JUL 0 1 2014

14 510(K) SUMMARY

14.1 General Information

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, California 91765 USA Phone: 909-839-8597 Fax: 909-839-8804
Date:	December 19, 2013
Contact Person:	Wayne R. Hohman Project Manager Regulatory Affairs
Authored By:	Moshe Hochmitz Quality and Regulatory Manager Biosense Webster (ISRAEL), Ltd.
Trade/Proprietary Device Name:	CARTO® 3 EP Navigation System, Version 4.2 and Accessories
Manufacturing Part Number:	FG-5400-00
Common Device Name:	Cardiac mapping system
Classification Name:	Programmable diagnostic computer Class II, 21 CFR 870.1425, Product Code DQK
Predicate Devices:	CARTO® 3 EP Navigation System, Version 3.0, cleared via 510(k) K120550, May 7, 2012. Referenced Device 1 Siemens MAGNETOM Skyra with Syngo MR D11, 510(k) K111242 cleared November 23, 2011. Reference Device 2 ST JUDE EnSite NavX™ CONTACT, 510(k) K130727 cleared August 29, 2013, included only for the VeriSense System Software.
Manufacturing Facilities:	Biosense Webster (Israel), Ltd. a Johnson & Johnson Company 4 Hatnufa Street, POB 275 Yokneam 20692 ISRAEL

Biosense Webster, Inc.
a Johnson & Johnson Company
3333 Diamond Canyon Road
Diamond Bar, California 91765 USA

14.2 Substantial Equivalence

The CARTO® 3 EP Navigation System, Version 4.2 is substantially equivalent to the legally marketed CARTO® 3 EP Navigation System, Version 3.0 and two Reference Devices as shown in the following Table:

Predicate Devices for CARTO® 3 EP Navigation System, Version 4.2		
Predicate/Reference Name	**510(k) Number**	**Equivalence Criteria**
CARTO® 3 EP Navigation System, Version 3.0	K120550	Main predicate for legacy functionality
Siemens MAGNETOM Skyra with Syngo MR D11	K111242	For segmentation functionality
ST JUDE EnSite NavX™ CONTACT, 510(k) cleared August 29, 2013, included	K130727	For segmentation functjonality

14.3 Description of Device

The CARTO® 3 System V4.2 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 in real-time. 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 real-time display of electrograms and cardiac maps based on the received intracardiac signals from the catheters in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms (IECG) may also be displayed on the display screen. The CARTO® 3 System V4.2 uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology.

14.4 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.

14.5 Technological Characteristics

The Proposed CARTO® 3 EP Navigation System, Version 4.2, has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 EP Navigation System, Version 3.0. A summary of the technological characteristics of the new device compared to the predicate device is as follows:

- The hardware platform of the new Version 4.2 is identical to the predicate Version 3.0 except for replacement of a Printed Circuit Board.

- The differences between CARTO® 3 System, Version 3.0 and Version 4.2 are mainly three added software features, one of which required a hardware change, as follows:

  - CARTOMERGE® Plus Image Integration Software Module Improvement.
  - Continuous ECG Visualization Module.
  - Tissue Proximity Indication (TPI) Module:
    - Software Feature: Added Tissue Proximity Indication (TPI) algorithms.
    - Hardware Feature: Modified ACL Tx card to add electrode voltage measurement.
  - SMARTTOUCH™ Module.

- In addition, Biosense Webster improved (i. e., enhanced) the capabilities of four previously cleared software features as follows:

  - Enhanced VisiTag™ II Module.
  - Enhanced Continuous Acquisition of Electroanatomical Points.
  - Enhanced Time-Sync Heart Rhythm for CARTOUNIVU™ Fluoro Background Cine Movies.
  - Enhanced Map Alignment Tool (MAT).

- Finally, Biosense Webster updated FDA on features that were incorporated via 510(k) Letters to File since the last submission: Two new Map Displays. New Signal Annotation Options, an additional Foot Pedal (ergonomic feature), support of New Catheters, and support of Dual Monitors.

14.6 Summary of Non-Clinical Performance Testing

The CARTO® 3 EP Navigation System, Version 4.2 underwent extensive Bench and Animal Testing to verify the new and modified features and to demonstrate with regression testing that the new/modified features did not negatively affect existing features. The CARTO® 3 EP Navigation System, Version 4.2 passed all tests in accordance with appropriate test criteria and standards, and the modified device did not raise new questions of safety or effectiveness.

14.7 Conclusions

The Bench and Animal Non-Clinical Testing demonstrated that the CARTO® 3 EP Navigation System, Version 4.2 is as safe, as effective, and performs as well as or better than the predicate device and two reference devices. This testing program supports the determination of substantial equivalence to the predicate/reference devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2014

Biosense Webster, Inc
Wayne R. Hohman
Product Manager Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K133916
Trade/Device Name: CARTO 3 EP Navigation System, Version 4.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 29, 2014
Received: June 2, 2014

Dear Mr. Hohman,

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.

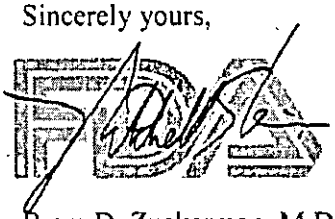
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

5 INDICATIONS FOR USE

510(k) No (if known): _____

Device Name: CARTO® 3 EP Navigation System, Version 4.2

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.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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