January 18, 2026

Biosense Webster, Inc.
℅ Elena Goldin
Regulatory Affairs Manager
Biosense Webster (Israel), Ltd.
4 Hatnufa St.
Yokneam, 2066717
Israel

Re: K254085
Trade/Device Name: CARTO™ 3 EP Navigation System V9.0 with PIU Plus
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 18, 2025
Received: December 18, 2025

Dear Elena Goldin:

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/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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.	K254085

Please provide the device trade name(s).

CARTO™ 3 EP Navigation System V9.0 with PIU Plus

Please provide your Indications for Use below.

The intended use of the CARTO™ 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO™ 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure. The system has no special contraindications.

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)

510(K) SUMMARY

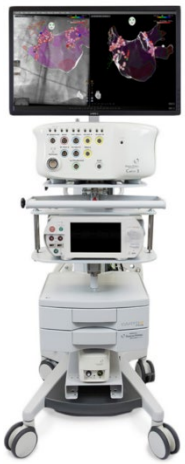
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Elena Goldin Regulatory Affairs Manager Biosense Webster (Israel), Ltd. Phone: +972-54-2053210
Authored by:	Elena Goldin Regulatory Affairs Manager Biosense Webster (Israel), Ltd. Keren Smulovitz Cohen Sr. Program Lead Regulatory Affairs Biosense Webster (Israel), Ltd.
Date:	Dec 17, 2025
Device Trade Name:	CARTO™ 3 EP Navigation System V9.0 with PIU Plus
Device Common Name:	Cardiac Mapping System
Manufacturing Number:	FG-5400-00, FG-5400-00U
Device Classification:	Programmable diagnostic computer Class II, 21 CFR 870.1425
Product Code	DQK
Predicate Device:	CARTO® 3 EP Navigation System Version 8.1 510(k)#: **K252302**

Manufacturing Facilities:

Biosense Webster (Israel), Ltd.
a Johnson & Johnson Company
4 Hatnufa Street
Yokneam, ISRAEL 2066717

Biosense Webster, Inc.,
23 Hubble Dr, Irvine, CA 92618
USA

Device Description:



The CARTO™ 3 EP Navigation System V9.0, is a catheter-based atrial and ventricular mapping system designed to acquire and analyze navigation catheter's location and intracardiac ECG signals and use this information to display 3D anatomical and electroanatomical maps of the human heart. The location information needed to create the cardiac maps and the local electrograms are acquired using specialized mapping catheters and reference devices. The CARTO™ 3 System uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO™ 3 System V9.0 consists of the following hardware components:

- Patient Interface Unit – (PIU Plus or PIU)
- Workstation with Graphic User Interface (GUI)
- Wide-Screen monitors, keyboard, and mouse
- Intracardiac In Port
- Intracardiac Out Port
- Power Supply
- Patches Connection Box and Cables (PU)
- Pedals
- Location Pad (LP)
- Signal Processing Unit (SPU) – supported with PIU only

All hardware components of the CARTO™ 3 system V9.0 are the same as those found in the predicate device, with improved Patient Interface Unit (PIU Plus).

Indications for Use:

The intended use of the CARTO™ 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO™ 3 System provides

information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure.
The system has no special contraindications.

The indications for use for the CARTO™ 3 System V9.0 are identical to the indications for use of the predicate device, the CARTO™ 3 System, software V8.1.

Technological Characteristics:

The modified CARTO™ 3 EP Navigation System V9.0 has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate CARTO™ 3 EP Navigation System, software V8.1 (K252302). A summary of the technological characteristics of the new device compared to the predicate device is as follows:

- Have identical intended use.
- Use the same fundamental scientific technology.
- Have the same hardware platform, with improved Patient Interface Unit (PIU Plus)
- Have identical magnetic and ACL location mapping technology.
- Have identical magnetic location sensor and ACL location accuracy.

The differences between the predicate device and the modified device are the addition of the improved Patient Interface Unit (PIU Plus) and software modifications supporting this change.

Performance Data:

The CARTO™ 3 EP Navigation System V9.0 underwent verification and validation testing under simulated clinical conditions to verify the new features and improved hardware to demonstrate with regression testing that the modifications performed did not negatively affect existing features.

Verification and Validation Testing

Software Verification and Validation testing completed for CARTO™ 3 System V9.0 included:

- Proof of Design – Testing was performed to verify the CARTO™ 3 System V9.0 design meets its accuracy specifications. All tests were successfully completed and met the acceptance criteria.
- Functional verification – Testing was performed to verify the functional requirements and hardware configurations,

regression testing of CARTO™ 3 System legacy features, system functionality for supported catheters, and interoperability with 3rd party compatible medical devices. Usability was tested per IEC 60601–1-6, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. All system features were found to perform according to specifications.

- Unit Tests – Testing was performed to verify the design implementation in CARTO™ 3 V9.0 software aligns perfectly with the design specifications. All tests were successfully completed and met the acceptance criteria.
- Electrical Safety and Electromagnetic Compatibility testing was performed per IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements. Test results were in compliance to the standards.

Animal Testing:

Animal testing was conducted to evaluate the CARTO™ 3 System V9.0 functionality under simulated clinical workflow and conditions. All test protocol steps were successfully completed and expected results were achieved.

All testing passed in accordance with appropriate test criteria, and the modified device did not raise new questions of safety or effectiveness.

Conclusions: The CARTO™ 3 EP Navigation System V9.0 is substantially equivalent to the currently cleared CARTO™ 3 EP Navigation System with software version V8.1, based on the comparison of indications for use, technological characteristics, and the results of verification and validation testing.