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

October 21, 2016

St. Jude Medical
Melissa Frank
Senior Regulaotry Affairs Specialist
One St. Jude Medical
St. Paul, Minnesota 55117

Re: K160187
Trade/Device Name: Ensite™ Velocity™ Cardiac Mapping System V5.0.1, Ensite™ AutoMap Module V1.0.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 17, 2016
Received: October 18, 2016

Dear Melissa Frank:

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)*
K160187

Device Name
EnSite(TM) Velocity(TM) Cardiac Mapping System v5.0.1 with EnSite(TM) AutoMap Module v1.0.1

Indications for Use *(Describe)*
Device Name: EnSite™ Velocity™ Cardiac Mapping System v5.0.1
Indications for Use:
The EnSite™ Velocity™ Cardiac Mapping System is a suggested Diagnostic tool in patients for whom electrophysiology studies are indicated.

When used with 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 system alone.
OR
When used with the 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

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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# 510KSUMMARY

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| 510(k) Number | K160187 |
| Date Prepared | October 20, 2016 |
| Submitter Information | |
| Manufacturer Name/Address | St. Jude Medical<br>One St. Jude Medical Drive<br>St. Paul, MN 55117 |
| Contact Person | Melissa Frank<br>Sr. Regulatory Affairs Specialist<br>Phone (651) 756-2954<br>Mfrank02@sjm.com |
| Device Information | |
| Trade Name | EnSite™ Velocity™ Cardiac Mapping System v5.0.1 with EnSite™ AutoMap Module v1.0.1 |
| 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) |
| Secondary Predicates | The EnSite™ Velocity™ Cardiac Mapping System v5.0.1 includes the following optional expansion software modules:<br>EnSite™ Verismo™ Segmentation Tool (K101697)<br>EnSite™ Derexi™ Module (K110549)<br>EnSite™ Courier™ Module (K101419)<br>EnSite™ Fusion™ Registration Module (K082467)<br>EnSite™ Contact Force Module (K141050)<br>VeriSense System Software Module (K130727) |
| Reference Applications | EnSite™ Velocity™ Surface Electrode Kit (K160186) |

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| Base System Device Description: | The EnSite™ Velocity™ Cardiac Mapping System with software version 5.0.1 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.<br><br>The EnSite Velocity™ Cardiac Mapping System, Model EE3000 consists of a display workstation subsystem (DWS) and an Amplifier subsystem. The EnSite Amplifier collects the data from the patient connections and sends them to the DWS Workstation. The Amplifier connects to the DWS through a fiber optic cable and a media converter to convert the optical signals to digital signals. The EnSite™ Velocity™ DWS software displays the cardiac signal data received from the Amplifier on the workstation monitors and stores it for later retrieval.<br><br>**Display Work Station (DWS) Subsystem**<br>• DWS - The DWS houses the system software and connects all the components together.<br>• Monitors - Two monitors display patient information. One monitor is positioned near the workstation and keyboard for system operation, and the physician places the second monitor near the patient table for use.<br>• Isolation transformer - All system components on the DWS connect to line power through a medical-grade isolation transformer.<br>• Printer - Allows for printing study data<br><br>**Amplifier Subsystem**<br>• Amplifier - contains electronic circuitry and firmware responsible for collecting and transmitting the electrical signal data of the patient to the DWS software application via fiber Ethernet. The Amplifier converts these signals to a digital format and sends them to the workstation for |

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| | processing.<br>• NavLink - Connects surface electrodes and the system reference surface electrode to the Amplifier.<br>• ArrayLink - Connects the EnSite Array Multi-electrode Diagnostic Catheter to the Amplifier. It also has a connection for an auxiliary unipolar reference electrode.<br>• CathLink - Connects the diagnostic catheters to the Amplifier<br>• GenConnect - Connects the ablation catheter and dispersive surface electrodes to the Amplifier.<br>• RecordConnect - The RecordConnect allows simultaneous connection for catheters and surface ECG to a recording system and to the Amplifier.<br>• ECG cable - The ECG cable connects standard ECG electrodes to the Amplifier.<br><br>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 v5.0.1 is designed for use in the EP laboratory in conjunction with other equipment. |
| Expansion Module Device Description: | The EnSite™ Velocity™ Cardiac Mapping System v5.0 includes the following optional expansion software modules: |
| | • **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. |

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| | • **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. |
| | • **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. |
| | • **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 models created from digital images from CT and MRI data can be imported onto the EnSite™ Velocity™ System. |
| | • **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. |
| | • **EnSite™ Velocity™ System VeriSense System Software Module** - an optional expansion module that allows the EnSite Velocity System to interface with St. Jude Medical's VeriSense Kit to display the graphical representation of Electrical Coupling Index (ECI). |
| | • **EnSite™ AutoMap Module** - a new optional module that automatically collects mapping points based on criteria set by the user |
| Base System Indications for Use | **Device Name: EnSite™ Velocity™ Cardiac Mapping System v5.0.1**<br>The EnSite Velocity Cardiac Mapping System is a suggested Diagnostic tool in patients for whom electrophysiology studies are indicated. |

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| | When used with 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 system alone.<br>OR<br>When used with the 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 |
| Expansion Module IFU Statement | Intended Use for the EnSite™ Velocity™ Cardiac Mapping System optional expansion software modules: |
| | • **EnSite™ Verismo™ Segmentation Tool (K101697) -** 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 (K110549) -** 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 (K101419) -** 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 (K082467) -** 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 (K141050) -** When used with the SJM Contact Force Unit, the EnSite™ Contact Force Module is intended to provide visualization of force information from compatible catheters. |
| | • **VeriSense System Software Module (K130727) -** When used with the VeriSense System Software Module, the EnSite System is intended for monitoring catheter tip-to-tissue electrical coupling, which may be indicative of catheter tip-to-tissue contact during cardiac electrophysiology procedures via a proprietary Electrical Coupling Index (ECI). |

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| | • **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 |
| Submission History | No prior submissions have been made to FDA for the device that is the subject of this submission. |
| Predicate Comparison | |
| Non-Clinical Testing Summary | Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that the software modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications.<br><br><u>Testing</u><br>The Ensite™ Velocity™ Cardiac Mapping System software was developed and tested in accordance with the following industry guidance documents and standards:<br>• FDA Reviewers and Compliance on Off-the-Shelf Software used in Medical Devices and IEC 62304 OTS classification<br>• Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices<br>• IEC 62304:2006 Medical Device Software - Software Life Cycle Processes<br>• Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff<br><br>Software Documentation for a Major 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.<br><br>The changes to the application software and operating system along with addition of the optional software module were evaluated through software verification and validation to show that the application software is acceptable |

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| | for use and meets requirements.<br><br>Risk Management<br>The changes to the application software and operating system along with addition of the optional software module 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.<br><br>The Ensite™ Velocity™ 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 devices 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. |