November 8, 2018

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

Re: K181918
Trade/Device Name: CardioInsight Cardiac Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 9, 2018
Received: October 10, 2018

Dear Janell Colley:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181918

Device Name
CardioInsight® Cardiac Mapping System

Indications for Use *(Describe)*
The CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

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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"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 per 21 CFR 807.92

Date Summary Prepared:	October 9, 2018
Applicant:	Medtronic, Inc.
	8200 Coral Sea Street NE
	Mounds View, MN 55112
	Establishment Registration Number 2012208
Contact Persons	
Primary Contact:	Janell Colley
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	Medtronic, Inc./AF Solutions
	8200 Coral Sea Street NE
	Mounds View, MN 55112
	Fax: 763.367.9903
Trade Name:	CardioInsight Cardiac Mapping System
Common Name:	Electrophysiological cardiac mapping system
Classification:	Class II
Panel:	Cardiovascular
Product Code:	DQK
Regulation:	21 CFR 870.1425
Predicate Device:	CardioInsight Cardiac Mapping System, K162440, Cleared November 4, 2016

Device Description	The CardioInsight Cardiac Mapping System is a non-invasive mapping system for beat-by-beat, multi-chamber, 3D mapping of the heart. The CardioInsight Cardiac Mapping System displays cardiac maps and virtual electrograms from real-time chest ECG signals (measured by a Sensor Array placed on the torso) and CT scan data. The ECG signals in concert with the CT scan information (geometrical information) are used in mathematical algorithms to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem. The CardioInsight Cardiac Mapping System software uses this data to provide various cardiac signal analyses and displays interactive 3D color maps including potential, activation, voltage, propagation, and phase maps. The CardioInsight Cardiac Mapping System is mobile and can be used for mapping at the patient's bedside or in the EP lab.

Model Numbers	
CardioInsight Cardiac Mapping System	CIT200
Sensor Array (Vest)	CITVST0001S (size small)
	CITVST0002M (size medium)
	CITVST0003L (size large)
	CITVST0004XL (size x-large)
Workstation Computer with Software	PN-0008-0001-0000
Amplifier	PN-0006-0001-0000
Signal Cables	PN-AT200-AMP-0002 (right side)
	PN-AT200-AMP-0003 (left side)
	PN-AT200-AMP-0004 (back left side)
	PN-AT200-AMP-0005 (back right side)
Patient Ground Reference Cable	PN-AT200-AMP-0021
Isolation Transformer	PN-0004-0008-0003
Monitor	PN-0004-0008-0007
USB Tool	CITUSB

Indications for Use:	The CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician. The Indications for Use statement is identical to the predicate device.

Comparison of Technological Characteristics	The CardioInsight Cardiac Mapping System uses the same technology, and has the same intended use, fundamental technology, principal of operation and performance as the predicate device. Modifications to software were made to enhance map processing/analysis capabilities and usability. Multiple anomalies were addressed, and off-the-shelf software updates and additions were made. Security features were added.

Characteristic	**CardioInsight Cardiac Mapping System v3.0 (Predicate System)**	**CardioInsight Cardiac Mapping System v3.5 (Proposed System)**
Intended Use	Individuals undergoing an EP Study	Identical
Indications for Use	The CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.	Identical
System components	Cart, Monitor, Core processor, Keyboard, Mouse, Isolation Transformer, Cabling, Sensor Array, Second monitor connections	Identical
Principles of Operation	Electrocardiographic potentials are measured from the torso sensors on the surface of the body. A CT scan is segmented to obtain the 3-dimensional location of each sensor and the detailed anatomy of the epicardial surface of the heart. From these data, the system uses mathematical algorithms to use the geometrical information to transform the measured body surface signals into epicardial signals via solving the cardiac inverse problem.	Identical
Software/ Firmware/ Algorithm	Creates patient records Segments heart and vest electrodes Acquires sensor array signals Creates and reviews maps	Identical workflows; software enhancements throughout.

Off the Shelf Software	In addition to other unchanged OTS/SOUP software, device uses the following OTS/SOUP software: • BBV Common 7.4 • SQL Server Express 12.0.2000.8 • SnagIt 9.1.3 • .NET 4.5.2 • DevExpress 14.2.4 • MVVM Light 3.0.0.29166	In addition to other unchanged OTS/SOUP software, • Appccelerate State 2.12.0 (formerly BBV Common) • SQL Server Express 12.0.5000.8 • SnagIt 12.4.1 • .NET 4.5.2 with Language Packs • DevExpress 14.2.4 with Language Packs • libFLAC 1.3.2 • Libogg 1.3.1 • FlacDotNet 1.5.0.0 • NASM 2.13.01 • Json.NET 10.0.3 • Ndesk.Options 0.2.1 • McAfee Endpoint Security for OEM 10.5.3 • McAfee Medical Devices Solution 7.2.4

Performance Data	Performance testing was completed on the CardioInsight Cardiac Mapping System which verified that the System complies with the safety and specifications and performs as designed; it is suitable for its intended use. Performance testing for the proposed system included the following:
	• Software verification and integration testing was performed and complied with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and AAMI / ANSI / IEC 62304:2006/AMD1:2015, Medical Device Software - Software Life Cycle Processes. The software in this system is considered moderate level of concern as failure could contribute to a hazard leading to non-serious injury. Testing evaluated the following: o Integration testing to conclude that the product design output meets the design input requirements of the integration of algorithm code. o Verification testing to conclude the product design output meets the design input requirements
	• Algorithm Testing and Integration – verified the algorithms met requirements and functioned as intended, and when integrated, performed as expected. Bench testing and simulated use testing evaluated the following: o Max –dV/dt vs. Mid-Point Activation Algorithm o Detection via new IBCD Algorithm o Remove bad channels from inverse calculation

	▪ System Verification and Validation testing for functionality and performance in a simulated environment. Testing evaluated the following: o Verification testing to conclude the product design output meets the design input requirements o Validation testing to conclude the design validation for the incremental changes made to the system performs as intended from the user perspective
	• Usability Testing per IEC 62366-1 Edition 1.0 2015-02 Usability testing consisted of Human Factors testing for the incremental changes made to the system, including formative evaluation activities, use error analysis, user interface design, mockup reviews, labeling review, and formal/informal simulated use evaluations.
Discussion	Modifications to the software and algorithms were made for usability and mapping enhancements. Updates were made to address anomalies. Off-the-shelf software changes were made to utilize latest versions and additions to support functionality. Security features including hard drive encryption and database permissions refinement have been added. Indications for use, principals of operations and fundamental technology do not change with these modifications.
Conclusion	The data presented in this submission demonstrate that the CardioInsight Cardiac Mapping System v3.5 is substantially equivalent to the predicate device identified in intended use, device design, fundamental technology and performance.