July 20, 2019

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

Re: K191660
Trade/Device Name: CARTO 3 EP Navigation System, Version 7.1 and Accessories
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 19, 2019
Received: June 21, 2019

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/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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191660

Device Name

CARTO® 3 EP Navigation System Version 7.1
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.

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:	Elena Goldin Quality and Regulatory Senior Specialist Biosense Webster (Israel), Ltd. And Phuong Chau Senior Regulatory Affairs Program Lead Biosense Webster, Inc.
Date:	June 19, 2019
Device Trade Name:	CARTO® 3 EP Navigation System Version 7.1 and Accessories
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 6.0 and Accessories with VISITAG SURPOINT 510(k)#: K180238
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 7.1 is a catheter-based atrial and ventricular mapping diagnostic system designed to acquire and analyze data points, and use this information to display 3D anatomical and electroanatomical diagnostic 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 system allows electrograms and cardiac maps display based on the received intracardiac signals from the catheters. The CARTO® 3 System V7.1 uses the same two distinct types of location technology as the predicate device – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO® 3 System V7.1 consists of the following hardware components:

- Patient Interface Unit (PIU) and Cables
- 3D Graphics Workstation
- 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 V7.1 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 7.1 has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System device. 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

The main difference between the predicate device and the modified device are the merging of previously cleared functions (CARTOFINDER K173978 and Coherent Mapping module K173977 reference devices) in a CARTO3 software version, new modifications, and the addition of Letter to File changes as described below:

Summary of Modifications

Mapping and Annotations:

- **LAT Histogram** – a graphical representation of the Local Activation Time (LAT) values of all points that contribute to the Active Map's LAT coloring, over a time interval (range) from the lowest to highest LAT value.

Letter To File Changes:

- LAT Hybrid Maps
- Improvements for displays (Map Consistency Display)
- Map filtering (Parallel Mapping)
- Signals displays (previous beat overlay)
- Signals annotations (Advanced Reference Annotation (ARA))
- Signals filtering (Power line noise rejection)
- GUI improvement to improve user experience (usability) such as high definition (HD) propagation style
- Updated Visualization Setup window display
- Increased limit of points in map
- Backup time reduction

Performance Data: The CARTO® 3 EP Navigation System, Version 7.1 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 in the predicate and reference devices. 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 7.1 and Accessories is substantially equivalent to the cleared CARTO® 3 EP Navigation System V6 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.