K132782

JAN 2 4 2014

14 510(K) SUMMARY

14.1 General Information

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765 USA Phone: 909-839-8597 Fax: 909-839-8804
Date:	September 3, 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 3.2 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 Device:	CARTO® 3 EP Navigation System, Version 3.0 and Accessories 510(k) K120550, May 7, 2012 Reference Device: CARTO® 3 XP EP Navigation, System Version 1.0 510(k) K093566, June 18, 2010
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 3.2 and Accessories are substantially equivalent to the legally marketed CARTO® 3 EP Navigation System, Version 3.0 and Accessories and the CARTO® XP EP Navigation System, Version 10 as shown in Table 7:

Table 7
Predicate Devices for CARTO® 3 EP Navigation System, Version 3.2

Device Name	510(k) Number	Equivalence Criteria
CARTO® 3 EP Navigation System, Version 3.0 and Accessories	K120550	Legacy Functionality
CARTO XP EP Navigation System, Version 10	K093566	Pace Mapping Software (PaSo™) Module

14.3 Description of Device

The CARTO®3 EP Navigation 3 System, Version 3.2 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 in real-time. The location information needed to create the cardiac maps and the local electrograms are acquired using a specialized mapping catheter and reference device. 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 V3.2 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.

14.4a Technological Characteristics

The Proposed CARTO® 3 Electrophysiology Navigation System, Version 3.2, has the same technological characteristics (i. e., design, material, chemical composition, energy source) as the predicate CARTO® 3 Electrophysiology 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 3.2 is identical to the predicate Version 3.0.

- The differences between Versions 3.2 and 3.0 involve only software as follows:

  - The main change in this submission is to activate an installed but previously blocked SMARTTOUCH™ Module.

  - The software of three other features of this system is enhanced (i. e., updated) in this submission: 1) Advanced FAM – Visual improvement of the V2 FAM Feature, 2) Remote Magnetic Technology (RMT) Improvements, and 3) Video Export to Recording System.

  - Finally, Biosense Webster is updating FDA on a feature that was incorporated via 510(k) Letter to File since the last submission: Improved Pace Mapping Software (PaSo™) Module. The PaSo™ Module was originally cleared via in an earlier version of this device and this device is included in this Application as a Reference Device for the PaSo™ Module feature: CARTO® XP EP Navigation System, Version 10 (510(k) K093566, cleared June 18, 2010).

14.5 Summary of Non-Clinical Performance Testing

The CARTO® 3 EP Navigation System, Version 3.2 underwent extensive Bench and Animal Testing to verify the modified features and to demonstrate with regression testing that the new features did not negatively affect existing features. The CARTO® 3 EP Navigation System, Version 3.2 passed all tests in accordance with appropriate test criteria and standards, and the CARTO® 3 EP Navigation System, Version 3.2 and Accessories did not raise new questions of safety or effectiveness.

14.6 Conclusions

Extensive Non-Clinical (Bench) Testing, Animal Testing, and an IDE Clinical Investigation all demonstrated that the CARTO® 3 EP Navigation System, Version 3.2 and Accessories as used with the activated SMARTTOUCH™ Module are as safe, as effective, and performs as well as or better than the Predicate Device and the Reference Device. This testing program supports the determination of substantial equivalence of the CARTO® 3 EP Navigation System, Version 3.2 and Accessories to existing predicate 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

January 24, 2014

Biosense Webster, Inc.
Wayne Hohman
3333 Diamond Canyon Rd
Diamond Bar, CA 91765 US

Re: K132782
Trade/Device Name: CARTO 3 EP Navigation System, version 3.2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 5, 2013
Received: November 6, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

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): K132782

Device Name: CARTO® 3 EP Navigation System, Version 3.2

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)

Digitally signed by Owen P. Faris -S
Date: 2014.01.24 16:20:52 -05'00'