October 29, 2021

Biosense Webster, Inc.
Khaled Hamad
Senior Regulatory Affairs Specialist
31 Technology Drive, Suite 200
Irvine, California 92618

Re: K213264
Trade/Device Name: CARTO® 3 EP Navigation System Version 7.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 27, 2021
Received: September 30, 2021

Dear Khaled Hamad:

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,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213264

Device Name
CARTO® 3 EP Navigation System Version 7.2

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 – K213264

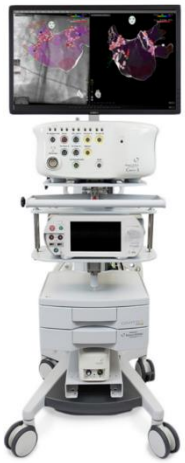
Applicant:	Biosense Webster, Inc. 31 Technology Drive, Suite 200 Irvine, CA 92618, USA Tel.: (800) 729-9010 Fax: (909) 839-8500
Contact Person:	Khaled Hamad Senior Regulatory Affairs Specialist Phone: 949-453-6350 Fax: 949-450-6886
Authored by:	Elena Goldin Quality and Regulatory Affairs Senior Specialist Biosense Webster (Israel), Ltd. and Khaled Hamad Senior Regulatory Affairs Specialist Biosense Webster, Inc.
Date:	September 27, 2021
Device Trade Name:	CARTO® 3 EP Navigation System Version 7.2
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 7.1 510(k)#: K191660 (primary predicate device**)** and CARTO® 3 EP Navigation System Version 7.61 with SPU (Signal Processing Unit) 510(k)#: K200484
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.

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
USA

Device Description:



The CARTO® 3 EP Navigation System, Version 7.2 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 V7.2 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO® 3 System V7.2 consists of the following components:

- Patient Interface Unit (PIU)
- Workstation with Graphic User Interface (GUI)
- Wide-Screen monitors, keyboard, and mouse
- Intracardiac In Port
- Intracardiac Out Port
- Power Supply
- Patches Connection Box and Cables (PU)
- Pedals
- Location Pad (LP)
- Signal Processing Unit (SPU) ((510(k)#: K200484)

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.

The indications for use for the CARTO® 3 System are identical to the indications for use of the primary predicate CARTO® 3 System V7.1

Technological Characteristics:

The modified CARTO® 3 EP Navigation System, V7.2 has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System, Version 7.1 (K191660) and Version 7.61 with SPU (Signal Processing Unit) (K200484). 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 identical magnetic location mapping technology.
- Have identical magnetic location sensor accuracy.

The main difference between the predicate device and the modified device are the upgrade of the CARTO® 3 software operating system to Windows 10, while restoring support of all legacy software modules and interoperabilities, cleared under 510k K191660, that were blocked under K200484. The CARTO® 3 EP Navigation System V7.2 includes the Signal Processing Unit (SPU), cleared under 510k K200484, that provides support to multi-electrode catheters up to 48 electrodes, such as the OCTARAY DX catheter.

This release also includes minor improvements to several legacy modules, without adding any new software module.

Performance Data:

The CARTO® 3 EP Navigation System V7.2 with accessories 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.

Bench Testing:

•Electrical Safety and Electromagnetic Compatibility testing was performed per IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements. Test results were in compliance to the standards.

•Proof of Design – verified visualization of catheters, system behavior, location accuracy of catheters position, ECG channel characteristics and performance,

load capacity, data synchronization, and the verification of legacy re-enabled modules. Tests were performed on a Windows 10 Operating System. All testing performed met the acceptance criteria.

•Functional verification – verified the functional requirements and hardware configurations, regression testing of CARTO® 3 System legacy features, system functionality for supported catheters, and interoperability with 3rd party compatible medical devices. Usability was tested per IEC 60601–1-6, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. All applicable functions on the CARTO® 3 V7.2 System were tested running on a Windows 10 Operating System. All system features were found to perform according to specifications and met acceptance criteria.

Animal Testing:

•Animal testing was conducted to evaluate the CARTO® 3 V7.2 System functionality under simulated clinical workflow and conditions. All test protocol steps were successfully completed and expected results were achieved.

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, V7.2 is substantially equivalent to the currently cleared CARTO® 3 EP Navigation System, Version 7.1 and Version 7.61 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.