August 17, 2022

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

Re: K221112
Trade/Device Name: CARTO® 3 EP Navigation System with Advanced Focus Mapping (AFM)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 14, 2022
Received: July 18, 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 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)*
K221112

Device Name
CARTO® 3 EP Navigation System with Advanced Focus Mapping (AFM)

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

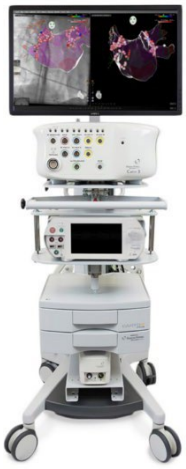
Date:	July 13, 2022
510(k) Number	K221112
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Phuong Park Associate Director Regulatory Affairs Phone: 949-923-4238 Fax: 949-450-6886
Authored by:	Orit Ohayon Senior Regulatory Affairs Specialist Biosense Webster (Israel), Ltd. and Phuong Park Associate Director Regulatory Affairs Biosense Webster, Inc.
Device Trade Name:	CARTO® 3 EP Navigation System with Advanced Focus Mapping (AFM)
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 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 AFM, software V7.3, is a catheter-based atrial and ventricular mapping system designed to acquire and analyze navigation catheters 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 AFM 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 AFM are identical to those described for 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 AFM 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 AFM, software V7.3 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 three new software features: Cycle Length (CL) Mapping, Potential Duration Mapping, Ripple Frequency, and an improvement of the legacy PASO™ Module

Description of Modifications

Cycle-Length Mapping (CLM) - The CLM feature is intended to help in diagnosing IC ECGs by determining bipolar IC cycle length (mean and standard deviation), combined with CFAE and scar information in the same map. The mean and standard deviation cycle lengths for this time period is calculated and displayed as two new maps: Cycle-Length Mean Map and Cycle-Length STD Dev. Map

Potential Duration Map (PDM) - The PDM feature automatically identifies sites with low-voltage and delayed fragmented electrograms during stable sinus rhythm. With duration maps the physician is able to identify abnormal areas of prolonged or delayed fragmented potentials.

Ripple Frequency - The Ripple Frequency feature is an alternative way to display the maps' bipolar electrogram data being used by the predicate device legacy Ripple Module.

PASO™ Module Improvement – The PASO™ Module presents the area between two Induced Signal (IS) in addition to the legacy correlation index.

Performance Data:

The CARTO® 3 EP Navigation System with AFM underwent verification and validation testing under simulated clinical conditions to verify the new features and to demonstrate with regression testing that these modifications did not negatively affect existing features.

Bench Testing:
Bench testing completed for CARTO® 3 System with AFM included:

- Proof of Design – CARTO® 3 System AFM algorithms were verified to meet specifications. All testing performed met the acceptance criteria.
- Functional verification - verified the functional requirements of CARTO® 3 System with AFM, including testing of the new AFM features 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 Test – these tests were performed to verify isolated software components that were modified for the CARTO® 3 System AFM version.

Animal Testing:
Animal testing was conducted to evaluate the CARTO® 3 System with AFM 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.

Conclusions:

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