June 1, 2018

Biosense Webster, Inc.
Phuong Chau
Senior Regulatory Affairs Program Lead
33 Technology Drive
Irvine, CA 92618

Re: K180238
Trade/Device Name: CARTO 3 EP Navigation System Version 6.0 and Accessories
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 24, 2018
Received: May 25, 2018

Dear Phuong Chau:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180238

Device Name
CARTO 3 EP Navigation System Version 6.0 and Accessories

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.

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

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510(k) Summary

Applicant:	Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Phuong Chau Senior Regulatory Affairs Program Lead Phone: 949-923-4238 Fax: 949-450-6886
Authored by:	Anna Gantman Quality and Regulatory Program Manager Biosense Webster (Israel), Ltd. And Phuong Chau Senior Regulatory Affairs Program Lead Biosense Webster, Inc.
Date:	April 10, 2018
Device Trade Name:	CARTO® 3 EP Navigation System Version 6.0 and Accessories
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 6.0 and Accessories 510(k)#: K170600
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

Device Description:

The CARTO® 3 EP Navigation System, Version 6.0 is a catheter-based atrial and ventricular mapping system designed to acquire and analyze data points, 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 a specialized mapping catheters and reference devices. The system allows electrograms and cardiac maps display based on the received intracardiac signals from the catheters. The CARTO® 3 System V6.0 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO® 3 System V6.0 consists of the following components:

- Patient Interface Unit (PIU)
- Graphic User Interface (GUI)
- Wide-Screen monitors, keyboard, and mouse
- Intracardiac In Port
- Intracardiac Out Port
- Power Supply
- Patches Connection Box and Cables
- Pedals
- Location Pad

All hardware components of the CARTO® 3 System V6.0with the VISITAG SURPOINT™ Module 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.

Technological Characteristics:

The modified CARTO® 3 EP Navigation System, Version 6.0 with VISITAG SURPOINT™ Module, has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System, Version 6.0. 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 location mapping technology.
- Have identical magnetic location sensor accuracy.

The main difference between the predicate device and the modified device is the enhancement of the VISITAG Module to add the VISITAG SURPOINT™ Module. The module is used to display Tag Index calculations performed by the VISITAG SURPOINT™ EPU device. Additionally, an HD Coloring feature was implemented to provide high definition coloring of electroanatomical maps. The HD coloring feature includes the following GUI enhancements: Cleaner map visualization, Enhanced wave propagation display, Enhanced visualization of projected points and Enhancements for the Early Meets Late mechanism.

Performance Data: The CARTO® 3 EP Navigation System, Version 6.0 with the VISITAG SURPOINT™ Module underwent extensive bench testing to verify the new and modified features and to demonstrate with regression testing that these modifications did not negatively affect existing features. 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, Version 6.0 and Accessories with the VISITAG SURPOINT™ Module is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System, Version 6.0 based on the completion of non-clinical bench testing and pre-clinical testing as well as similar principles of design, operation and indications for use.