



November 25, 2020

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

Re: K200484

Trade/Device Name: CARTO® 3 EP Navigation System with Signal Processing Unit
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 28, 2020
Received: October 29, 2020

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,

Mark Fellman
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

Indications for Use

510(k) Number (if known)

K200484

Device Name

CARTO® 3 EP Navigation System with Signal Processing Unit

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

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And

Khaled Hamad
Senior Regulatory Affairs Specialist
Biosense Webster, Inc.

Date: November 25, 2020

Device Trade Name: CARTO® 3 EP Navigation System with Signal Processing Unit

Software Version V7.61

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 and Accessories
510(k)#: K191660

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 with SPU 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 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

The CARTO[®] 3 System with SPU 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
- SPU

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 with SPU, has the same technological characteristics as the predicate CARTO[®] 3 EP Navigation System, Version 7.1 (K191660). 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 differences between the predicate device and the modified device is the addition and support of a Signal Processing Unit (SPU), as an accessory to the CARTO® 3 System, upgrade to Windows 10 Operating System, and the following blocked optional features:

- ACCURESP™ Module
- CARTOMERGE® Image Integration Module
- CARTOSEG™ CT Segmentation Module
- CARTOSEG™ MR Segmentation Module
- CARTOREPLAY™ Module
- CARTOSOUND® Image Integration Module
- CARTOUNIVU™ Module, including:
 - Fluoroscope Effect Reduction (FER)
 - Integration with fluoroscopy systems
- Complex Fractionated Atrial Electrogram (CFAE) Module
- CONFIDENSE™ Module, including Tissue Proximity Indication (TPI)
- FAM Dx
- HD Coloring
- PASO™ Module
- CARTO PRIME™ Module, including:
 - COHERENT Mapping
 - CARTOFINDER™ Module
 - LAT Hybrid Maps
 - Parallel Mapping
- CARTO SMARTTOUCH™ Module
- CARTO VISITAG™ Module
- VISITAG SURPOINT™ Module with External Processing Unit (EPU)
- CARTO VIZIGO™ Software
- Interoperability with Archiving System (PACS)
- Review of studies from previous versions

The SPU is used to connect Multi Electrode Diagnostic (Dx) catheters with up to 48 electrodes to the CARTO® 3 System. The SPU processes ECG and location data obtained from

diagnostic catheters and transfers the information to the CARTO® 3 System Workstation via the CARTO® 3 System PIU.

Performance Data:

The CARTO® 3 EP Navigation System with the SPU accessory underwent extensive bench and pre-clinical testing under simulated clinical conditions to verify the extended channel capacity of the CARTO® 3 System and to demonstrate with regression testing that the modifications involved did not negatively affect existing features. All testing passed in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

Bench Testing:

Bench testing completed for CARTO® 3 EP Navigation System with Signal Processing Unit (SPU) included:

- 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, and data synchronization of the CARTO® 3 System when connected to the SPU. All testing performed met the acceptance criteria.
- Functional verification – verified the functional requirements and hardware configurations with the SPU, regression testing of CARTO® 3 System legacy features, system functionality for supported catheters, and usability testing (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 EP Navigation System with SPU were tested running on the Windows 10 Operating System. All system features were found to perform according to specifications and met the tests acceptance criteria.

Animal Testing:

Animal testing was conducted to evaluate the CARTO[®] 3 EP Navigation System with SPU functionality under simulated clinical workflow and conditions. All test protocol steps were successfully completed and expected results were achieved.

Conclusions:

The CARTO[®] 3 EP Navigation System with SPU is substantially equivalent to the currently cleared CARTO[®] 3 EP Navigation System Version 7.1 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.