November 27, 2020

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

Re: K202066
Trade/Device Name: EnSite X EP System
Advisor VL Circular Mapping Catheter, Sensor Enabled
Advisor HD Grid High Density Mapping Catheter, Sensor Enabled
Advisor FL Circular Mapping Catheter, Sensor Enabled
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK

Dear Alyssa Timmers:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 25, 2020. There was an error in the Trade/Device Name section of the previous letter where Advisor FL Circular Mapping Catheter, Sensor Enabled was inadvertently omitted from the list of devices. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Fellman, OHT2: Office of Cardiovascular Devices, 301-796-6357, Mark.Fellman@fda.hhs.gov.

Sincerely,

Mark S. Fellman -S

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

November 25, 2020

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

Re: K202066
Trade/Device Name: EnSite X EP System, Advisor VL Circular Mapping Catheter, Sensor Enabled, Advisor HD Grid High Density Mapping Catheter, Sensor Enabled
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 26, 2020
Received: October 27, 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 S. Fellman -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202066

Device Name

EnSite™ X EP System, Advisor™ VL Circular Mapping Catheter, Sensor Enabled™, Advisor™ FL Circular Mapping Catheter, Sensor Enabled™, Advisor™ HD High Density Mapping Catheter, Sensor Enabled™

Indications for Use *(Describe)*

EnSite™ X EP System:
The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures.

EnSite™ X EP System Contact Force Software License:
When used with the TactiSys™ Quartz Equipment, the EnSite™ X EP System Contact Force Module is intended to provide visualization of force information from compatible catheters.

EnSite™ X EP System Surface Electrode Kit:
The EnSite™ X EP Surface Electrode Kit is indicated for use with the EnSite™ X EP System in accordance with the EnSite™ X EP System indications for use.

Advisor™ VL Circular Mapping Catheter, Sensor Enabled™:
Advisor™ VL Circular Mapping Catheter, Sensor Enabled™ is a steerable electrophysiology catheter with integrated sensors. The catheter is 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.

Advisor™ FL Circular Mapping Catheter, Sensor Enabled™:
The Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is steerable electrophysiology catheter with integrated sensors. The catheter is 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.

Advisor™ HD High Density Mapping Catheter, Sensor Enabled™:
The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of 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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510(k) Information	
510(k) Number	K202066
510(k) Type	Bundled Traditional 510(k)
Date Prepared	24 July 2020
Submitter Information	
Manufacturer Name & Address	Abbott Medical One St. Jude Medical Drive, St. Paul, Minnesota, 55119, USA Manufacturer of the EnSite™ X EP System
	St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol Alajuela, Costa Rica 1897-4050 Manufacturer of the EnSite™ X EP System Surface Electrode Kit
	Abbott Medical 5050 Nathan Lane North Plymouth, Minnesota, 55442, USA Manufacturer of the Sensor Enabled™ Diagnostic Catheters
Contact Person	Alyssa Timmers Senior Regulatory Affairs Specialist 651-756-3706 alyssa.timmers@abbott.com
EnSite™ X EP System Device Information	
Trade Name	EnSite™ X EP System
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 (K201181)
Reference Device	Carto 3 EP Navigation System (K180238)
Device Description	The EnSite™ X EP System is a catheter navigation and mapping system. A catheter navigation and mapping system is capable of displaying the 3-dimensional (3-D) position of conventional and Sensor Enabled™ (SE) electrophysiology catheters, as well as displaying cardiac electrical activity as waveform traces and as three-dimensional (3D) isopotential and isochronal maps of the cardiac chamber. The contoured surfaces of the 3D maps are based on the anatomy of the patient's own cardiac chamber. The system creates a model by collecting and labeling the anatomic locations within the chamber. A surface is created by moving a selected catheter to locations within a cardiac structure. As the catheter moves, points are collected at and between all electrodes on the catheter. A surface is wrapped around the outermost points.

Indications for Use	**EnSite™ X EP System** The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures. **EnSite™ X EP System Contact Force Software License** When used with the TactiSys™ Quartz Equipment, the EnSite™ X EP System Contact Force Module is intended to provide visualization of force information from compatible catheters. **EnSite™ X EP System Surface Electrode Kit** The EnSite™ X EP Surface Electrode Kit is indicated for use with the EnSite™ X EP System in accordance with the EnSite™ X EP System indications for use.
Predicate Comparison	The EnSite™ X EP System has the same intended use, and similar indications for use as the predicate device. The EnSite™ X EP System operates using the same fundamental scientific technology to facilitate catheter position and orientation, as well as cardiac mapping and model creation with some differences. The subject device enables the use of a magnetic-primary catheter navigation mode or an impedance-based catheter navigation mode. The predicate device does not have a magnetic-primary catheter navigation mode but has an impedance-based catheter navigation mode and allows for magnetic field scaling. The reference device utilizes a magnetic-primary or impedance for catheter navigation. No new questions of safety or effectiveness were raised.
Advisor™ VL Circular Mapping Catheter, Sensor Enabled™	
Trade Name	Advisor™ VL Circular Mapping Catheter, Sensor Enabled™
Common Name	Diagnostic Electrophysiology Catheter
Class	II
Classification Name	870.1220, Electrode recording catheter or electrode recording probe
Product Code	DRF
Predicate Device	Advisor™ VL Circular Mapping Catheter, Sensor Enabled™ (K192037)
Device Description	Advisor™ VL Circular Mapping Catheter, Sensor Enabled™ (Advisor VL) is a variable radius, circular mapping catheter. It has an adjustable 4 French (F) distal loop size with a diameter ranging from 15mm – 25mm with models containing both ten (10) equidistant or twenty (20) paired platinum-iridium electrodes. The catheter has integrated sensors with two impedance-based navigational electrodes and two magnetic sensors located at the distal end of the shaft. The catheter is intended to be used with the EnSite Precision™ Cardiac Mapping System, or the EnSite™ X EP System.
Indications for Use	Advisor™ VL Circular Mapping Catheter, Sensor Enabled™ is a steerable electrophysiology catheter with integrated sensors. The catheter is 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.
Predicate Comparison	The subject and predicate device have the same intended use and indications for use. The subject and predicate device have identical device design, fundamental scientific technology and device functionality. The primary difference between the

