October 22, 2021

Abbott Medical
Jamie Glaser
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, Minnesota 55117

Re: K212061
Trade/Device Name: EnSite™ X EP System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 30, 2021
Received: July 1, 2021

Dear Jamie Glaser:

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,

Aneesh Deoras
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)*
K212061

Device Name
EnSite™ X EP System

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.

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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5. 510(K) SUMMARY

510(k) Information	
510(k) Number	K212061
510(k) Type	Traditional 510(k)
Date Prepared	30 June 2021
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
Contact Person	Jamie Glaser Senior Regulatory Affairs Specialist 651-756-5091 jamie.glaser@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™ X EP System (K202066)
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	
Comparison	EnSite™ X v1.1 and the predicate EnSite™ X v1.0.1 have the same intended use and indications for use. They use the same fundamental scientific technology to facilitate catheter position and orientation, as well as cardiac mapping and model creation. There were no changes to the hardware. The subject device software was revised to include the following updates; • Displays calculated waveforms of the optimal bipole (maximum voltage) independent of catheter orientation • Displays activation direction arrows on maps • Displays calculated wave speed maps • Displays deflection direction indicators to assist in determining deflection direction • Allows for exporting electrograms and electrode locations over ethernet during a live study to a 3rd party client • Allows more targeted map editing using the Sandpaper tool • Expands the use case for the remote support tool EnSite™ Connect (formerly SJM Connect) • Displays map points in real time using EnSite™ LiveView Dynamic Display • Displays catheter visualization differently under certain scenarios • Fixes minor known software issues (bug fixes) All risks were mitigated to acceptable levels. No new questions of safety or effectiveness were raised.
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 safe and effective. **Testing** The EnSite™ X EP System v1.1 in scope of this submission was 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 14971:2019 Medical Devices – Application of Risk Management to Medical Devices

	Types of Testing Performed – EnSite X EP System v1.1 - Software Verification at unit, software and system level - Performance Testing of updated feature functionality - Bench studies to evaluate substantial equivalence - Preclinical Validation Testing to confirm the system could meet user requirements and its intended use after modifications - Human Factors Evaluations to confirm the user interface of the subject device can be used as intended by the defined user groups
Statement of Equivalence	All subject and predicate devices have the same intended use, and same 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. The testing completed and submitted in this Traditional 510(k) provides objective evidence the subject device is at least as safe and effective as the predicate device and that the subject device is substantially equivalent to the predicate device.