DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 13, 2016

St. Jude Medical
Marlene Peterson
Sr. Regulatory Affairs Manager
One St. Jude Medical Dr
St. Paul, Minnesota 55117

Re: K160210
Trade/Device Name: EnSite Precision Cardiac Mapping System V2.0.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 23, 2016
Received: September 26, 2016

Dear Marlene Peterson:

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.

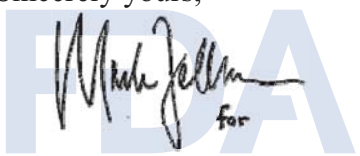
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 yours,



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)*
K160210

Device Name
EnSite Precision™ Cardiac Mapping System, v2.0.1

Indications for Use *(Describe)*
The EnSite Precision™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated.

The EnSite™ Precision System interfaces to either the MediGuide™ Technology system or the EnSite Precision Module to combine and display magnetic processed patient positioning and navigation mapping information.

When used with the EnSite™ Array™ Catheter, the EnSite Precision™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

OR

When used with an EnSite Precision™ Surface Electrode Kit, the EnSite Precision™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.

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.

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510K SUMMARY

510(k) Number	K160210
Date Prepared	October 25, 2016
Submitter Information	
Manufacturer Name/Address	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 551177
Contact Person	Marlene Peterson Sr. Regulatory Affairs Manager Phone (651) 756-3268 mpeterson07@sjm.com
Device Information	
Trade Name	EnSite Precision™ Cardiac Mapping System, v2.0.1
Common Name	Programmable Diagnostic Computer
Class	II
Classification Name	870.1425, computer, diagnostic, programmable
Product Code	DQK
Predicate Device	EnSite™ Velocity™ Cardiac Mapping System K141050 MediGuide Technology K120301
Reference Files	K160187 - EnSite™ Velocity™ Cardiac Mapping System v5.0 • EnSite Precision™ v2.0 is a software module that runs on EnSite™ Velocity™ Cardiac Mapping System v5.0 base software which is in parallel review under K160187. K160186 – EnSite™ Velocity™ Surface Electrode Kit • A branding name change was made to the Indications for Use within this submission in relation to the NavX Surface Electrode Kit. The name was changed to the EnSite Precision™ Electrode Kit. The EnSite Precision™ Electrode Kit contains a special convenience kit which includes the magnetic sensor patches (which are part of the new hardware introduced in this submission) under review for this submission. The modified EnSite™ Velocity™ Surface Electrode Kit is in parallel review under K160186. K160335 – Advisor™ FL, Circular Mapping Catheter, Sensor Enabled™ • The Advisor™ FL, Circular Mapping Catheter, Sensor Enabled™ is a sensor-enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart. The catheter will be used with the subject device to achieve its intended use.

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Device Description	The EnSite Precision™ Cardiac Mapping System is a catheter navigation and mapping system capable of displaying the three-dimensional (3D) position of conventional electrophysiology catheters, as well as displaying cardiac electrical activity as waveform traces and as dynamic 3-D isopotential maps of the cardiac chamber. The contoured surfaces of these three-dimensional maps are based on the anatomy of the patient's own cardiac chamber. The EnSite Precision™ Cardiac Mapping System with version 2.0 software is a new module that is designed to allow the system to interface to the EnSite Precision™ Module, Sensor Enabled, which is an alternative magnetic field-based medical positioning hardware kit for magnetic field scaling functionality.
Indications for Use	The EnSite Precision™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ Precision System interfaces to either the MediGuide™ Technology system or the EnSite Precision Module to combine and display magnetic processed patient positioning and navigation mapping information. When used with the EnSite™ Array™ Catheter, the EnSite Precision™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. OR When used with an EnSite Precision™ Surface Electrode Kit, the EnSite Precision™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.
Submissions History	No prior submissions have been made for the subject device.
Predicate Comparison	The proposed EnSite Precision™ Cardiac Mapping System with Precision™ software version 2.0 and associated accessories has the same intended use and fundamental scientific technology as the predicate devices, the EnSite™ Velocity™ Cardiac Mapping System, version 4.0.2 software, cleared under K141050, and MediGuide Technology, cleared under K120301. The upgrade to the EnSite Precision™ Cardiac Mapping System with Precision™ version 2.0 software and associated the EnSite Precision™ Module, Sensor Enabled hardware has 3 main objectives: **1.** Introduce a new software module called EnSite Precision™ v2.0, **2.** Introduce a new compatible magnetics hardware called the EnSite Precision™ Module, Sensor Enabled , and **3.** Update the amplifier firmware to allow communication and synchronization to the new hardware.

