November 1, 2024

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

Re: K241828
Trade/Device Name: Affera Integrated Mapping System; Impedance Localization Patch Kit
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 24, 2024
Received: June 24, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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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)*

K241828

Device Name

Affera Integrated Mapping System;
Impedance Localization Patch Kit

Indications for Use *(Describe)*

Affera Integrated Mapping System:
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.

Impedance Localization Patch Kit:
Refer to the instructions for use accompanying the compatible electrophysiology catheter(s) 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.

510(k) Summary

Date Summary Prepared: October 31, 2024

Applicant:
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Device Trade Name:
- Affera Integrated Mapping System
- Impedance Localization Patch Kit

510(k) Number: K241828

Common Name: Mapping system

Classification Name: Computer, Diagnostic, Programmable

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

Product Code: DQK

Predicate Devices:
- **Affera Integrated Mapping System**: Affera Mapping System – K233943
- **Impedance Localization Patch Kit**: EnSite Precision Surface Electrode Kit – K201148

Device Description:

Affera Integrated Mapping System

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.

Impedance Localization Patch Kit

The Impedance Localization Patch Kit is an accessory device used with the Affera Integrated Mapping System that includes 6 surface localization patches. Patches are placed in fixed positions in contact with the patient's skin to deliver low energy patient auxiliary signals to enable the integrated mapping system to allow visualization of catheters that do not contain electromagnetic location sensors, and to support detection of respiratory motion and to provide information regarding patient position and movement.

Intended Use:

The Affera Integrated Mapping System and Impedance Localization Patch Kit are intended for catheter-based electrophysiological mapping and stimulation.

Indications for Use:

Affera Integrated Mapping System

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.

Impedance Localization Patch Kit

Refer to the instructions for use accompanying the compatible electrophysiology catheter(s) 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 tables:

Affera Integrated Mapping System		
Attribute	**Affera Mapping System (K233943)**	**Affera Integrated Mapping System (K241828)**
Intended Use	Catheter-based electrophysiological mapping	Same
Fundamental Scientific Technology (Navigation/ localization)	• Magnetic-based tracking of embedded sensor	• Magnetic-based tracking of embedded sensor • Hybrid electromagnetic-impedance tracking of catheter electrodes
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

Stimulation/ Pacing	Internally (20 mA max) and externally generated pacing	Same
ECG Signal Acquisition	Body surface ECG signals imported from hospital recording system	Body surface ECG signals recorded directly by the Affera Integrated Mapping System
EGM Acquisition	Intracardiac electrogram signals generated from electrodes from the connected catheters	Same

Impedance Localization Patch Kit		
Attribute	**EnSite Precision Surface Electrode Kit (K201148)**	**Impedance Localization Patch Kit (K241828)**
Intended Use	Catheter-based electrophysiological mapping	Same
Supported Tracking and Navigation Modalities	• Magnetic-based tracking • Impedance-based tracking	Same
Patch Configuration	• 6 surface electrodes/patches • 2 additional patches for connection of magnetic sensors	• 6 surface electrodes/patches
Sterility	Non-sterile	Same
Use Limitations	Single-use	Same

The Affera Integrated Mapping System and Impedance Localization Patch Kit share the following same or similar technological characteristics with the predicate device:

- Same intended use. Differences in indications for use statements between the subject and predicate devices do not constitute a different intended use.
- Magnetic-based tracking of sensor-equipped compatible catheters
- 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.
- Same patient data management functionality with respect to the features offered by the subject devices.
- The Impedance Localization Patch Kit contains a subset of the contents of the predicate device (6 surface electrodes/patches)

The differences in technological characteristics involve the following:

- The Affera Integrated Mapping System is designed and intended for magnetic-based tracking of embedded sensors as well as hybrid electromagnetic-impedance tracking of catheter electrodes; whereas the predicate device includes magnetic-based tracking only.
- The Affera Integrated Mapping System has the capability to directly acquire ECG signals, while the predicate device can only acquire ECG signals from the hospital recording system.
- The Impedance Localization Patch Kit does not include a reference electrode or separate patches for connection of magnetic sensors, which are included in the predicate device, as these components are not required for use.

These differences do not raise different questions of safety and effectiveness and do not preclude a meaningful comparison with the predicate devices.

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 Impedance Localization Patch Kit, 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
- Biocompatibility testing (AFR-00015)
- 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.

Pre-determined Change Control Plans (PCCPs)

Within K241828, Medtronic has included notification of two PCCPs for planned modifications for devices in scope, to be implemented after market authorization:

1. The shelf life for the Impedance Localization Patch Kit is planned to be changed from 6-months to 24-months, post submission, supported by appropriate design verification evidence.
2. Subsequent to clearance of K241828, Medtronic intends to incorporate AFR-00016 software updates and hardware modifications to support compatibility with additional third-party, 510k-cleared mapping catheters.

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.