January 17, 2025

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

Re: K243892
Trade/Device Name: Affera Integrated Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 18, 2024
Received: December 18, 2024

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.

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

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.

510(k) Number *(if known)*
K243892

Device Name
Affera Integrated Mapping System

Indications for Use *(Describe)*
The Affera Integrated 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 body surface electrocardiograms 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Summary Prepared:	Dec 18, 2024
Applicant:	Medtronic, Inc. 8200 Coral Sea Street NE Mounds View, MN U.S.A. 55112 1.800.328.2518 **Establishment Registration No.** 3001504994
Official Correspondent:	Matthew Lobeck Principal Regulatory Affairs Specialist Medtronic 8200 Coral Sea Street Mounds View, MN 55112 Mobile: 612-202-5925 Fax: 763.367.9903 Email: matthew.lobeck@medtronic.com
Device Trade Name:	Affera Integrated Mapping System
510(k) Number	K243892
Common Name:	Mapping system
Classification Name:	Computer, Diagnostic, Programmable
Classification & Panel:	Class II, 21 CFR 870.1425, Cardiovascular
Product Code:	DQK
Predicate Device:	Affera Integrated Mapping System – K241828
Device Description:	The Affera Integrated Mapping System (integrated 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 compatible catheters within the body. The integrated mapping system provides real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The integrated 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 electromagnetic sensors embedded in the catheter. In addition to

magnetic-based tracking and navigation, the integrated mapping system provides optional capability for hybrid electromagnetic-impedance tracking and navigation, including the ability to visualize Medtronic and third-party therapeutic and diagnostic devices that do not contain electromagnetic location sensors.

The integrated mapping system collects and displays surface electrocardiogram (ECG) signals using commercially available body surface electrodes. Electrogram signals from electrodes on connected catheters can also be collected. Data derived from these signals can be overlayed on the reconstructed anatomy to display cardiac maps in multiple formats. The integrated mapping system can connect to electrophysiology (EP) catheter lab equipment such as external stimulators to deliver pacing stimuli through third-party intracardiac (IC) catheters. Internally generated pacing stimuli can also be routed directly from the integrated mapping system CIU.

The integrated mapping system can be used with compatible cardiac ablation systems for tracking and navigation of catheters during ablation procedures. When connected via a communication link to a compatible ablation system, the integrated mapping system displays ablation data such as temperature and power on the user interface.

Intended Use:

The Affera Integrated Mapping System is intended for catheter-based electrophysiological mapping and stimulation.

Indications for Use:

The Affera Integrated 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 body surface electrocardiograms and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

Comparison of Technological Characteristics:

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

Attribute	PREDICATE Affera Integrated Mapping System (K241828)	SUBJECT Affera Integrated Mapping System (K243892)
Intended Use	Catheter-based electrophysiological mapping	Same
Fundamental Scientific Technology (Navigation/ localization)	• Magnetic-based tracking of embedded sensor • Hybrid electromagnetic-impedance tracking of catheter electrodes	Same

Key System Components	• Catheter and equipment interface unit (CIU) • Magnetic field generator • Software and workstation	Same
Electroanatom-ical Maps	3D geometric shell, voltage, activation, and propagation maps	Same
Methods for measurement of impedance reference during hybrid electromagnetic-impedance tracking and navigation	Measured from stable intracardiac catheter.	• Can be measured from stable intracardiac catheter. • Can be computed from electrocardiogram (ECG) measurements from the body surface.
Stimulation/ Pacing	Internally (20 mA max) and externally generated pacing	Same
ECG Signal Acquisition	Body surface ECG signals recorded directly by the Affera Integrated Mapping System	Same
EGM Acquisition	Intracardiac electrogram signals generated from electrodes from the connected catheters	Same

The Affera Integrated Mapping System shares the following same or similar technological characteristics with the predicate device:

- Same intended use and Indications for Use statement.
- Magnetic-based tracking of sensor-equipped compatible catheters.
- Hybrid electromagnetic-impedance tracking of catheter electrodes.
- Utilization of a central interface unit for connection with a workstation, compatible catheter, and magnetic field generator.
- Inclusion of 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.
- Same patient data management functionality with respect to the features offered by the subject devices.

The differences in technological characteristics involve the following:

- The modified Affera Integrated Mapping System in scope of this premarket notification has been developed with an additional software feature to allow functionality in accordance with the intended use of the device. The subject device allows the user to

select ECG electrodes as the Impedance Reference, which establishes the zero point for impedance measurements. This functional difference from the predicate does not raise different questions of safety and effectiveness from those of the predicate device and does not preclude a meaningful comparison with the predicate device.

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 Integrated Mapping System, and all acceptance criteria were met in accordance with appropriate standards:

- Design verification testing
- Design validation
- Summative usability evaluation
- Pre-clinical animal testing
- Software validation and cybersecurity testing
- Electrical safety and EMC testing
- Packaging validation

No new questions of safety or effectiveness are raised as a result of the testing, and the subject devices are considered substantially equivalent to the predicate devices based on the performance data collected.

Conclusion:

The subject and predicate devices share the same intended use and have similar underlying technological characteristics. 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 respective predicate devices.