August 7, 2024

Medtronic, Inc.
Matthew Lobeck
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K233433
Trade/Device Name: Sphere-9Dx Diagnostic Catheter (AFR-00009)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: October 12, 2023
Received: October 12, 2023

Dear Matthew Lobeck:

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.

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

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.

Submission Number *(if known)*

K233433

Device Name

Sphere-9Dx Diagnostic Catheter (AFR-00009)

Indications for Use *(Describe)*

The Sphere-9Dx Diagnostic Catheter is indicated for electrophysiological mapping (recording and stimulation) of cardiac structures in the heart. This catheter is intended to obtain electrograms in the atrial regions of the heart. The catheter provides location information when used with a compatible Affera Mapping System.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K233433

Date Summary Prepared: October 13, 2023

Applicant:
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1.800.328.2518
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Device Trade Name and Model: Sphere-9Dx Diagnostic Catheter, AFR-00009

Common Name: Electrophysiology Catheter

Classification Name: Electrode Recording Catheter

Classification & Panel: Class II, 21 CFR 870.1220, Cardiovascular

Product Code: MTD

Predicate Device: PENTARAY Nav eco High Density Mapping Catheter (K201750)

Device Description: The Sphere-9Dx Diagnostic catheter (AFR-00009) is a steerable irrigated multi-electrode catheter with a bidirectional deflecting tip intended for intracardiac mapping (stimulation and recording). The catheter includes an expandable lattice electrode array that fits a 2.7 mm (8 Fr) straight introducer sheath or a 2.8 mm (8.5 Fr) curved or deflectable sheath and expands to a 9.3 mm diameter in the cardiac chamber. The catheter is supplied with an insertion tool that must be used to aid in collapsing the expandable lattice electrode array for insertion into an introducer or guiding sheath. The expandable lattice electrode array

contains 9 mini surface electrodes mounted on its surface with roughly 5 mm spacing to collect local electrograms and monitor local impedance. All mini surface electrodes may be used for recording or stimulation.

Intended Use:

The Sphere-9Dx Diagnostic Catheter is intended for intracardiac mapping (stimulation and recording).

Indications for Use:

The Sphere-9Dx Diagnostic Catheter is indicated for electrophysiological mapping of cardiac structures in the heart (recording and stimulation). This catheter is intended to obtain electrograms in the atrial regions of the heart. The catheter provides location information when used with a compatible Affera Mapping System.

Comparison of Technological Characteristics:

There are no significant differences in the fundamental scientific technology between the predicate and subject devices. There Sphere-9Dx Diagnostic Catheter features the following similarities with the predicate device:

- Same intended use
- Same fundamental scientific technology
    - Deflectable, high-density mapping catheter
    - Use of electrode arrays for intracardiac mapping (recording and stimulation)
    - Utilization of magnetic sensor for navigation and tracking with a magnetic-based mapping system
- Similar catheter working lengths, allowing for placement of the catheter tip in the intended anatomical locations
- Both devices are designed to allow for catheter irrigation during use to prevent thrombus formation

The differences in technological characteristics involve the following:

- Differences in tip design, number of electrodes, and electrode spacing due to the unique proprietary design of each catheter.
- Deflection type: unidirectional, multiple models (predicate) vs bi-directional (subject)

	These changes do not constitute a difference in the fundamental scientific technology between the subject and predicate devices. The physical and technological characteristics of the subject and predicate devices are considered substantially equivalent and do not raise questions of safety or effectiveness.
Safety and Performance Data:	Performance testing applicable to the subject device was completed to ensure it performs as intended per the product specifications and requirements, including specifications and requirements related to use with a compatible Affera mapping system. The following testing has been completed in support of the Sphere-9Dx Diagnostic Catheter, and all acceptance criteria were met in accordance with appropriate standards: • Design Verification Testing • Design Validation • Summative Usability Evaluation • Pre-clinical Animal Testing • Biocompatibility Testing • Sterilization Validation and Adoption • Packaging Validation No questions of safety or effectiveness are raised as a result of the testing, and the subject device is considered substantially equivalent to the predicate device based on the performance data collected.
Conclusion:	The subject and predicate devices share the same intended use and have similar underlying technological characteristics (i.e. deflectable, magnetic-based catheter intended for atrial and ventricular mapping and stimulation). Differences between the subject and predicate devices do not result in differences in overall device performance or fundamental scientific technology, and the subject device is considered substantially equivalent to the predicate device.