



December 5, 2024

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

Re: K243435

Trade/Device Name: Affera Integrated Mapping System; Magnetic Localization Patch Kit  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable diagnostic computer  
Regulatory Class: Class II  
Product Code: DQK  
Dated: November 5, 2024  
Received: November 5, 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](mailto: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

510(k) Number (if known)  
K243435

Device Name  
Affera Integrated Mapping System;  
Magnetic 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.

#### Magnetic 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.

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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## 510(k) Summary

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**Date Summary Prepared:** December 3, 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  
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**Device Trade Name:** Affera Integrated Mapping System;  
Magnetic Localization Patch Kit

**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; Impedance Localization Patch Kit (K241828)

**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 overlaid 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.

Magnetic Localization Patch Kit:

The Magnetic Localization Patch Kit is an accessory device that includes 2 surface localization patches and is used with the Affera Integrated Mapping System for electromagnetic-based tracking and navigation only. The patches are placed in fixed positions in contact with the patient's skin and provide a provide a stable mounting point for magnetic sensors within the intended connecting cable, which are used to provide information regarding patient position and movement during electromagnetic-based tracking and navigation procedures.

**Intended Use:**

The Magnetic Localization Patch Kit is 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.

Magnetic 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:**

There are no changes to the Affera Integrated Mapping System in scope of K243435. This premarket notification involves changes to the Impedance Localization Patch Kit only, resulting in a modified subject device that will be commercialized as the Magnetic Localization Patch kit under model AFR-00021.

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

Attribute	Predicate Device Impedance Localization Patch Kit (K241828)	Subject Device Magnetic Localization Patch Kit (K243435)
Intended Use	Catheter-based electrophysiological mapping	Same
Supported Tracking and Navigation Modalities	<ul style="list-style-type: none"> <li>• Electromagnetic-based tracking</li> <li>• Impedance-based tracking</li> </ul>	<ul style="list-style-type: none"> <li>• Electromagnetic-based tracking</li> </ul>
Localization patch Configuration	6 surface electrodes/patches: <ul style="list-style-type: none"> <li>• Anterior Patch</li> <li>• Posterior Patch</li> <li>• Left Patch</li> <li>• Right Patch</li> <li>• Superior Patch</li> <li>• Inferior Patch</li> </ul>	2 surface electrodes/patches: <ul style="list-style-type: none"> <li>• Anterior Patch</li> <li>• Posterior Patch</li> </ul>
Localization patch dimension	100 mm x 65 mm	50mm x 40mm
Sterility	Non-sterile	Same
Use Limitations	Single-use	Same

The Magnetic Localization Patch Kit shares the following same or similar technological characteristics with the predicate device:

- Same intended use and indications for use statement
- Supports electromagnetic-based tracking
- Contains similar patch contents as the predicate device (Anterior and Posterior patches)

The differences in technological characteristics involve the following:

- The Magnetic Localization Patch Kit is intended for electromagnetic-based tracking and navigation and does not support hybrid impedance-based tracking and navigation, which is supported by the predicate device.
- The Magnetic Localization Patch Kit does not include Left, Right, Superior, or Inferior patches, which are not needed for electromagnetic-based tracking and navigation.
- The dimensions of the Anterior and Posterior patches of the Magnetic Localization Patch Kit have been reduced as compared to the predicate.

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

**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. The following testing has been completed in support of the Magnetic Localization Patch Kit, and all acceptance criteria were met in accordance with appropriate standards:

- Design verification testing
- Design validation
- Pre-clinical animal testing
- Biocompatibility testing
- Packaging validation

No new 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 the same or similar underlying technological

K243435

characteristics. 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 respective predicate device.