DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 4, 2016

Medtronic Inc.
Laurie Lewandowski
Regulatory Associate
8200 Coral Sea St NE
Mounds View, MN 55112

Re: K162440
Trade/Device Name: Medtronic CardioInsight® Cardiac Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 6, 2016
Received: October 7, 2016

Dear Laurie Lewandowski:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162440

Device Name
Medtronic CardioInsight® Cardiac Mapping System

Indications for Use *(Describe)*
The Medtronic 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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510(k) Summary per 21 CFR §807.92

Date Summary Prepared:	October 4, 2016
Applicant:	Medtronic (Owner/Operator) CardioInsight Technologies 11000 Cedar Avenue Suite 210 Cleveland, OH 44106 **Establishment Registration No.**: 3006526833
Contact Persons:	
Primary Contact:	Laurie Lewandowski Regulatory Affairs Specialist (consultant) Telephone: 612-770-4038 Email: laurie.a.lewandowski @medtronic.com
Alternate Contact:	Kristyn Benson Director, Regulatory Affairs Telephone 763-526-2523 Email: Kristyn.m.benson@medtronic.com
	Medtronic Inc./AF Solutions 8200 Coral Sea Street NE Mounds View, MN 55112 Fax: 763.367.9903
Trade Name:	Medtronic CardioInsight® Cardiac Mapping System
Common Name:	Electrophysiological cardiac mapping system
Classification Name:	Programmable diagnostic computer,
Classification &	Class II
Panel:	Cardiovascular
Product Code:	DQK
Regulation:	21 CFR 870.1425
Predicate Device(s):	ECVUE MAPPING SYSTEM, (K150990)

Device Description:

The Medtronic CardioInsight® Cardiac Mapping System is a non-invasive mapping system for beat-by-beat, multichamber, 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 system is mobile and can be used for mapping at the patient's bedside or in the EP lab.

Model numbers of the system components are as follows:

System or Component	**Model Number**
CardioInsight Cardiac Mapping System	CIT 200
Work Station Computer	CIT 200-PC-0001 (w/SW)
Sensor Array (Vest)	CIT200-SA-0001 (S) CIT 200-SA-0002 (M) CIT 200-SA-0003 (L) CIT 200-SA-0004 (XL)
Cart	200-WC-0 001
Amplifier	CIT 200-AMP-0001
Connector Cables	CIT 200-AMP-0002 Signal Cable (Right) CIT 200-AMP-0003 Signal Cable (Left) CIT 200-AMP-0004 Signal Cable (Back Left) CIT 200-AMP-0005 Signal Cable (Back Right
Patient/Ground Reference Cable	CIT 200-AMP-0021

Indications for Use:

The Medtronic 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 were made for processing capacity and usability.

Characteristic	Medtronic CardioInsight Cardiac Mapping System (Proposed System)	CardioInsight ECVUE Mapping System (Predicate System)
Intended Use	Identical	For individuals undergoing an EP Study
Indications for Use	Identical	The CardioInsight ECVUE Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician
System	Cart, Monitor, Core Processor, Keyboard, Mouse, Isolation Transformer, Cabling, Sensor Array, Second Monitor connection	Cart, Monitor, Core Processor, Keyboard, Mouse, Isolation Transformer, Cabling, Sensor Array, Printer, UPS
Principal of Operation	Identical	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.

Characteristic	Medtronic CardioInsight Cardiac Mapping System (Proposed System)	CardioInsight ECVUE Mapping System (Predicate System)
Software / Firmware / Algorithm	Equivalent functionality – improved usability, reducing manual input required and fixing bugs OTS software	Create patient records Segment heart and vest electrodes Acquire sensor array signals Create and review maps
Off the Shelf Software	Updated to latest versions. Added additional Off the Shelf Software to support functionality • Fellow Oak DICOM • Boost C++ Libraries • DevExpress • WPF Components Library • Parallel Studio XE Composer	Entity Framework SQL Server Express OpenInventor 64-bit .NET Framework

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:

Hardware Verification compliance with dimensions, cart functionality and mechanical safety as well as the amplifier mechanical and electrical functionality and electrical safety.
Labeling Verification to applicable requirements
Electrical Safety compliance per
ANSI/AAMI ES 60601-1:2005/A1:2012
IEC 60601-1:2005/A1:2012
EN 60601 1:2006/A1:2013
All excluding: excluding biocompatibility (cl. 11.7), usability (cl. 12.2 and 15.1), and EMC (cl. 17)
EMC/EMI compliance per
AAMI / ANSI / IEC 60601-1-2:2007/(R)2012

Mechanical Safety compliance per
ANSI/AAMI ES 60601-1:2005/A1:2012
IEC 60601-1:2005/A1:2012
EN 60601 1:2006/A1:2013
All excluding: excluding biocompatibility (cl. 11.7), usability (cl. 12.2 and 15.1), and EMC (cl. 17)

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, 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. Algorithm Testing and Integration – verified the algorithms met requirements and functioned as intended and when integrated performed as expected. Firmware Verification – demonstrated that the firmware met requirements Packaging Validation was performed and demonstrated that the packaging and the system met the environmental conditioning and simulated shipping per the applicable sections of ASTM D4332-14 and ASTM D4169. Usability Testing System Verification and Validation testing for functionality and performance in a simulated environment. Preclinical and clinical testing were not required for the CardioInsight Cardiac Mapping System. Testing demonstrated that the CardioInsight Cardiac Mapping System met the requirements and functioned as intended.
Discussion	Minor differences in technology, update of hardware due to obsolescence, removal of the printer that was not used, removal of the UPS for portability and not necessary for function of current system and the addition of an optional second monitor do not change the fundamental technology. Modifications to the software, firmware and algorithms were made for usability, reducing the manual interaction required. Updates were made to firmware for bug fixes, off the shelf software to update to the latest versions and additions to support functionality. 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 Medtronic CardioInsight Cardiac Mapping System is substantially equivalent to the predicate device identified in intended use, device design, fundamental technology and performance.