October 25,2019

Boston Scientific Corporation
Nicole Lyden
Senior Regulatory Affairs Specialist
4100 Hamline Ave North
St. Paul, Minnesota 55112

Re: K192360
Trade/Device Name: IntellaMap Orion High Resolution Mapping 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 29, 2019
Received: August 30, 2019

Dear Nicole Lyden:

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192360

Device Name
IntellaMap Orion™ High Resolution Mapping Catheter

Indications for Use *(Describe)*
The IntellaMap Orion™ High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

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
IntellaMap Orion™ High Resolution Mapping Catheter K192360

1. Submitter

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Date Prepared: August 29, 2019

2. Device

Trade Name: IntellaMap Orion™
Common Name: IntellaMap Orion High Resolution Mapping 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: IntellaMap Orion™
Manufacturer: Boston Scientific Corporation
Clearance Number: K143481
Common Name: IntellaMap Orion High Resolution Mapping 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

4. Device Description

The lntellaMap Orion High Resolution Mapping Catheter is an 8.5 French (Ø 2.82mm), 115 cm working length, and a 64-electrode steerable catheter. The basket-shaped distal region consists of 8 splines that compose the electrode array. The proximal end has a handle that extends to a cable with a connector. The handle includes bi-directional articulation controls and a deployment slider that activates the electrode array into a basket shape once inside the heart. A flushing port extends from the back of the connector for connection to a continuous pressurized saline drip. The catheter is supplied with an 8.5F insertion sleeve for insertion through the hemostasis valve on an introducer sheath. A sensor in the catheter tip enables the position of the distal region of the catheter to be tracked in space when used with the RHYTHMIA HDx™ Mapping System.

5. Indications for Use

The lntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

6. Technological Characteristics

The lntellaMap Orion High Resolution Mapping Catheter incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device.

7. Substantial Equivalence

The proposed modifications to the lntellaMap Orion High Resolution Mapping Catheter flexible printed circuit assembly, feeder tube, feed tube strain relief, and insertion sleeve do not impact the device's substantial equivalence to the previously cleared version of this device. The modified 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

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and design verification tests to provide evidence of substantial equivalence for the lntellaMap Orion High Resolution Mapping Catheter. The device has been verified through the following:

Design Verification Bench Testing

The Design Verification Bench Testing included:

Test	Results
Electrical Testing	Pass
Reliability Testing	Pass
Catheter Joint Strength	Pass
Tip Buckle	Pass
Visual Inspections and Dimensions	Pass
Simulated Use	Pass

Biocompatibility Testing

The following Biocompatibility Testing was completed on the lntellaMap Orion High Resolution Mapping Catheter in compliance with the requirements of ISO 10993-1: 2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

Test	Results
Cytotoxicity	Pass
Hemolysis Direct Contact and Extract Methods	Pass
Sensitization Maximization	Pass
Intracutaneous Irritation	Pass
Acute Systemic Toxicity	Pass
Materials Mediated Rabbit Pyrogen	Pass
Partial Thromboplastin Time	Pass
In Vitro Hemocompatibility	Pass
Complement Activation	Pass
USP Physicochemical Test	Pass
Latex Assay	Pass

The test results demonstrate that the lntellaMap Orion High Resolution Mapping Catheter is considered safe and effective for its intended use.

9. Conclusion

The proposed lntellaMap Orion High Resolution Mapping Catheter is equivalent in indications for use, intended use, classification, product functions, materials, configuration, and sterility to the predicate device. Therefore, Boston Scientific asserts the proposed

lntellaMap Orion High Resolution Mapping Catheter to be substantially equivalent to the predicate lntellaMap Orion High Resolution Mapping Catheter (cleared in K143481).