June 26, 2020

Abbott Medical
Alyssa Timmers
Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K201148
Trade/Device Name: EnSite Precision™ Cardiac Mapping System v2.6
EnSite™ Velocity™ Cardiac Mapping System v5.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: April 28, 2020
Received: April 29, 2020

Dear Alyssa Timmers:

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/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 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 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,

Mark Fellman
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201148

Device Name
EnSite Precision™ Cardiac Mapping System v2.6
EnSite™ Velocity™ Cardiac Mapping System v5.2

Indications for Use *(Describe)*
EnSite™ Velocity™ Cardiac Mapping System v5.2:

The EnSite™ Velocity™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated.

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

EnSite Precision™ Cardiac Mapping System v2.6:

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.

EnSite™ Verismo™ Segmentation Tool:

The EnSite Verismo™ Segmentation Tool is indicated for use in generating 3D models from CT, MR or rotational angiography DICOM image data. Generated models are intended to be displayed on the EnSite Velocity System.

EnSite™ Derexi™ Module:

When used with EnSite™ Derexi ™ Module, the EnSite System interfaces to the EP-WorkMate™ System / WorkMate Claris™ System for synchronizing and display of patient information.

EnSite™ Courier™ Module:

When used with EnSite Courier Module allows the patient data to be archived to, and retrieved from, a DICOM conformant PACs server.

EnSite™ Fusion™ Registration Module:

EnSite Fusion is indicated for registering the EnSite NavX navigation system to anatomic models, derived from CT scans, of the four individual cardiac chambers.

EnSite™ Contact Force Module:

When used with the SJM Contact Force Unit, the EnSite™ Contact Force Module is intended to provide visualization of force information from compatible catheters.

EnSite™ AutoMap Module:

When used with the EnSite AutoMap Module, the EnSite System is intended to automatically collect mapping points based on criteria set by the user.

AutoMark Module:

When used with compatible hardware, the AutoMark Module is intended to automatically catalog and display various parameters associated with RF information on the 3D model in real-time.

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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510(k) Information	
510(k) Number	K201148
510(k) Type	Traditional 510(k)
Date Prepared	28 April 2020
Submitter Information	
Manufacturer Name & Address	Abbott Medical One St. Jude Medical Drive, St. Paul, Minnesota, 55119, USA
Contact Person	Alyssa Timmers Regulatory Affairs Specialist 651-756-3706 alyssa.timmers@abbott.com
Device Information	
Trade Name	EnSite Precision™ Cardiac Mapping System v2.6 EnSite™ Velocity™ Cardiac Mapping System v5.2
Common Name	Programmable Diagnostic Computer
Class	II
Classification Name	870.1425, computer, diagnostic, programmable
Product Code	DQK
Predicate Device	EnSite™ Velocity™ Cardiac Mapping System v5.2 and EnSite Precision™ Cardiac Mapping System v2.2 (K183128)
Reference Device	Not Applicable
Device Description	The EnSite™ Velocity™ Cardiac Mapping System v5.2 / EnSite Precision™ Cardiac Mapping System v2.6 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™ Velocity™ Cardiac Mapping System is used as a diagnostic tool in electrophysiology (EP) Studies. An EP study involves the introduction of one or more electrode catheters into the heart to record its electrical activity. These catheters connect to the EnSite™ Velocity™ Cardiac Mapping System through specialized catheter input modules (CIMs). The EnSite™ Velocity™ Cardiac Mapping System is designed for use in the EP laboratory in conjunction with other equipment. The EnSite™ Velocity™ Cardiac Mapping System consists of hardware and software elements. The EnSite™ Velocity™ / EnSite Precision™ System consists of software, a display workstation (DWS) subsystem (DWS, Monitors, DWS Accessory Kit, and DWS Power Kit), and an amplifier subsystem (Amplifier and Amplifier Accessory Kit). The DWS houses the system software and connects all the components together. The amplifier contains electronic circuitry and firmware responsible for collecting and transmitting the electrical signal data of the patient to the DWS software. Its primary function is to collect and transmit via Ethernet the electrical data detected from the patient. The amplifier accepts

