DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 25, 2017

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

Re: K170600
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: June 16, 2017
Received: June 19, 2017

Dear Phoung 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170600

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.

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510(k) Summary – K170600

Applicant:	Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618, USA Phone: 909-839-8500 Fax: 909-839-8804
Contact Person:	Phuong Chau Senior Regulatory Affairs Program Lead Phone: 909-839-7249 Fax: 909-839-8804
Authored by:	Moshe Hochmitz Quality and Regulatory Manager Biosense Webster (Israel), Ltd. And Phuong Chau Senior Regulatory Affairs Program Lead Phone: 909-839-7249 Fax: 909-839-8804
Date:	February 28, 2017
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 4.2 and Accessories 510(k)#: K133916
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 V6.0 are identical to those described for the predicate CARTO® 3 System V4.2.

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 proposed CARTO® 3 EP Navigation System, Version 6.0, has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System, Version 4.2. 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 CARTO® 3 System V4.2 and CARTO® 3 System V6.0 is to enhance the following areas:

Enhancements	**CARTO® 3 System V6.0**	**Rationale for Difference**
Annotations	ConfiDENSE Module has two new types of point annotations • Body Surface Morphology Matching • Complex Point Identification	Addition of two new filters to assist physicians with points acquisition.
Visualization	CARTO VIZIGO™ Software	Addition of CARTO VIZIGO Software to support visualization of the VIZIGO™ Bi-Directional Guiding Sheath.
Fluoro Integration	Addition of TOSHIBA to the CARTOUNIVU module supported X-ray systems library.	Compatibility with TOSHIBA X-ray Systems has been established.
Imaging	CARTOSEG CT and CARTOSEG MR library update.	Update to add Siemens to the library has no impact on system functionality or workflow.

Usability	• Software Graphical User Interface (GUI) modifications to allow Intuitive use of most used features • Usability features for Maps	Usability changes for improved CARTO® 3 System look and feel. No impact on system functionality or workflow.

Performance Data: The CARTO® 3 EP Navigation System, Version 6.0 underwent extensive bench and pre-clinical testing under simulated clinical conditions to verify the new and modified features and to demonstrate with regression testing that these modifications did not negatively affect existing features. The CARTO® 3 EP Navigation System, Version 6.0 passed all tests 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 is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System, Version 4.2 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.