelf life.

Packaging Verification Testing

The Packaging Design Verification testing provides evidence that the catheter packaging configurations meet the predetermined design input specification and maintain sterility in conformance with ISO 11607-1.

8. Conclusion

The subject EP•XT, Dynamic Tip, and Dynamic XT Steerable Diagnostic Catheters are substantially equivalent in indications for use, design, product function, materials, and sterility to the predicate Steerable Diagnostic Catheters. The performance data supports that the subject catheters are substantially equivalent to their respective predicate devices.