May 28, 2025

Boston Scientific Corporation
Derek Charchuk
Senior Regulatory Affairs Specialist
4100 Hamline Avenue North
Saint Paul, Minnesota 55112-5798

Re: K251344
Trade/Device Name: OptiMap™ System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: April 29, 2025
Received: April 30, 2025

Dear Derek Charchuk:

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
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251344

Please provide the device trade name(s).

OptiMap™ System

Please provide your Indications for Use below.

The OptiMap System is used to analyze electrogram (EGM) signals and display results in a visual format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary in Compliance with 21 CFR 807.92

I. Submitter Information

Submitter Name: Boston Scientific Corporation

Submitter Address: 4100 Hamline Avenue North
St. Paul, Minnesota
USA 55112-5798

Contact #1: Derek Charchuk
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Contact #2: Mary Korte
Senior Regulatory Affairs Manager
Phone: (612) 965-5145
Email: mary.korte@bsci.com

Date Prepared: 29-April-2025

II. Device Information

Generic Name: OptiMap™ System

Trade Name: OptiMap™ System

Product Code: DQK
Device Class: Class II
Review Panel: Cardiovascular (DQK)
Classification Regulation: (21 CFR 870.1425): Programmable diagnostic computer
510(k) Number: K251344

III. Predicate Device Information

Predicate Device: Ablamap® System
Manufacturer: Ablacon, Inc.
510(k): K230008
FDA Clearance Date: June 8th, 2023
Product Code: DQK
Device Class: Class II
Classification Regulation: (21 CFR 870.1425): Programmable diagnostic computer

IV. Indications for Use

The OptiMap™ System is used to analyze electrogram (EGM) signals and display results in a visual

format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.

IV. Intended Use

The OptiMap™ System is intended to be used during electrophysiology procedures on patients for whom an electrophysiology procedure has been prescribed and only by qualified medical professionals who are trained in electrophysiology.

V. Device Description

The OptiMap™ System is an electrophysiology mapping system for assisting in the diagnosis of complex cardiac arrhythmias. The system consists of several hardware elements including an Amplifier, Cart, Monitor, and Workstation that contains proprietary mapping software. Signals from a 64-electrode mapping basket catheter are transmitted to the Workstation by the Amplifier, processed by the mapping software, and the results are displayed on the Monitor.

The OptiMap System utilizes proprietary algorithms to process intra-cardiac electrogram (EGM) signals from a 64-electrode unipolar mapping basket catheter. The software transforms the time domain waveform information from the electrodes into space domain information which calculates the Electrographic Flow ™ (EGF ™) vectors for Atrial Fibrillation. The system also has algorithms that display action potential wavefront propagation or Activation Cycle Path (ACP). The ACP maps are a reconstruction of the activation wavefront propagation and may be used to visualize organized atrial arrhythmias.

The software output includes static and dynamic EGF maps that graphically depict the temporal activity and location of sources of EGF with respect to the catheter electrodes. The software displays active sources of flow and passive flow phenomena, detects spatial and temporal stability of sources of flow and detects the prevalence of sources of flow. In addition, the software output includes ACP maps displaying isochrones and a wavefront animation for each cycle.

VI. Substantial Equivalence & Comparison of Technological Characteristics

Comparison of Subject OptiMap™ System (Software Version 1.3) vs. Predicate Ablamap® System

Characteristic	Subject Device: OptiMap™ System (K251344) (Cortex, Inc.)	Predicate Device: Ablamap® System (K230008) (Ablacon, Inc.)
Device Classification, Classification Name, and Product Code	Class II, Programmable Diagnostic Computer (21 CFR 870.1425), DQK	Same
Indications for Use	The OptiMap™ System is used to analyze electrogram (EGM) signals and display results in a visual format for evaluation by a physician in order to assist in the diagnosis of complex cardiac arrhythmias.	Same with exception of device name
Intended use	The OptiMap™ System is intended to be used during electrophysiology procedures on patients for whom an electrophysiology procedure has been prescribed and only by qualified medical professionals who are trained in electrophysiology.	Same with exception of device name
System Components	Amplifier, Workstation, Monitor, Proprietary Software	Same
Compatible Diagnostic Catheters	64 electrode unipolar basket mapping catheters: - 50mm and 60mm sizes - 8 electrodes/splines	Same
Electrographic Flow (EGF) Recording Duration	Reject if <55 sec or >240 sec	Same
EGF QRS Detection	QRS complex detection and notification if >150 or <40; reject if >170	Same
Activation Cycle Path (ACP) Mapping	ACP algorithm is an interpolation method that leverages the spatio-temporal activation wavefront reconstruction method similarly to using EGM signals from a "basket" catheter with 64-electrode and 8 splines on 2-second segment signals.	N/A – ACP feature was not available with predicate device
Cybersecurity	Total product lifecycle (TPLC) cybersecurity risk assessment and adoption of a Secure Product Development Framework (SPDF) per FDA Guidance: *Cybersecurity in Medical Devices: Quality System*	N/A

Characteristic	Subject Device: OptiMap™ System (K251344) (Cortex, Inc.)	Predicate Device: Ablamap® System (K230008) (Ablacon, Inc.)
	Considerations and Content of Premarket Submissions (September 27, 2023).	

VII. Summary of Non-Clinical Performance Testing

Software verification and validation testing was completed on the subject device demonstrating that the OptiMap System with Version 1.3 Software (including ACP functionality) successfully performed at the unit, integration and system levels. All open issues from the verification and validation activities have been resolved or documented as unresolved anomalies. The OptiMap System met the acceptance criteria listed in the test protocols, performs as designed, and is suitable for its intended use.

Cybersecurity Testing was completed to align with FDA Guidance: *Cybersecurity in Medical Devices – Quality System Considerations and Content of Premarket Submissions (September 27, 2023)*.

There are no changes to the hardware design of the OptiMap System; as such, no additional physical/mechanical, electrical safety, or EMC related verification or validation activities were completed for the addition of ACP functionality or cybersecurity hardening updates.

VIII. Conclusion

Based on the intended use, fundamental technological characteristics, and performance testing, the subject OptiMap™ System with Version 1.3 Software has been shown to be appropriate for its intended use and is substantially equivalent to the predicate device.