February 20, 2026

Biosense Webster, Inc.
℅ Dorit Eizenberg
Senior Regulatory Affairs Program Lead
Biosense Webster, Ltd.
4 Hatnufa Street
Yokneam, 2066717
Israel

Re: K252972
Trade/Device Name: CARTO™ 3 EP Navigation System V8.4
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 17, 2025
Received: September 17, 2025

Dear Dorit Eizenberg:

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.

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Aneesh S. Deoras -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.	K252972

Please provide the device trade name(s).

CARTO™ 3 EP Navigation System V8.4

Please provide your Indications for Use below.

The intended use of the CARTO™ 3 System 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 (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

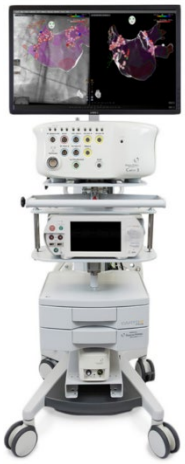
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Dorit Eizenberg Regulatory Affairs Manager Biosense Webster (Israel), Ltd.
Authored by:	Dorit Eizenberg Regulatory Affairs Manager Biosense Webster (Israel), Ltd. Eyal Hendel Associate Director of Regulatory Affairs Biosense Webster (Israel), Ltd.
Date:	September 16, 2025
Device Trade Name:	CARTO™ 3 EP Navigation System V8.4
510(k) Number	K252972
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 V8.4, 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 electro anatomical 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 V8.4 consists of the following hardware components:

- Patient Interface Unit (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)
- Pedal
- Location Pad (LP)
- Signal Processing Unit (SPU)

All hardware components of the CARTO™ 3 system V8.4 are the same as those found in the predicate device.

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 V8.4 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 V8.4 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.
- 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 new software features. The legacy CARTOSOUND FAM Module is not supported in CARTO™ 3 EP Navigation System V8.4., as its functionality has been replaced with CARTOSOUND™ REVEAL.

1 NEW FEATURES

a. CARTOSOUND™ REVEAL Module

CARTOSOUND™ REVEAL is an automated ultrasound mapping module for the left atrium (LA), left ventricle (LV), and their substructures. The module is designed to enhance the fast anatomical mapping (FAM) workflow by reducing manual contouring and supporting integration with the SOUNDSTAR™ family of catheters and the NUVISION™ NAV Ultrasound Catheter.

The CARTOSOUND™ REVEAL module uses locked AI algorithms for:

- Automatic identification of cardiac structures overlayed on the ICE images.
- Automatic 2D contours creation of cardiac structures

- Automatic 3D sell creation to be used as a baseline for LA and LV chambers reconstruction.

Data for training and validation of the DL algorithm was collected from a representative range of LA and LV chamber volumes and geographical locations, using a variety of ultrasound system settings, ULS scanners, and catheters.

The anatomical labeling and automatic contouring algorithms were developed and tested using CARTO™ 3 System cases with ultrasound information.

The 3D shell model was developed and tested using CT and CARTO™ 3 System cases with FAM.

b. LA FAM Module

The LA FAM Module uses a locked Artificial Intelligence (AI) algorithm to facilitate Fast Anatomical Mapping (FAM) by generating a 3D shell of the Left Atrium (LA) when mapping with the VARIPULSE™ Catheter. The acquired volume can be further optimized using existing CARTO™ 3 System FAM mapping tools.

Data for training and validation of the DL algorithm consisted of CT and CARTO™ 3 System cases with FAM and was collected from a representative range of LA chamber volumes, geographical locations, and catheters.

For CARTOSOUND REVEAL and LA FAM modules, post-market user feedback and complaints will be routinely monitored and evaluated under Biosense Webster quality system.

CARTO™ 3 EP Navigation System V8.4 will be updated in accordance with the Predetermined Change Control Plan (PCCP) which includes modifications as detailed below.

1. Additional dataset to retrain the current AI models
2. AI Models Optimizations
3. Inclusion of additional anatomical structures in CARTOSOUND REVEAL Module.
4. Additional input devices for LA FAM Module
5. Additional CARTO map coloring

6. Presentation of information imported from an external medical device on a CARTO map.

   Testing of the modifications in the PCCP will be similar to testing performed for CARTO™ 3 EP Navigation System V8.4.

Performance Data:

The CARTO™ 3 EP Navigation System V8.4 underwent verification and validation testing under simulated clinical conditions to verify the new features and 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 V8.4 included:

- Unit Tests – Testing was performed to verify the design implementation in CARTO™ 3 V8.4 software aligns perfectly with the design specifications. All tests were successfully completed.
- Proof of Design – Testing was performed to verify the CARTO™ 3 System V8.4 design meets its accuracy specifications. All tests were successfully completed.
- Functional verification – Testing was performed to verify the functional requirements of CARTO™ 3 System V8.4, including testing of the new features and improvements. All system features were found to perform according to specifications.
- Retrospective Validation Tests – Testing was performed retrospectively, on clinical recorded data from historic EP procedures performed with the CARTO™ 3 System in order to validate the clinical functionality and quality of the introduced modules. All testing performed were successfully completed.

Animal Testing:

Animal testing was conducted to evaluate the CARTO™ 3 System V8.4 clinical workflow under simulated clinical conditions. All test protocol steps were successfully completed and expected results were achieved.
The modified device did not raise new questions of safety or effectiveness.

Conclusions:

The CARTO™ 3 EP Navigation System V8.4 is substantially equivalent to the currently cleared CARTO™ 3 EP Navigation System with software

version V8.1, based on the completion of verification and validation testing.