	subject and predicate device are the labeling updates to indicate compatibility with the EnSite™ X EP System. No new questions of safety or effectiveness were raised.
Advisor™ FL Circular Mapping Catheter, Sensor Enabled™	
Trade Name	Advisor™ FL Circular Mapping Catheter, Sensor Enabled™
Common Name	Diagnostic Electrophysiology Catheter
Class	II
Classification Name	870.1220, Electrode recording catheter or electrode recording probe
Product Code	DRF
Predicate Device	Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ (K160335)
Device Description	Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ (Advisor FL, SE) is a circular mapping catheter for performing electrophysiology mapping procedures and providing pacing signals to the heart during electrophysiology procedures. The catheter handle and shaft design allows for improved maneuverability. A magnetic sensor in the distal shaft pocket provides compatibility with visualization and navigation systems. The catheter is compatible with Abbott's EnSite Precision™ Cardiac Mapping System, MediGuide™ System, or EnSite™ X EP System.
Indications for Use	The Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is steerable electrophysiology catheter with integrated sensors. The catheter is 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.
Predicate Comparison	The subject and predicate devices have the same intended use and similar indication for use statements. There are slight differences in verbiage, however the overall intent remains the same. The subject and predicate device have identical device design, fundamental scientific technology and device functionality. The only difference between the subject and predicate device are the labeling updates to indicate compatibility with the EnSite™ X EP System. No new questions of safety or effectiveness were raised.
Advisor™ HD Grid High Density Mapping Catheter, Sensor Enabled™	
Trade Name	Advisor™ HD High Density Mapping Catheter, Sensor Enabled™
Common Name	Catheter, Intracardiac Mapping, High-Density Array
Class	II
Classification Name	870.1220, Electrode recording catheter or electrode recording probe
Product Code	DRF & MTD
Predicate Device	Advisor™ HD High Density Mapping Catheter, Sensor Enabled™ (K172393)
Device Description	The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is a sterile, single use, irrigated, high-density mapping catheter with a 7.5F shaft and an 8F distal shaft deflectable section. It is available in a D-F bi-directional curve model that is deflected using the actuator located on the catheter handle. The catheter working length is 110 cm. The device consists of a paddle-shaped distal tip with 16 electrodes, two distal shaft ring electrodes, two magnetic sensors, polymer braided shaft, handle, fluid lumen extension with a luer, and an electrical connector. The catheter also has an introducer tool intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an introducer sheath.

	The catheter is compatible with the EnSite™ Velocity, EnSite Precision™, and EnSite™ X EP Cardiac Mapping Systems and other accessories, including the connecting cable and commercially available irrigation pumps.
Indications for Use	The Advisor™ HD Grid Mapping Catheter, Sensor Enabled™, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.
Predicate Comparison	The subject and predicate device have the same intended use and indications for use. The subject and predicate device have identical device design, fundamental scientific technology and device functionality. The only difference between the subject and predicate device are the labeling updates to indicate compatibility with the EnSite™ X EP System. No new questions of safety or effectiveness were raised.
Non-Clinical Testing Summary for EnSite™ X EP System and Sensor Enabled™ Catheters	
Non-Clinical Testing Summary	Design verification activities were performed and met their respective acceptance criteria to ensure that the devices in scope of this submission are safety and effective. **Testing** The EnSite™ X EP System and Sensor Enabled™ catheters in scope of this submission were developed and tested in accordance with the following industry guidance documents and standards: - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - IEC 62304: 2015-06 Edition 1.1, Medical Device Software - Software Life Cycle Processes - EN ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices **Types of Testing Performed – EnSite™ X EP System** - Software Verification at a unit, software and system level - Performance Testing of each device in the EnSite™ X EP System including functional, shipment, etc. - In vivo Preclinical Studies to evaluate substantial equivalence - Human Factors Evaluations to confirm the user interface of the subject device can be used as intended by the defined user groups **Types of Testing Performed – Sensor Enabled™ Catheters** - In vivo Preclinical Studies to evaluate substantial equivalence - EEPROM Functional Tests No additional non-clinical tests were required for the Sensor Enabled™ catheters for compatibility with the EnSite™ X EP system.
Statement of Equivalence for EnSite™ X EP System and Sensor Enabled™ Catheters	
Statement of Equivalence	All subject and predicate devices have the same intended use, and similar indications for use. All devices operate using the same fundamental scientific technology to facilitate catheter position and orientation, as well as cardiac mapping and model creation with some differences. Bench and In-vivo preclinical data for the subject device, predicate device, and reference device demonstrate substantial equivalence. The testing completed and submitted in this Traditional 510(k) provides objective evidence the subject devices are at least as safe and effective as the predicate devices.