August 24, 2018

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

Re: K173978
Trade/Device Name: CARTO 3 EP Navigation System, Version 5.2 and Accessories with CARTOFINDER Module
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK,
Dated: July 31, 2018
Received: August 1, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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

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)*
K173978

Device Name
CARTO® 3 EP Navigation System Version 5.2 and Accessories with CARTOFINDER Module

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. 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: 949-923-4238 Fax: 949-450-6886
Authored by:	Moshe Hochmitz Associate Director, Quality and Regulatory Biosense Webster (Israel), Ltd. And Phuong Chau Senior Regulatory Affairs Program Lead
Date:	July 27, 2018
Device Trade Name:	CARTO® 3 EP Navigation System Version 5.2 and Accessories with CARTOFINDER™ Module
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 5.2 and Accessories 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 V5.2 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO® 3 EP Navigation System Version 5.2 is a modification to the CARTO® 3 EP Navigation System Version 4.2 to add the CARTOFINDER™ Module and workstation as an accessory to the CARTO® 3 System. The CARTOFINDER™ Module sends recorded electrical signals collected from multi-connector electrode catheters to the CARTOFINDER™ workstation, which generates new visual format maps to be displayed in the CARTO® 3 EP Navigation System. The new visual format maps generated by the CARTOFINDER™ Workstation are divided into two categories:

1. Dynamic mapping algorithms: Wherein the physiological scoring is changing over time after inspecting the input signals in a certain window of interest.
2. Static mapping algorithms: These maps set a single physiological scoring per electrode, after analyzing the input signals during the full recording time.

The CARTOFINDER™ Workstation creates the following Dynamic and Static Maps:

1. 4D LAT: Dynamic map of the Local Activation Time.
2. Cycle Length (CL) Unipolar Signal: Static map showing the dominant cycle length measured on each recorded channel per recording/data acquisition set.
3. Cycle Length (CL) Variation: Static map showing the standard deviation cycle length measured on each recorded channel.
4. CARTOFINDER™ Region of Interest (ROI) – Focal: This map will identify the area with QS morphology on the unipolar electrograms that are activated early compared to the

surrounding multi-connector (MC) electrode catheter recorded channels.

5. CARTOFINDER™ (ROI) – Rotational: This map will identify rotational activation patterns that occupy at least 50% of the cycle length map (this condition requires sufficient spatial and temporal resolution).

CARTO® 3 EP Navigation System Version 5.2 and Accessories 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
- CARTOFINDER™ Workstation
- Non-Biosense Webster basket catheter interface cable (CA-5400-61)

Because CARTOFINDER™ is only available on this version, the CARTO® 3 System V5.2 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 5.2, has the same technological characteristics 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 provided in the following table.

	CARTO 3 System V4.2 (K133916)	**CARTO® 3 EP Navigation System Version 5.2 with CARTOFINDER™ Module (K173978)**
Indications for Use	The intended use of the CARTO® 3 System is catheter-based cardiac electrophysiological (EP)	Same

	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.	
System	• Patient Interface Unit (PIU) • Workstation Computer with standard keyboard and mouse • Single monitor display • Intracardiac Port • Intracardiac Out Port • Power Supply • Patch Connections Box and Cables • Pedals • Location Pad	Addition of the CARTOFINDER™ Workstation (Workstation specifications are same as CARTO 3 System Workstation specifications)
Sensors catheters support	Mapping and visualization based on Basic triangulation of Magnetic Location algorithm	Same
Non-Sensors catheters support	Mapping and visualization based on Current based location (ACL) algorithm	Same
Interface for Data transfer CARTOFINDER™ Module	Interfacing with compatible devices (such as Ultrasound systems, EP recording systems, Fluoroscopic systems, RF Generators)	Extended interface abilities to support the CARTOFINDER™ Workstation data.
Offers Display Options for Review of Processed Signals	LAT (including propagation of single beat) Anatomical Unipolar & Bipolar Voltage maps Impedance	• 4D LAT • enhanced to review signal propagation over the complete periods of time of signal recording • CL Stability • CL Variation • ROI – Focal • ROI - Rotational
Supports Multi Electrode Catheter Recordings	Yes	MEM capability was expanded to high number of electrodes, including interface cable (CA-5400-61) to support basket catheter.

The CARTO® 3 System V5.2 is substantially equivalent to the CARTO® 3 System V4.2, as the mechanism of the diagnostic maps of both devices remains the same. Both devices use IC annotated signal in a known location and present them in a sequence that determines the propagation direction of the signal in the tissue allowing the physician to diagnose the arrhythmia pattern. Except for the CARTOFINDER™ Workstation, the hardware components of the CARTO® 3 System V5.2

are identical to those described for the predicate CARTO® 3 System V4.2.

Performance Data: The CARTO® 3 EP Navigation System, Version 5.2 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 5.2 passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

Bench Testing:
Non-clinical performance testing completed for the CARTO® 3 EP Navigation System, Version 5.2 included:

- CARTO® 3 System Version 5.2 – verify the functional requirements and hardware configurations with the new CARTOFINDER™ Module and Workstation, regression testing of all CARTO® 3 System legacy features, verify system functionality for all supported catheters, and usability testing.
- CARTOFINDER™ Workstation testing – verify the signal pre-processing and annotation detection, maps and catheter generation and coloring, CARTOFINDER™ functionality (including MC catheter support), stimulation detection and blanking, coloring projection and interpolation, power reject algorithm performance, and usability testing.
- CARTOFINDER™ integration – verify that the new module interface with the CARTOFINDER™ Workstation meets requirements and functions as intended when integrated with the CARTO® 3 system.
- Interface cable – verification testing was completed for the interface cable connected to a non-Biosense Webster basket catheter with the CARTO® 3 System.

Animal Testing:
Animal testing was performed to evaluate the CARTO® 3 System Version 5.2 and CARTOFINDER™ Workstation workflow under simulated clinical workflow.

Clinical Data:
Clinical data from Biosense Webster sponsored studies, published literature, and manuscripts were used to support the clinical performance of the new maps for their respective intended use. The data also supported the clinical performance of the compatible catheters with the new maps. The information provided by these maps

are for diagnostic purposes only. Therapeutic treatment should rely on all available information in the EP lab.

Conclusions: The CARTO® 3 EP Navigation System, Version 5.2 is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System, Version 4.2 based on the completion of non-clinical bench testing, pre-clinical testing, and clinical data as well as similar principles of design, operation and indications for use.