DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 7, 2016

St. Jude Medical
Yumi Wackerfuss
Senior Regulatory Specialist
One St. Jude Medical Drive
St. Paul, MN 55117

Re: K160186
Trade/Device Name: EnSite™ Velocity™ Cardiac Mapping System v4.0.2 with EnSite™ Velocity™ Surface Electrode Kit
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 08, 2016
Received: September 09, 2016

Dear Yumi Wackerfuss:

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)*
K160186

Device Name
EnSite™ Velocity™ Cardiac Mapping System v4.0.2 with EnSite™ Velocity™ Surface Electrode Kit

Indications for Use *(Describe)*

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.

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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6. 510(k) Summary

The 510(k) Summary is provided on the following page as required by 21 CFR 807.92(c).

510(k) Summary	
510(k) Number	K160186
Submitter Information:	
Date Prepared:	February 23 2016
Manufacturer	St. Jude Medical
Name &Address:	One St. Jude Medical Drive St. Paul, MN 55117 Establishment Registration Number: 3005188751
Contact Person:	Yumi Wackerfuss Senior Regulatory Affairs Specialist Phone (651) 756-2678 Fax (651) 756-3301 ywackerfuss@sjm.com
Device Information:	
Trade Name:	EnSite™ Velocity™ Cardiac Mapping System v4.0.2 with EnSite™ Velocity™ Surface Electrode Kit
Common Name:	Electrophysiology mapping system
Classification Name:	870.1425, Programmable diagnostic computer
Product Code:	DQK
Class:	Class II
Predicate Device:	EnSite™ Velocity™ Cardiac Mapping System (version 4.0.2) with EnSite™ NavX™ Surface Electrode Kit, K141050, cleared June 6, 2014
Device Description:	The EnSite™ Velocity™ 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™ Velocity™ Surface Electrode Kit contains single use surface electrodes and patches for use in conjunction with St. Jude Medical's EnSite System. The kit contains the following devices • The electrode patches • The Electrocardiogram (ECG) electrodes • The system reference patch electrode

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	The surface electrodes transmit information from the patient to the EnSite™ System for signal conditioning and data inference.
Intended Use: (Indications for Use)	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.
Comparison to Predicate Devices	The proposed EnSite™ Velocity Cardiac Mapping System with EnSite™ Velocity™ Surface Electrode Kit has the same intended use and fundamental scientific technology as the predicate device, the EnSite™ Velocity™ Cardiac Mapping System with EnSite™ NavX™ Surface Electrode Kit, K141050. Changes from predicate include : • Electrode patches change from rectangular to circular shape • Change in conductive hydrogel type • Replacement of ECG electrode with a market released 3M ECG electrode • Change in manufacturer • Change in product name from EnSite™ NavX™ Surface Electrode Kit to EnSite™ Velocity™ Surface Electrode Kit
Summary on Non-Clinical Testing	The proposed EnSite™ Velocity Cardiac Mapping System with EnSite™ Velocity™ Surface Electrode Kit has the same indications for use as the predicate device. The technological characteristic of the device is the same as predicate device. Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that electrode patch modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. Bench and animal testing was performed to verify the device met the pre-determined acceptance criteria. The following tests were performed.

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	• Performance Test:
	  · Gel Adhesion
	  · Electrode impedance
	  · Electrode Capacitance
	  · Impedance Stability
	  · Cable Wire Resistance
	  · Cable Flex Life
	  · Current dispersion
	  · Maximum Temperature
	  · Dielectric Strength
	  · Cable Pullout Force
	• Biocompatibility Test
	• Shelf Life Test
	• Packaging Test
	• Usability Test:
	• Non-GLP Animal Test
	
	The changes to the Surface Electrode Kit were evaluated through design verification and validation to show that the proposed EnSite™ Velocity™ Surface Electrode Kit is acceptable for use and meets requirements.
	
	The EnSite™ Velocity™ Surface Electrode Kit conforms to the following standards:
	
	• EN ISO 14971 (2012) Medical Devices – Applications of risk management to medical devices
	• IEC 60601-1 (2005 + CORR.1 (2006) + CORR.2 (2007) + Ed 3.1 EN: 2012 + CORR1: 2012) 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 disturbances - requirements and tests
	• EN ISO 10993-1:2009 Biological Evaluation of medical device – Part 1: Evaluation and testing within a risk management process
	• EN ISO 10993-5:2009 Biological Evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	• EN ISO 10993-10:2013 Biological Evaluation of medical devices – Part 10: Test for irritation and sensitization
	
	<u>Risk Management</u>
	
	The changes to the Surface Electrode Kit were evaluated

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	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.
Statement of Equivalence	The proposed EnSite™ Velocity Cardiac Mapping System with EnSite™ Velocity™ Surface Electrode kit have the same indications for use as the predicate device. The technological characteristics for the device 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 shown to be substantially equivalent.