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	Both the subject and predicate devices operate using the same fundamental scientific technology to display catheter location and navigation. The subject device uses the new compatible magnetic hardware, the EnSite Precision™ Module, Sensor Enabled as an alternate to the MediGuide™ System cleared under K120301 as a source for generating a magnetic field to facilitate field scaling for model optimization. Both apply a known magnetic field to the cardiac region to monitor induced current on a small coil type magnetic sensor embedded in an enabled device. The magnetic field-based catheter localization used for field scaling during model creation involves sensing of the magnetic fields generated through small coil sensors embedded inside the enabled device. Both the MediGuide Technology and the new compatible magnetics hardware interface to the EnSite Precision Cardiac Mapping System to provide the user the ability to import, combine and display magnetic positioning and orientation information. The frequencies used for collecting sensor positions used between the MediGuide Technology and the new compatible magnetics hardware differ. However, There is no impact to safety and effectiveness as both sets of transmitted frequencies are specifically chosen for their characteristics of being above the biological signal frequency band and thus not interfering with other lab equipment. Safety and effectiveness is demonstrated per International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines for Limiting Exposure to Time-varying Electric, Magnetic and Electromagnetic Fields (up to 300GHz) – 1998 and the verification and validation testing performed which includes accuracy testing for use with the magnetic field scaling feature. There are differences between the proposed system and the MediGuide Technology in terms of catheter positioning error. In the subject device magnetic data from either the EnSite Precision™ Module, Sensor Enabled or MediGuide Technology is used in relation to the NavX generated impedance locations which has lower precision. In the MediGuide Technology System, MediGuide magnetic data is used to project onto an x-ray image with higher precision. While the accuracy requirements for the subject and predicate devices are different, both must meet the same system level accuracy requirement for magnetic field scaling. Since magnetic field scaling is a correction factor applied to the impedance coordinate system, once the proposed device (EnSite Precision™ Module, Sensor Enabled™ hardware) magnetic accuracy requirements are met the impedance coordinates themselves become the limiting factor to the correction and further differences between the two system's magnetics coordinate errors are no longer significant with respect to magnetic field scaling.

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Non-Clinical Testing Summary	Design verification/validation activities were performed with their respective acceptance criteria to ensure that the modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. <u>Testing</u> The Ensite Precision™ Cardiac Mapping System was developed and tested in accordance with the following industry guidance documents and standards: • FDA Reviewers and Compliance on Off-the-Shelf Software used in Medical Devices and IEC 62304 OTS classification • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices • IEC 62304:2006 Medical Device Software - Software Life Cycle Processes • IEC 62366:2012 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff • IEC 60601-1 (2005 + COOR.1 (2006) + COOR.2 (2007) Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance • IEC 60601-1-2 2007 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic disturbance – requirements and tests • ISO 10993-1:2009 Biological Evaluation of Medical Devices • EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as part of this submission. Software Documentation for OTS software classified as a Moderate Level of Concern, Class B according the FDA guidance, FDA Reviewers and Compliance on Off-the-Shelf Software used in Medical Devices and IEC 62304 OTS classification is included as part of this submission. Design verification and validation testing of the EnSite Precision™ Cardiac Mapping System including the EnSite Precision™ Module Sensor Enabled™ hardware and accessories was conducted to ensure that the proposed system meets requirements and is suitable for its intended use. Testing included: • Electrical, • Mechanical, • Accuracy and Repeatability, • Packaging, shelf life,

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	• Biocompatibility, • Preclinical Animal Studies Both Dynamic Wetlab Bench Comparative and Preclinical Animal testing was completed utilizing the subject device and the predicate devices in support of a substantial equivalence determination. The testing included the following: • Comparisons between the subject and predicate devices in regards to both model rendering and location of catheter electrodes with magnetic field scaling applied. • Comparisons between the subject and predicate devices in regards to catheter electrode localization where Respiration Gating was turned on in the subject device and Respiration Gating was not available in the predicate devices. • Comparisons between the subject and predicate devices in regards to workflow and system performance when Positional Reference Tool (PRT) with EnGuide Stability Monitor is active in the subject device while only PRT is active in the predicate devices. The results demonstrated that the features of the subject device are substantially equivalent to the existing functionality of the predicate devices, and that the new technological characteristics of the subject device do not raise new questions regarding safety and effectiveness compared to those of the predicate devices. The results of the verification and validation testing met acceptance criteria demonstrating that the proposed system continues to meet all requirements affected by the device modifications described herein, is suitable for its intended use, and is substantially equivalent to the listed predicate devices. <u>Risk Management</u> The changes were evaluated through review of risk management to ensure no new hazards have been introduced by this change. The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The EnSite Precision™ Cardiac Mapping System conforms to the Cybersecurity requirements through the cybersecurity risk management process comprised of a risk assessment, risk control, and maintenance of cybersecurity activities.
Statement of Equivalence:	The technological characteristics for the device are the same as the predicate devices. Based on this and the data provided in this pre-market notification, the subject devices and predicate devices have been shown to be substantially equivalent.