



April 20, 2026

Abbott Medical
Christine Kim
Regulatory Affairs Specialist
One St. Jude Medical Dr.
St. Paul, Minnesota 55117

Re: K260212

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: January 23, 2026
Received: January 23, 2026

Dear Christine Kim:

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 (the 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 available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for: **MARCO CANNELLA -S**

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260212

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Please provide the device trade name(s).

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EnSite™ X EP System

Please provide your Indications for Use below.

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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.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) SUMMARY

The 510(k) Summary was drafted in accordance with 21 CFR 807.92 and is included below.

510(k) Information	
510(k) Number	K260212
510(k) Type	Traditional 510(k)
Date Prepared	23 January 2026
Submitter Information	
Manufacturer Name & Address	<p>Abbott Medical One St. Jude Medical Drive, St. Paul, Minnesota, 55117, USA Manufacturer of the EnSite X EP System</p> <p>Abbott 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</p>
Contact Person	<p>Christine Kim Regulatory Affairs Specialist 839-246-1228 christine.kim1@abbott.com</p>
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 (K251234 and K252013)
Device Description	<p>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.</p> <p>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.</p>
Indications for Use	<p>EnSite™ X EP System</p> <p>The EnSite™ X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated.</p>

	<p>The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures.</p> <p>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.</p> <p>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.</p>
Predicate Comparison	
<p>Comparison</p>	<p>EnSite™ X EP System Version 6.0 with TactiFlex™ Duo Software Licenses installed and the predicate EnSite™ X v5.0 and v4.0 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. The subject device software was revised to include the following updates:</p> <ul style="list-style-type: none"> • Compatibility with TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ <p>All risks were mitigated to acceptable levels. No new questions of safety or effectiveness were raised.</p> <p>A PCCP is included with planned modifications to the EnSite™ X EP System Field Frame to include new hardware.</p>
<p>Non-Clinical Testing Summary</p>	<p>Design verification and validation activities were performed and met their respective acceptance criteria to ensure that the devices in scope of this submission are substantially equivalent to the predicate device.</p> <p>Testing</p> <p>The EnSite™ X EP System with TactiFlex™ Duo Software Licenses in scope of this submission was developed and tested in accordance with the following industry guidance documents and standards:</p> <ul style="list-style-type: none"> • 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 • IEC 60601-1-2:2020-09 Edition 4.1, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests • ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices • IEC 62366-1:2015+A1:2020 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices <p>Types of Testing Performed – EnSite X EP System with TactiFlex™ Duo Software License</p> <ul style="list-style-type: none"> • Software Verification at unit, software and system level • System Verification at the device and system level

	<ul style="list-style-type: none">• Design Validation to ensure user needs are met• Human Factors Validation to ensure no new use errors introduced <p>Types of Testing to be Performed (PCCP) – EnSite X EP System Field Frame</p> <ul style="list-style-type: none">• Software Verification at unit, software and system level• System Verification at the device and system level• Hardware Verification at the device level
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 that the subject device is substantially equivalent to the predicate device. The device as modified by the PCCP will remain substantially equivalent to the predicate device.