5. 510(K) SUMMARY

Applicant:

Biosense Webster, Inc.
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Diamond Bar, CA 91765
USA
Phone: 800-729-7272
Fax: 909-839-8804

OCT 13 2009

Date: December 31, 2008

Contact Person:

Balaka Das
Senior Specialist, Regulatory Affairs

Proprietary Device Name: CARTO® 3 V1.0 EP Navigation System and Accessories

Common Device Name: Cardiac mapping system

Classification Name: Programmable diagnostic computer
(per 21 CFR 870.1425, Product Code DQK)

Predicate Device:
CARTO® III EP Navigation System (K072202)
CARTO® RMT V8 EP Navigation System (K060047)
CARTO® V9 XP EP Navigation System (K070240)

Manufacturing Facilities:

System & System Cables
Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel, 39120
Israel

Accessories (Accessory Cables and Patches)
Biosense Webster, Inc.
15715 Arrow Highway
Irwindale, CA 91706 USA

5.1 Substantially Equivalent To:

The CARTO® 3 V1.0 EP Navigation System is substantially equivalent to the predicate devices shown in Table 1 below:

Table 1: Predicate Devices for CARTO® 3 V1.0 EP navigation System

Submission Name	510(K) Number	Equivalence Criteria
CARTO® III EP Navigation System	K072202	System hardware, accessories, magnetic location technology, ACL Technology
CARTO® XP V9 EP Navigation System	K070240	CARTOSOUND™ and CARTOMERGE® PLUS functionalities, impedance mapping
CARTO® RMT V8 EP Navigation System	K060047	Stereotaxis Niobe® system integration and compatibility, impedance mapping

5.2 Description of the Device Subject to Premarket Notification:

The CARTO® 3 V1.0 EP Navigation System 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 intra cardiac signals from the catheters in a number of different formats. For example, maps may be displayed as anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, cardiac chamber geometry and ECG fragmentation maps. The acquired patient signals, including body surface ECG and intracardiac electrograms (IECG) may also be displayed on the display screen.

The CARTO® 3 V1.0 System uses two distinct types of location technology – magnetic sensor technology and Advanced Catheter Location (ACL) technology. The system utilizes magnetic sensor technology to locate the magnetic location sensor housed within a navigational catheter. The system uses "ACL technology" in conjunction with the magnetic sensor technology to locate the catheter electrodes. ACL was previously referred to as "Active Current Localization" in the CARTO® III 510(k) submission (K072202). Following clearance of K072202, the acronym "ACL" was changed to Advanced Catheter Location for marketing purposes. External reference patches are needed for magnetic sensor-based as well as for ACL-based localization. The external reference patches are accessories to the system. Three patches are placed on the patient's

chest and three are placed on the patient's back. Each patch connects to a location sensor mounted on the patch unit cables that extend from the CARTO® 3 System.

Magnetic sensor location is calculated in reference to an axis origin based on external references. In order to locate the magnetic location sensor of mapping (navigational) catheters (such as the NAVISTAR catheter), the system compares the location of the mapping catheter sensor to the mean calculation obtained from the three sensors located on the patch cables attached to the patient's back.

In order to locate and visualize the electrodes on a catheter using ACL technology, three patch cables must be attached to the patches placed on the patient's chest and three patch cables must be attached to the patches placed on the patient's back.

The CARTO® 3 V1.0 System was implemented on the same hardware and software platform as the predicate CARTO® III System, cleared on November 17, 2007 via the CARTO® III 510(k) K072202.. The purpose of this 510(k) is to expand functionalities on the base CARTO® III System. The information presented below details the system's enhanced or additional functionality.

