September 7, 2023

Biosense Webster, Inc.
Caleb Lau
Senior Regulatory Affairs Program Lead
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K231207
Trade/Device Name: CARTO™ 3 EP Navigation System Software V8.0
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: August 8, 2023
Received: August 8, 2023

Dear Caleb Lau:

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)*
K231207

Device Name
CARTO™ 3 EP Navigation System Software V8.0

Indications for Use *(Describe)*
The intended use of the CARTO™ 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTOTM 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

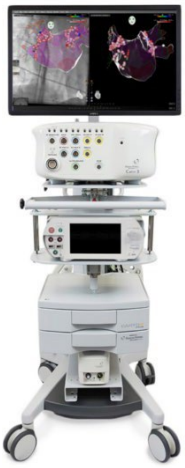
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Caleb Lau Senior Regulatory Affairs Program Lead Phone: 949-704-1584 Fax: 949-450-6886
Authored by:	Dorit Eizenberg Senior Regulatory Affairs Program Lead Biosense Webster (Israel), Ltd. and Caleb Lau Senior Regulatory Affairs Program Lead Biosense Webster, Inc.
Date:	August 8, 2023
Device Trade Name:	CARTO™ 3 EP Navigation System V8.0
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 with CARTOSOUND™ 4D Version 7.4 510(k)#: K223733

Manufacturing Facilities:

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

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

Device Description:



The CARTO™ 3 EP Navigation System V8.0, 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 V8.0 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 V8.0 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 V8.0 are identical to the indications for use of the predicate device, the CARTO® 3 System with CARTOSOUND™ 4D, software V7.4.

Technological Characteristics:

The modified CARTO™ 3 EP Navigation System V8.0 has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System with CARTOSOUND™ 4D, software V7.4 (K223733). 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 features, improvements of the legacy modules.

DESCRIPTION OF MODIFICATIONS:

1.1 MULTIPOLAR MAPPING

The Multipolar Mapping provides an additional annotation to the Wavefront Annotation mechanism, designed to enable a better discrimination between local activation and far-field potentials, and results in an improved consistency of the LAT annotation and Voltage measurements.

1.2 AUTO PATTERN ACQUISITION

Auto Pattern Acquisition automatically acquires BS ECG or IC EGMs patterns for either ventricular or atrial mappings. Automatic acquisition is achieved through a clustering mechanism using incoming beats, grouped based on similar morphology, to create different maps for the patterns of interest.

1.3 COMPLEX SIGNALS IDENTIFICATION

The Complex Signals Identification (CSI) module is a machine learning locked algorithm that automatically tags fractionated IC ECG signals. This module allows the identification and visualization of complex signals during continuous mapping mode or retrospectively. In addition, tools for viewing the identified complex signals in specific regions of interest are provided.

For developing and validating the algorithm, a control database was created using input from multiple stable atrial typical and atypical flutter cases. This data was sourced from Medical Centers in Europe and the United States of America. It included data from different catheters, with complex signals, single activations, noisy signals, and so on.

1.4 CARTOSOUND™ FAM

The CARTOSOUND™ FAM Module is used to automatically reconstruct an editable 3D volume with automatic 3D segmentation of the Left Atrium (LA) anatomies, based on a series of 2D ultrasound gated input frames acquired from the Right Atrium (RA, Fossa Ovalis) and/or the Right Ventricular Outflow Tract (RVOT).

The CARTOSOUND™ FAM Module incorporates a Deep Learning (DL) algorithm. Data for training and validation of the DL algorithm was collected from diverse locations and populations, using a variety of ultrasound system settings, scanners, and Catheters.

1.5 LAT VELOCITY VECTORS (LVV)

The LAT Velocity Vectors (LVV) enables a visual display of the conduction mechanism in the chamber via velocity vectors on top of the 3D map, indicating the speed and direction of the activation wave as it propagates through the chamber.

1.6 CATHETERS SUPPORT

CARTO™ 3 system improved support of QDOT Micro™ Catheter:

CARTO™ 3 system V8.0 includes the following QDOT Module Improvements on the CARTO software version that was part of PMA P210027: enhanced ECG channels filters, addition of nGEN PUMP

real-time flow rate display, display improvement, reflection of irrigation changes for focal ablation and during ablation only.

