February 16, 2023

Biosense Webster, Inc.
Phuong Park
Associate Director, Regulatory Affairs
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K223733
Trade/Device Name: CARTO® 3 EP Navigation System with CARTOSOUND 4D version 7.4
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: December 13, 2022
Received: December 13, 2022

Dear Phuong Park:

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 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

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)*
K223733

Device Name
CARTO® 3 EP Navigation System with CARTOSOUND 4D version 7.4

Indications for Use *(Describe)*
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.

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) SUMMARY

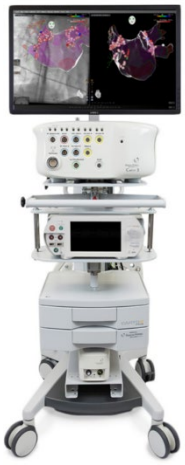
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Phuong Park Associate Director, Regulatory Affairs Phone: 949-923-4238 Fax: 949-450-6886
Authored by:	Eyal Hendel Regulatory Affairs Manager Biosense Webster (Israel), Ltd. and Phuong Park Associate Director, Regulatory Affairs Biosense Webster, Inc.
Date:	February 15, 2023
Device Trade Name:	CARTO® 3 EP Navigation System with CARTOSOUND 4D version 7.4
Device Common Name:	Cardiac Mapping System
Manufacturing Number:	FG-5400-00
Device Classification:	Programmable diagnostic computer Class II, 21 CFR 870.1425
Product Code	DQK
Predicate Device:	CARTO® 3 EP Navigation System Version 7.2 510(k)#: **K213264**

Manufacturing Facilities:

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

Biosense Webster, Inc.
15715 Arrow Hwy
Irwindale, CA 91706
USA

Device Description:



The CARTO® 3 EP Navigation System with CARTOSOUND™ 4D, software V7.4, 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 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 with CARTOSOUND™ 4D 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)
- Pedals
- Location Pad (LP)
- Signal Processing Unit (SPU)

All hardware components of the CARTO® 3 system with CARTOSOUND™ 4D are the same to 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 with CARTOSOUND™ 4D are identical to the indications for use of the predicate device, the CARTO® 3 System V7.2.

Technological Characteristics:

The modified CARTO® 3 EP Navigation System with CARTOSOUND™ 4D, software V7.4 has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System, Version 7.2 (K213264). 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 a new software feature, CARTOSOUND™ 4D, improvements of the legacy CARTOSOUND™ Module and the addition of Letter to File changes as described below.

Note: The CARTOSOUND™ module was cleared with the CARTO® 3 System V1, K090017.

Description of Modifications

CARTOSOUND™ 4D

The addition of the CARTOSOUND™ 4D Module combines 3D real-time ultrasound image data with CARTO® 3 System Maps. 4D (real-time volumetric imaging with a field of view of up to 90° x 90°) multi-planar, and 2D ultrasound images are acquired with the compatible NUVISION™ NAV Ultrasound Catheter (K223766). The catheter includes an ultrasound transducer and a location sensor. The NUVISION™ Nav catheter has a bifurcated 'tail' originating from the handle. One part terminates in a connector receptacle which mates with a NUVISION Connector Cable to connect the catheter to a compatible ultrasound system. The other part enables connection to the CARTO® 3 Navigation System with CARTOSOUND™ 4D Module via an extension cable. A steering mechanism controls orientation of the image plane by rotating both the NUVISION Nav Catheter's tip and providing variable bi-directional deflection. The real-time ultrasound images are displayed in the CARTO® 3 System and the compatible GE

Healthcare's Vivid S70N Ultrasound System (Vivid S70N, SW version 206.z, K223832), which is specialized for use with cardiac images.

This module also enables acquisition of clips from the ultrasound system, transferred with a digital communication protocol over an Ethernet connection (LAN) cable. The user can draw contours of the required anatomy on any frame of the ultrasound clip and add this information to a 3D anatomical map reconstruction. The ultrasound clip can be saved with these contours, and the frames containing the contours are marked for easy identification. The ultrasound clip can be also stored to the CARTO® 3 system for future contouring. Contour data contributes anatomical information to the map. Contours and Ultrasound clips are listed in the Map Point List.