Device Description (continued)	signals from NavLink, ArrayLink, CathLink, ECG Cable, RecordConnect, and GenConnect, converts these signals to a digital format, and sends them to the workstation for processing. The NavLink connects surface electrodes and the system reference surface electrode to the Amplifier. The ArrayLink connects the EnSite Array Multielectrode Diagnostic Catheter to the Amplifier. It also has a connection for an auxiliary unipolar reference electrode. The CathLink connects the diagnostic catheters to the Amplifier. The GenConnect connects the ablation catheter and dispersive surface electrodes to the Amplifier. The RecordConnect allows simultaneous connection for catheters and surface ECG to a recording system and to the Amplifier. The ECG cable connects standard ECG electrodes to the Amplifier. The system operates using impedance only or impedance plus magnetics based upon its configuration. The EnSite™ Velocity™ Cardiac Mapping System base software only collects impedance data. Adding EnSite Precision™ software to the base software allows the system to receive both magnetic data from the MediGuide™ Technology System or the EnSite Precision™ Module hardware and impedance data when using magnetic sensor enabled tools. The EnSite Precision™ Module and EnSite Precision™ software (added to the base software) together make up the EnSite Precision™ Cardiac Mapping System. The EnSite Precision™ software interfaces to the MediGuide™ Technology System or the EnSite Precision™ Module to collect magnetic position and orientation information. The EnSite Precision™ software uses the magnetic data for magnetic field scaling (NavX SE), shift detection (EnGuide Stability Monitor), and respiration gating. NavX SE field scaling adjusts the dimensions of the navigation field based on both the positon and orientation of magnetic sensors and the electrodes on Sensor Enabled™ (SE) tools, optimizing the appearance of the model. The system uses EnGuide Stability Monitor to notify the user of a potential shift based on a correlation of magnetic and impedance locations when using any Sensor Enabled catheter. The system uses respiration gating to compensate to the end-point of the respiration cycle using magnetic data to determine respiration phase. The EnSite Precision™ Module consists of hardware to support magnetic navigation. The hardware components consist of the EnSite Precision™ Link, EnSite Precision™ Field Frame, and EnSite Precision™ Patient Reference Sensors.
Expansion Module Device Description	The EnSite Precision™ Cardiac Mapping System v2.6 includes the following optional expansion software modules: **1. EnSite™ Verismo™ Segmentation Tool** - an optional expansion module used in generating 3D models from CT, MR or rotational angiography DICOM image data and displaying images on the EnSite™ Velocity™ Cardiac Mapping System. The EnSite™ Verismo™ Segmentation Tool accepts DICOM images from CT and MRI scanners and converts the images into a 3D model of cardiac structures. **2. EnSite™ Derexi™ Module** - an optional expansion module that that allows the EnSite Velocity System to interface with the WorkMate™ Recording System to support the exchange of mapping point data and patient setup information between the two systems. **3. EnSite™ Courier™ Module** - The EnSite™ Courier™ Module is an optional expansion module that allows the EnSite™ Velocity™ Cardiac Mapping System to communicate with the hospital PACS (Picture Archiving and Communication System) server for the purposes of storing and retrieving patient data in DICOM format. **4. EnSite™ Fusion™ Registration Module** - an optional expansion module that provides non-fluoroscopic navigation, mapping, and labeling on a Digital Image Fusion (DIF) model. The module is used with the EnSite™ NavX™ Navigation and Visualization Technology Surface Electrode Kit and CT or MR scans segmented into a compatible file format. 3D