CARTO™ 3 system support of OPTRELL™ Mapping Catheter through SPU:

Visualization and mapping capabilities for the OPTRELL ™ Mapping catheter. OPTRELL support includes Local Conduction Vectors (LCV), showing visualization of the wave propagation through the OPTRELL™ Catheter, indicating direction and speed.

CARTO™ 3 system support of LASSOSTAR NAV:

Visualization and mapping capabilities for LASSOSTAR NAV Circular Mapping Catheter.

1.7 LEGACY FEATURES MODIFICATIONS

VISITAG Module - Compensated VISITAG Stability Algorithm:

The VISITAG stability indication in the predicate device CARTO® 3 System V7.4 is based on the ACCURESP™ algorithm that provides the ablation catheter end-expirium locations, meaning that stability indication is updated once every respiration cycle. A modified respiration decomposition ("Compensated") algorithm was developed that estimates the catheter motion in real-time based on the respiration originated motion and subtracting it from the measured location. The Compensated Stability algorithm enables faster feedback to user at the beginning of ablation ensuring VISITAG early appearance, when the stability conditions are maintained.

Late Annotation Mapping (LAM):

Late Annotation Mapping provides an additional mapping criterion that allows a Late Boundary (LB) annotation line to be placed within the standard LAT Window of Interest (WOI).

CONFIDENSE Module – SmartMap:

In the legacy CONFIDENSE™ Module design, the map is colored according to the first point that passed the CONFIDENSE™ filter thresholds and was acquired in every specific location, and such that new potential points will be filtered out if the position is already occupied, even if they also passed the CONFIDENSE™ filter thresholds (first comes, first stays).
With SmartMap, each potential point in the study is rated with a Smart Index, indicating its relative quality based on quality parameters

(Pattern matching, Respiration, LAT stability, Position stability, Tissue proximity, Signal sharpness). SmartMap prioritizes high Smart Index score points over low Smart Index score points when building maps, by swapping points in the map according to their Smart Index score (best comes, best stays even if not first).

Performance Data:

The CARTO™ 3 EP Navigation System V8.0 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 V8.0 included:

- Proof of Design – Testing was performed to verify the CARTO™ 3 System V8.0 design meets specifications. 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 V8.0, including testing of the new features and improvements as well as regression testing to verify continued functionality of CARTO® 3 System legacy features. All system features were found to perform according to specifications and met the tests acceptance criteria.
- Unit Tests – Testing was performed to verify the design implementation in CARTO™ 3 V8.0 software is compatible with the design. All testing performed were successfully completed and met the acceptance criteria.
- Retrospective Validation Tests – Testing was performed to validate the clinical functionality and quality of new introduced modules. Testing was performed retrospectively, on clinical recorded data from historic EP procedures performed with the CARTO™ 3 System. All testing performed were successfully completed and met the acceptance criteria.

Bench Testing:

Bench Testing completed for CARTO™ 3 System V8.0 included Usability Testing: Summative Usability testing was conducted to validate that CARTO™ 3 System V8.0 User Interface is safe and effective for use. In light of the usability validation study results, it is concluded that CARTO™ 3 System V8.0 has been found to be safe and effective for the intended users, uses and use environments.

Animal Testing:

Animal testing was conducted to evaluate the CARTOTM 3 System V8.0 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.

Clinical Testing:
A Real-World Evidence study (REAL AF Registry Sub-Study) evaluating the safety and acute effectiveness of Paroxysmal Atrial Fibrillation ablation with a zero/low fluoroscopy workflow was performed. The data from the study demonstrated the safety and effectiveness of zero/low fluoroscopy workflow. The primary safety and secondary acute effectiveness endpoints were met in the REAL AF Registry population. The safety of the zero/low fluoroscopy workflow was further corroborated by the comparable cumulative incidences of the secondary safety endpoint between the zero/low fluoroscopy group and the conventional fluoroscopy group.

Conclusions: The CARTO™ 3 EP Navigation System V8.0 is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System with CARTOSOUND™ 4D, software version V7.4, based on the completion of verification and validation testing.