The CARTOSOUND™ 4D Module 4D advanced feature presents a 4D rendered reconstruction on the CARTO main map viewer and additional windows in a real-time fashion.

CARTOSOUND™ Module Improvements

Improvements were implemented to the user interface of the legacy CARTOSOUND™ module while maintaining the same functionality. The user interface change includes layout and controls for assigning contours to maps and an updated toolbar.

Video Over LAN

Improvement was implemented to the CARTO® 3 System, by replacing the Analog interface with a digital communication protocol over an Ethernet connection (LAN) cable with the compatible ultrasound system, by enabling transmitting compressed videos from the GE Healthcare's Vivid S70N Ultrasound System (Vivid S70N, SW version 206.z) to CARTO® 3 System with CARTOSOUND™ 4D using industrial standard compressing protocol H.264 format.

Note: To maintain compatibility with all other Ultrasound Systems, the CARTO® 3 System with CARTOSOUND™ 4D also supports the legacy solution in which data is sent in an analog format (typically VGA) and images are grabbed via a Frame Grabber in the CARTO® 3 System workstation.

Letter to File changes

Improvement to OCTARAY DX catheter support through Signal Processing Unit

- Updated coefficients of the Dynamic Threshold (Catheter XML Change) to receive the optimal S2 electrode detection in/out of the sheath

Signal Processing Unit (SPU) enhancements

- Improvement to SPU Build in Test (BIT) mechanism to run the BIT only at SPU startup, to avoid possible delays during the clinical procedure.
- Tissue Proximity Indicator (TPI) Card update:
  - HW change: removal of non-functional amplifiers in the TPI card, to decrease the total current (load and self-consumption) of the -5 Volt voltage supply, assembled on the Power Card, in order to reduce the possibility of saturation in extreme conditions.
  - HW change: replacement of 4 resistors in the TPI card to 0 [ohm], to reduce open loop noise due to the removal of the amplifiers. Note: these TPI changes have no impact on the TPI performance.
- Firmware update:
  - FPGA Firmware update: updating the calibration multiplier factor with an overflow protected multiplier to address an observed ECG visualization artifact.
    Note: The SPU has an analog amplifier (ASIC) followed by an A/D converter and a calibration multiplier. When a full-scale signal is set to the SPU, it may seldom cause an overflow at the multiplier and an ECG visualization artifact

Security Enhancements

- Secure login mode is disabled by default, although selectable by the user
- Security and drivers update

Support removal

- The support for the Siemens Sequoia Ultrasound system was removed due to end of life of the ULS system.

Performance Data:

The CARTO® 3 EP Navigation System with CARTOSOUND™ 4D 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.

Bench Testing:
Bench testing completed for CARTO® 3 System with CARTOSOUND™ 4D included:

- Proof of Design (POD) – Testing was performed to verify the CARTO® 3 System specifications while connecting it to the NUVISION™ NAV Ultrasound catheter and GE Healthcare's Vivid S70N Ultrasound System (Vivid S70N, SW version 206.z). All testing performed were successfully completed and met the acceptance criteria.

- Functional verification – Testing was performed to verify the functional requirements of CARTO® 3 System with CARTOSOUND™ 4D, including testing of the new CARTOSOUND™ 4D features and CARTOSOUND™ improvements as well as regression testing to verify continued functionality of CARTO® 3 System legacy features and Letter To File modifications. All system features were found to perform according to specifications and met the tests acceptance criteria.
- Image Quality assessment – Testing was conducted to evaluate the ULS image quality as displayed in the monitor of the CARTO® 3 System with CARTOSOUND™ 4D. The test was conducted under simulated clinical workflow and conditions. Assessment was successfully completed and expected results were achieved.

Animal Testing:
Animal testing was conducted to evaluate the CARTO® 3 System with CARTOSOUND™ 4D 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 standards, and the modified device did not raise new questions of safety or effectiveness.

Usability Testing:
Summative Usability testing was conducted to validate that CARTOSOUND™ 4D Module User Interface ease of use. In light of the usability validation study results, it was concluded that the operation of the CARTOSOUND™ 4D Module has been found to be safe and effective for the intended users, uses and use environments.

Conclusions: The CARTO® 3 EP Navigation System with CARTOSOUND™ 4D software version V7.4 is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System, Version 7.2 based on the completion of verification and validation testing.