March 8, 2024

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

Re: K233943
Trade/Device Name: Affera™ Mapping System, AFR-00003
Location Reference Patch Kit, AFR-00007
System Cart, AFR-00013
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 14, 2023
Received: December 14, 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,

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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)*

K233943

Device Name

Affera™ Mapping System, AFR-00003
Location Reference Patch Kit, AFR-00007
System Cart, AFR-00013

Indications for Use *(Describe)*

Affera Mapping System: The Affera mapping system is intended to be used for catheter-based cardiac electrophysiological mapping. The mapping system allows pacing and real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The acquired patient signals, including intracardiac electrograms, may also be recorded and displayed on the system's display screen.

Location Reference Patch Kit: Refer to the instructions for use accompanying the compatible navigation-enabled electrophysiology catheter that is used with the compatible mapping system for the specific indications for use.

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

Date Summary Prepared: December 14, 2023

Applicant: Medtronic, Inc.
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1.800.328.2518
Establishment Registration No. 3001504994

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Device Trade Name and Model: Affera™ Mapping System, AFR-00003
Location Reference Patch Kit, AFR-00007
System Cart, AFR-00013

Common Name: Mapping system

Classification Name: Computer, Diagnostic, Programmable

Classification & Panel: Class II, 21 CFR 870.1425, Cardiovascular

Product Code: DQK

510(k) Number K233943

Predicate Device: CARTO® 3 EP Navigation System Version 7.2 (K213264)

Device Description: Affera Mapping System (AFR-00003):
The Affera Mapping System (mapping system) is a computerized storage and display system with embedded software designed to present the user with information regarding the state and location of one or more magnetic sensors connected to cardiac catheters. The mapping system provides real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The mapping system uses magnetic localization technology

similar to localization systems used in other EP mapping systems, with a magnetic field generator placed under the table and one or more passive magnetic sensors embedded in the catheter.

The Affera Mapping System connects to electrophysiology (EP) catheter lab equipment such as the EP recording system and external stimulators. The mapping system can also be connected to third-party intracardiac (IC) catheters to display electrograms from and deliver pacing stimuli.

The mapping system can be used with cardiac ablation systems for tracking and navigation of magnetic sensor-equipped catheters during ablation procedures. When used with the Affera Ablation System, the mapping system displays ablation data on the workstation user interface.

Location Reference Patch Kit (AFR-00007):
The Location Reference Patch (LRP) Kit is a disposable device sold separately from the mapping system. The LRP Kit includes two non-sterile single-use patches, each containing a passive magnetic location sensor, which are placed in fixed positions on the patient's body surface (one anterior (A-patch) and one posterior (P-patch) to detect respiratory motion and to provide information regarding patient position and movement, respectively. The LRP Kit employs a hydrogel adhesive material for skin contact and for repositioning/ reapplication, and which is intended for extended duration topical use.

Intended Use:

The Affera Mapping System and accessory devices are intended for catheter-based electrophysiological mapping and stimulation.

Indications for Use:

Affera Mapping System (AFR-00003): The Affera mapping system is intended to be used for catheter-based cardiac electrophysiological mapping. The mapping system allows pacing and real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The acquired patient signals, including intracardiac electrograms, may also be recorded and displayed on the system's display screen.

Location Reference Patch Kit (AFR-00007): Refer to the instructions for use accompanying the compatible

navigation-enabled electrophysiology catheter that is used with the compatible mapping system for the specific indications for use.

Comparison of Technological Characteristics:

A comparative overview of the subject and predicate devices is provided in the following table:

Attribute	CARTO® 3 EP Navigation System Version 7.2 (K213264)	Affera Mapping System, Location Reference Patch Kit (K233943)
Intended Use	Catheter-based electrophysiological mapping and stimulation.	Same
Fundamental Scientific Technology (Navigation/ localization)	• Magnetic-based tracking of embedded sensor • Impedance-based tracking of catheter electrodes	• Magnetic-based tracking of embedded sensor
Key System Components	• Catheter and equipment interface unit (PIU) • Magnetic field generator (Location Pad) • Software and workstation	• Catheter and equipment interface unit (CIU) • Magnetic field generator • Software and workstation
Electroanato-mical Maps	3D geometric shell, voltage, activation, and propagation maps	Same
Stimulation/ pacing	Externally generated pacing only	Internally (20 mA max) and externally generated pacing
Location Patch Configuration	• 3 back patches • 3 chest patches	• 1 back patch • 1 chest patch
Location Patch Design/ Function	System provides body surface reference via magnetic sensors to enable tracking of patient movement and its effect on catheter tracking and navigation.	Same