Expansion Module Device Description (continued)	models created from digital images from CT and MRI data can be imported onto the EnSite™ Velocity™ System. **5. EnSite™ Contact Force Module** - an optional expansion module that provides the display of information from the TactiSys Quartz System. The EnSite Velocity System's EnSite Contact Force Module is intended to provide visualization of force information from compatible catheters. **6. EnSite™ AutoMap Module** - an optional module that automatically collects mapping points based on criteria set by the user. **7. AutoMark Module** - module allows the user to set parameters and the software automatically displays the lesion marks on the EnSite Velocity model during RF ablation. The user set parameters is based on data from Ensite™ Contact Force Module, the Ampere Generator, and the WorkMate Claris™ System which is displayed on the AutoMark Module as lesion marks on the during RF ablation. The color, size, and ranges of the AutoMark are defined by the user.
Indications for Use	**EnSite™ Velocity™ Cardiac Mapping System v5.2:** The EnSite™ Velocity™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. When used with the EnSite™ Array™ Catheter, the EnSite™ Velocity™ 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™ Velocity™ Surface Electrode Kit, the EnSite™ Velocity™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart. **EnSite Precision™ Cardiac Mapping System v2.6:** 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. **EnSite™ Verismo™ Segmentation Tool:** The EnSite Verismo™ Segmentation Tool is indicated for use in generating 3D models from CT, MR or rotational angiography DICOM image data. Generated models are intended to be displayed on the EnSite Velocity System. **EnSite™ Derexi™ Module:** When used with EnSite™ Derexi ™ Module, the EnSite System interfaces to the EP-WorkMate™ System / WorkMate Claris™ System for synchronizing and display of patient information.

Indications for Use (continued)	**EnSite™ Courier™ Module:** When used with EnSite Courier Module allows the patient data to be archived to, and retrieved from, a DICOM conformant PACs server. **EnSite™ Fusion™ Registration Module:** EnSite Fusion is indicated for registering the EnSite NavX navigation system to anatomic models, derived from CT scans, of the four individual cardiac chambers. **EnSite™ Contact Force Module:** When used with the SJM Contact Force Unit, the EnSite™ Contact Force Module is intended to provide visualization of force information from compatible catheters. **EnSite™ AutoMap Module:** When used with the EnSite AutoMap Module, the EnSite System is intended to automatically collect mapping points based on criteria set by the user. **AutoMark Module:** When used with compatible hardware, the AutoMark Module is intended to automatically catalog and display various parameters associated with RF information on the 3D model in real-time.
Submission History	No prior submissions have been made to FDA for the device that is the subject of this submission.
Predicate Comparison	
Comparison	Both the subject and predicate devices have the same intended use, indications for use, and operate using the same fundamental scientific technology to facilitate catheter position and orientation, as well as cardiac mapping and model creation. The proposed EnSite Precision Cardiac Mapping System v2.6 software release is a minor level software release to enable implementation of a software feature, EnSite LiveView, which provides the users the ability to display real-time mapping data without the need to save mapping points, addresses open software anomalies, and improves the system's ability to limit personally identifiable information when archiving studies. There are no new or increased risks that result from the proposed modifications presented within the submission, and the changes do not raise any new questions of safety and effectiveness in regards to the subject device.
Non-Clinical Testing Summary	Design verification activities were performed with their respective acceptance criteria to ensure that the proposed modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. **Testing** The EnSite Precision Cardiac Mapping System v2.6 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 – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff – EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

Non-Clinical Testing Summary (continued)	– EN ISO 62304 Edition 1.1 2015-06 Medical Device Software - Software Life Cycle Processes **Types of Testing Performed** – Software verification testing to ensure the software continues to meet requirements following the proposed modifications – Design validation studies to ensure the installation process for updating the software meets requirements – An acute system level animal study to ensure the modified system had acceptable performance **Risk Management** The changes to the EnSite Precision™ Cardiac Mapping System was evaluated through review of risk management to ensure no new hazards have been introduced by this change.
Statement of Equivalence	The technological characteristics for the subject device, and the indications for use are the same as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device have been demonstrated to be substantially equivalent.