November 27, 2019

Boston Scientific Corporation
Lee Margolin
Senior Regulatory Affairs
125 Cambridgepark Drive
Cambridge, Massachusetts 02140

Re: K192438
Trade/Device Name: RHYTHMIA HDx™ Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 5, 2019
Received: September 6, 2019

Dear Lee Margolin:

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,

Nicole Gillette
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192438

Device Name

RHYTHMIA HDx™ Mapping System

Indications for Use *(Describe)*

The RHYTHMIA HDx™ Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

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
510(K) SUMMARY COMPLYING WITH 21 CFR 807.92

I. SUBMITTER

Boston Scientific Corporation
125 Cambridgepark Drive, Suite 600
Cambridge, MA 02140
Phone: 617-218-3823
Fax: 617-218-3850
Contact Person: Lee Margolin
Date Prepared: August 30, 2019

II. DEVICE

Name of Device: RHYTHMIA HDx™ Mapping System

III.

Common or Usual Name: Cardiac Mapping System
Classification Name: Programmable diagnostic computer (21 CFR 870.1425)
Regulatory Class: Class II
Product Code: DQK

IV. PREDICATE DEVICES

Primary Predicate: RHYTHMIA HDx™ Mapping System Boston Scientific Corporation (K173837, S.E. 07/25/2018)
Secondary Predicate: CARTO® 3 EP Navigation System version 6.0, Biosense Webster, Inc. (K180238, S.E. 06/01/2018)

V. DEVICE DESCRIPTION

The RHYTHMIA HDx™ Mapping System is a catheter-based atrial and ventricular mapping system designed to display 3D anatomical and electroanatomical maps of the human heart in real-time. The mapping system is intended to be used during electrophysiology procedures for cardiac mapping and storage of cardiac electrophysiological data. In addition, based on user-defined criteria, the system is able to acquire data over multiple cardiac beats. It is capable of real-time display through construction of maps using catheter magnetic and impedance localization technology and data from intracardiac and surface electrograms.
The Signal Station and related accessories provide data connection pathways for external input/output devices (e.g. catheters and recording systems) and serve as the data conduit to the system Workstation computer and software.
The subject device is reusable capital equipment that is intended to be used in an electrophysiology laboratory by physicians fully trained in cardiac electrophysiology.

V. INDICATIONS FOR USE

The RHYTHMIA HDx™ Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence of the RHYTHMIA HDx™ Mapping System with Software Version 4.0 was established in terms of design features, performance testing, and indications for use as compared to the predicates RHYTHMIA HDx™ Mapping System and CARTO® 3 EP Navigation System Version 6.0. The subject device system has a similar design to the primary predicate device to include the same primary system components, operating principle, catheter tracking methods, and same intended use while incorporating the same feature functionality as the secondary predicate feature.

The technological differences between the subject device and the predicate RHYTHMIA HDx™ Mapping System include the following software enhancements:

- AutoTag provides an ablation workflow which includes automatic tag placement.
- Stability Filtering provides a filter to compensate for respiration when calculating a catheter's position.
- Minor bug fixes.

VII. PERFORMANCE DATA

Testing was performed to verify functional performance, safety, and to support substantial equivalence determination. The subject RHYTHMIA HDx™ Mapping System with Software Version 4.0 passed all tests in accordance with appropriate test acceptance criteria and standards. As a result of hazard analysis of SW v4.0 features, no new questions of safety and effectiveness were raised.

Software Verification and Validation

Software verification testing was conducted based on 'major' level of concern in accordance with FDA Guidance for Industry and FDA Staff: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005.

Performance Testing

- Mapping and Visualization - Confirmed that incorporation of the new software features does not negatively impact the ability to use the subject mapping system to: (1) accurately create 3D maps of the cardiac chambers of the heart; and (2) support visualization of magnetic and impedance tracked catheters.
- Software Performance - Confirmed that the new software features meet the functional requirements.
- Summative Usability - Confirmed system level functionality under expected use conditions.

VIII. CONCLUSIONS

The software hazard analysis, verification and performance testing demonstrated that the RHYTHMIA HDx™ Mapping System with Software Version 4.0 performs as intended. This data supports that the subject device is substantially equivalent to identified predicate devices.