There are three basic categories of added functionality for the CARTO® 3 V1.0 system:

a) **Enhanced base model features:** These are features that were included in the previously cleared CARTO® III System. However, the features have been enhanced for the CARTO® 3 V 1.0 System.
   The enhanced base model features discussed in this submission include:
   i. Improved Magnetic Location Algorithm.
   ii. Improved ECG signal quality.
   iii. Catheter visualization using an enhanced ACL algorithm.
   iv. Gated and Non-gated catheter visualization.

b) **Features acquired from predicate devices:** These are CARTO® 3 features that have been adopted from previously cleared CARTO® Systems.
   The features acquired from predicate CARTO® Systems discussed in this submission include:
   i. Integration with Stereotaxis Niobe® Catheter Magnetic Navigation System - Remote Magnetic Technology (RMT)
   ii. Integration with Ultrasound (ULS) Systems - CARTOSOUND™ Module.
   iii. Fusion of CT and MRI images - CARTOMERGE® PLUS Image Integration Module with Image Processing Package.
   iv. Impedance mapping.

c) **Features new to the CARTO® platform**: These are new features not yet reviewed and cleared by the FDA.
   The new features discussed in this submission include:
   i. Fast Anatomical Mapping (FAM).
   ii. Complex Fractionated Atrial Electrogram (CFAE) mapping tool.
   iii. Window of interest templates.

5.3 Indications for Use:

The CARTO® 3 V1.0 System is intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, cardiac chamber geometry maps and ECG fragmentation maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the System's display screen. The CARTO® 3 V1.0 System is also intended to support EP procedures, maintaining CARTO® System capabilities, in the presence of a high metallic environment and magnetic field strengths upto 0.1 T and provide a data communication channel to the Stereotaxis Niobe® Catheter Navigation System. The CARTO® 3 V1.0 System includes CARTOMERGE® PLUS functionality to import, register and merge CT or MRI structural images with CARTO® map's physiological information and real time catheter navigation. The system includes the Fast Anatomical Mapping (FAM) functionality that allows for the quick creation of cardiac anatomical volumes using catheters with magnetic location sensors. The system's CARTOSOUND™ image integration functionality enables integration of intracardiac echo (ICE) to enable visualization of 3D combined maps. In addition to the use of specialized navigation catheters with magnetic location sensors, the system is also intended for use with conventional, non-navigational, electrophysiology catheters without magnetic location sensors.

5.4 Performance Data and Conclusion:

The CARTO® 3 V1.0 EP Navigation System underwent bench and electrical testing and was also tested under simulated use conditions in animals. The System passed all intended criteria in accordance with appropriate test criteria and standards and no new questions of safety or effectiveness were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Biosense Webster, Inc
c/o Ms. Bakala Das
Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

OCT 13 2009

Re: K090017
Trade/Device Name: CARTO 3 V1.0 EP Navigation System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: July 10, 2009
Received: July 14, 2009

Dear Ms. Das:

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.

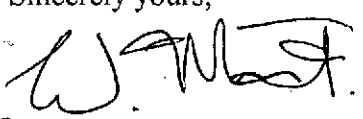
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K090017

Device Name: CARTO® 3 V1.0 EP Navigation System

Indications for Use:

The CARTO® 3 V1.0 System is intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as anatomical maps, cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, cardiac chamber geometry maps and ECG fragmentation maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the System's display screen. The CARTO® 3 V1.0 System is also intended to support EP procedures, maintaining CARTO® System capabilities, in the presence of a high metallic environment and magnetic field strengths upto 0.1 T and provide a data communication channel to the Stereotaxis Niobe® Catheter Navigation System. The CARTO® 3 V1.0 System includes CARTOMERGE® PLUS functionality to import, register and merge CT or MRI structural images with CARTO® map's physiological information and real time catheter navigation. The system includes the Fast Anatomical Mapping (FAM) functionality that allows for the quick creation of cardiac anatomical volumes using catheters with magnetic location sensors. The system's CARTOSOUND™ image integration functionality enables integration of intracardiac echo (ICE) to enable visualization of 3D combined maps. In addition to the use of specialized navigation catheters with magnetic location sensors, the system is also intended for use with conventional, non-navigational, electrophysiology catheters without magnetic location sensors.

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)

M. A. Hillebrenner

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K090017