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

Re: K160218
Trade/Device Name: EnSite Velocity Cardiac Mapping System v5.0.1
with AutoMark Module v1.0.1
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 20, 2016
Received: September 21, 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)*
K160218

Device Name
EnSite™ Velocity™ Cardiac Mapping System v5.0.1 with AutoMark 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

Device Name: AutoMark Module v1.0.1
Indications for Use:
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510KSUMMARY

510(k) Number	K160218
Date Prepared	October 18, 2016
Submitter Information	
Manufacturer Name/Address	St. Jude Medical One St. Jude Medical Drive St. Paul, MN 55117
Contact Person	Melissa Frank Sr. Regulatory Affairs Specialist Phone (651) 756-2954 Mfrank02@sjm.com
Device Information	
Trade Name	EnSite™ Velocity™ Cardiac Mapping System v5.0.1 with AutoMark 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	WorkMate Claris™ System (K151911)
Reference Devices	EnSite™ Velocity™ Cardiac Mapping System v5.0.1 with AutoMap Module v1.0.1 (K160187) EnSite Precision™ Cardiac Mapping System v2.0.1 (K160210)
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. 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.

Display Work Station (DWS) Subsystem

- DWS - The DWS houses the system software and connects all the components together.
- 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.
- Isolation transformer - All system components on the DWS connect to line power through a medical-grade isolation transformer.
- Printer - Allows for printing study data

Amplifier Subsystem

- 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 processing.
- NavLink - Connects surface electrodes and the system reference surface electrode to the Amplifier.
- ArrayLink - Connects the EnSite Array Multi-electrode Diagnostic Catheter to the Amplifier. It also has a connection for an auxiliary unipolar reference electrode.
- CathLink - Connects the diagnostic catheters to the Amplifier
- GenConnect - Connects the ablation catheter and dispersive surface electrodes to the Amplifier.
- RecordConnect - The RecordConnect allows simultaneous connection for catheters and surface ECG to a recording system and to the Amplifier.
- ECG cable - The ECG cable connects standard ECG electrodes to the Amplifier.

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 as described in the labeling.
Expansion Module Device Description:	The AutoMark Module is an optional add-on module to the EnSite™ Velocity™ System v5.0.1. The software module allows the user to set criteria for ablation-related parameters and the software automatically displays the lesion marks on the EnSite Velocity model during RF ablation when the user set criteria are met. The color, size, and ranges of the AutoMark are defined by the user.
Secondary Predicate Device Descriptions	The following secondary predicate devices are provided to ensure that all features of the proposed AutoMark Module are demonstrated to be substantially equivalent to features of currently cleared medical devices **WorkMate Claris System** The WorkMate Claris™ System is a fully computerized system for capturing and measuring physiological data in the clinical electrophysiology (EP) laboratory. It provides digital signal acquisition and display of those electrical signals on high resolution monitors. The WorkMate Claris System is connected to electrophysiology catheters that are guided into various locations within the heart, and to surface electrocardiogram (ECG) cables. Intracardiac and ECG signals are then acquired from electrodes on the indwelling catheters and ECG leads connected to the amplifier, which amplifies and conditions the signals before they are received by the WorkMate Claris System computer for display, measurement and storage. During the procedure, cardiac signals are acquired and an automated software waveform detector (trigger) performs online recognition of cardiac activation on preselected leads. Temporal interval measurements are computed on a beat-by-beat basis on multiple channels and dynamically posted on the Real Time display. Intervals are calculated between waveforms from the same source on a specific channel (intra-channel measurements) and from multi-source signals across two or more channels (inter-channel measurements).

	Signals are also presented on a review monitor for measurement and analysis. Continuous capture of the digitized signals can be invoked, and the user can also retrieve and display earlier passages of the current study without interruption of the real-time display. The system can also acquire, display and record data from other interfaced devices in use during the procedure, such as imaging devices and ablation generators.
Base System Indications for Use	**Device Name: EnSite™ Velocity™ Cardiac Mapping System v5.0.1** 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 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 System is intended to display the position of conventional electrophysiology (EP) catheters in the heart
Expansion Module Indications for Use	**Device Name: AutoMark Module v1.0.1** 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 subject of this submission.
Predicate Comparison	
Comparison	The AutoMark module was developed to provide additional functionality to the predicate devices in allowing the user to set parameters and the software automatically displays the lesion marks on the EnSite Velocity model during RF ablation. The proposed AutoMark Module has the same intended use and fundamental scientific technology as the predicate devices, EnSite™ Velocity™ Cardiac Mapping System v4.0.2 and WorkMate Claris™ System
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. Testing The AutoMark software module 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 • Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff 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. The changes to the optional AutoMark software module were evaluated through software verification and validation to show that the software is acceptable for use and meets the requirements. Risk Management The changes to the AutoMark software 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 AutoMark software module 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	The technological characteristics for the device are the same as the predicate devices.

Equivalence:	Based on this and the data provided in this pre-market notification, the subject device and predicate devices have been shown to be substantially equivalent.