



June 14, 2018

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

Re: K173977

Trade/Device Name: CARTO 3 EP Navigation System, Version 4.35 and Accessories
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 10, 2018
Received: May 11, 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K173977

Device Name
CARTO® 3 EP Navigation System Version 4.35 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

Applicant: Biosense Webster, Inc.
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Biosense Webster (Israel), Ltd.
And
Phuong Chau
Senior Regulatory Affairs Program Lead

Date: December 27, 2017

Device Trade Name: CARTO® 3 EP Navigation System Version 4.35 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 4.35 and Accessories with COHERENT MAPPING module 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 electro-anatomical maps of the human heart. The location information needed to create the cardiac maps and the local electrograms are acquired using a set of 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 V4.35 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

CARTO® 3 EP Navigation System Version 4.35 and Accessories with COHERENT MAPPING module consists of the following components:

- Patient Interface Unit (PIU)
- 3D graphical Workstation that serves as the 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 V4.35 are identical to those described for the predicate CARTO® 3 System V4.2.

This File covers the functionality, introduced by the changes made in the CARTO®3 Navigation System 4.35 and Accessories with COHERENT MAPPING module

Because CARTO® 3 System V4.35 with COHERENT MAPPING module is only available on this version, the CARTO® 3 System V4.35 will be marketed in parallel with the CARTO® 3 System V6.0 software. Future software releases, may incorporate this functionality pending company business decisions.

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 4.35, 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 V4.35 with COHERENT MAPPING Module is to improve the representation of the electric wave propagation over the atria by adding new coloring and electric wave direction vector. This new coloring is an additional option on top of the basic coloring of CARTO3® V4.2 cleared By FDA (K133916). This improved representation of conduction velocity vectors may help the physician to focus his/her attention on the displayed path of cyclic arrhythmia propagation.

Performance Data:

The CARTO® 3 EP Navigation System, Version 4.35 underwent extensive bench, pre-clinical testing under simulated clinical conditions and retrospective validation to verify the new COHERENT MAPPING feature to demonstrate with regression testing that these modifications did not negatively affect existing features. The CARTO® 3 EP Navigation System, Version 4.35 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 4.35 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.