There are no significant differences in the fundamental scientific technology between the predicate and subject devices. The Affera Mapping System and accessory devices share the same or similar technological characteristics with the predicate device:

- Same intended use
- Same fundamental scientific technology
  - Magnetic-based tracking of embedded sensor
- Both devices utilize a central interface unit for connection with a workstation, compatible catheter, and magnetic field generator.
- Both devices include proprietary software designed to present the user with information regarding the state and location of magnetic sensors for creation of electroanatomical maps (3D geometric shell, voltage, activation, and propagation maps), and lesion tagging.
- Similar patient data management functionality with respect to the features offered by the subject devices.

The differences in technological characteristics involve the following:

- Certain features offered by the predicate are not offered by the Affera Mapping System, such as:
  - ultrasound catheter and CFAE mapping
  - 12-Lead ECG Morphology Matching
  - Contact Force Indication
  - certain image integration functionality.
- Both subject and predicate devices utilize pacing stimuli generated from external sources (i.e. external recording system). Unlike the predicate device, the Affera Mapping System can also internally generate and route up to 20 mA pacing stimuli.
- ECG signals are acquired by the predicate device using ECG patches connected directly to the central interface unit; whereas the Affera Mapping System utilizes ECG signals imported from hospital recording systems.

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 devices was completed to ensure it performs as intended per the product specifications and requirements, including specifications and

requirements related to use with compatible catheters and ablation systems. The following testing has been completed in support of the Affera Mapping System and accessory devices, and all acceptance criteria were met in accordance with appropriate standards:

Testing	Outcome
Design Verification Testing	Verification and validation activities conducted on the Affera Mapping System and Location Reference Patch Kit confirm that all user requirements and product specifications have been met.
Design Validation	
Performance-based Characterization Testing	Tracking and navigation performance of the Affera Mapping System was further evaluated via separate characterization testing.
Summative Usability Evaluation	Critical tasks related to the Affera Mapping System and Location Reference Patch Kit were independently evaluated via summative usability studies. All tasks were completed with no uncorrected Serious Use Errors attributable to the design of the user interfaces.
Pre-clinical Animal Testing	A chronic GLP study was completed to evaluate the safety and performance of the Affera Mapping System, including electroanatomical mapping (EAM) in all four chambers and an evaluation performance as compared to prior experience with existing mapping systems. All study endpoints were met through the GLP study.
Software Verification and Validation Testing and Cybersecurity	Software verification and validation was successfully completed to ensure that all specifications are met and that risk mitigations have been successfully implemented. Controls have been implemented as part of the design and development of the Affera Mapping System to assure medical device functionality and safety with respect to cybersecurity.
Electrical Safety and EMC Testing	System safety and electrical testing, including IEC 60601 and EMC/EMI testing, has been successfully completed on the Affera Mapping System.
Biocompatibility Testing (AFR-00007)	The Location Reference Patch Kit (AFR-00007) is a patient contacting device intended for placement on intact skin for a limited duration (< 24 hours) per ISO 10993-1. Biocompatibility testing per ISO 10993-1: 2018 was successfully completed on the Location Reference Patch Kit, including testing for irritation, sensitization, and cytotoxicity.
Packaging Validation	Packaging qualification including appropriate pre-conditioning exposure was successfully completed on the Affera Mapping System.
Clinical Evaluation	Investigator scoring of electroanatomical mapping was collected from the Sphere-Per-AF

	clinical study as a secondary performance endpoint, including scoring using the Affera Mapping System and a control device. Based on the mapping assessment data reported, no statistical difference was found between the investigational and control populations across the investigator scoring of geometries, voltage maps, and activation maps. Investigator scoring was "good" or better in at least 97% of cases across all mapping categories for both treatment groups.

No questions of safety or effectiveness are raised as a result of the testing, and the subject devices are 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. magnetic-based tracking of embedded sensor). Differences between the subject and predicate devices do not result in differences in overall device performance or fundamental scientific technology, and the subject devices are considered substantially equivalent to the predicate device.