JUN 18 2010

5. 510(K) SUMMARY

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Rd, Diamond Bar, CA 91765 USA Phone: 800-729-9010 Fax: 909-839-8804
Date:	April 28, 2010
Contact Person:	Wayne R. Hohman Project Manager Regulatory Affairs
Proprietary Device Name:	CARTO® XP System with CARTOXPRESS™ Module (V10) Model No.: FG-4900-00 Model No.: KT-4705-00 (Upgrade Kit)
Common or usual Device Name:	Cardiac mapping system
Classification Name:	Programmable diagnostic computer (per 21 CFR 870.1425, Product Code DQK)
Predicate Devices:	1. CARTO® XP EP Navigation System, Version 9 510(k) K070240 2. CARTO® 3 EP Navigation System, Version 1.0 510(k) K090017
Manufacturer:	Biosense Webster (Israel) Ltd. 4 Etgar Street Tirat HaCarmel 39120 Israel
Manufacturing Site:	Biosense Webster (Israel) Ltd. 4 Etgar Street Tirat HaCarmel 39120 Israel

5.1 SUBSTANTIAL EQUIVALENCE

The CARTO® XP System with CARTOXPRESS™ Module (V10) is substantially equivalent to the predicate devices shown in Table 1:

Predicate Devices for CARTO® XP System with CARTOXPRESS™ Module (V10)		
Submission Name	**510(K) Number**	**Equivalence Criteria**
CARTO® XP EP Navigation System, Version 9	K070240	System platform, CARTOSOUND™ and CARTOMERGE® PLUS functionalities
CARTO® 3 EP Navigation System, Version 1.0	K090017	Fast Anatomic Mapping (FAM), Supports LASSO® NAV Variable Catheter, Complex Fractionated Atrial Electrograms (CFAE) functionality

Table 1: Predicate Devices for CARTO® XP System with CARTOXPRESS™ Module (V10)

5.2 DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The CARTO® XP System with CARTOXPRESS™ Module (V10) (aka CARTO XP V10 System), is designed to acquire cardiac anatomic and physiologic data and display catheter position in real time superimposed on a reconstructed 3D electroanatomical map of the human heart.

Maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. Maps may be displayed as electrical activation maps, electrical propagation maps, electrical potential maps, impedance maps and chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be displayed in real-time on the display screen.

The CARTO® XP V10 System continues to include all features from CARTO® XP EP Navigation System, Version 9 (aka CARTO XP V9 System), including:

1. CARTOMERGE® capability to import, register, and merge CT or MRI structural images with CARTO Maps physiological information and real-time catheter navigation.
2. CARTOSOUND™ functionality that allows for the real time integration of intracardiac echo (ICE) to provide 3D combined maps. The CARTO® XP V10 System interfaces with several ultrasound machines from various manufacturers.
3. Support of the NAVISTAR® family of catheters except for the new LASSO® NAV Catheter that is added in this submission.

CARTO® XP V10 System adds the following features to CARTO® XP V9 System:

1. Fast Anatomical Mapping (FAM): The method used to create a 3D anatomical surface of a heart chamber and its vessels using locations gathered continuously from the mapping catheter. FAM creates high-resolution anatomic maps as the EP physician moves the mapping catheter through the cardiac chamber. This method provides an accurate way to map the heart chambers faster than the regular gated electroanatomical CARTO method of mapping. FAM technology also permits detailed visual enhancement of a specific area of interest within the heart. FAM maps can be combined with electroanatomical maps, CARTOSOUND contour maps, or previously acquired FAM maps.
2. Support of LASSO® NAV Catheter: This new catheter adds new functionalities that enable display of this catheter's circular loop based on the position of magnetic single axial sensors (SAS), selective pacing through the loop electrodes, and perform fast anatomical mapping of the atrial heart chambers. (The LASSO® NAV Catheter is in pending 510(k) K093376.)
3. Complex Fractionated Atrial Electrograms (CFAE): The capability to display maps that are colored according to the duration and repetitions of fragmented electrograms.
4. Pace Mapping Software (PaSo) Module: Provides for paperless comparison between recorded induced ECG signals and pace mapping signals.
5. Support of two additional ultrasound systems: Siemens Acuson X300 and GE Vivid i/q.

5.3 INTENDED USE

The intended use of the CARTO® XP System with CARTOXPRESS™ Module (V10) is catheter-based atrial and ventricular mapping.

The CARTO® XP System with CARTOXPRESS™ Module (V10) allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, impedance maps, and cardiac chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real-time on the system display screen.

CARTO® XP System with CARTOXPRESS™ Module (V10) includes the CARTOMERGE® capability to import, register, and merge CT or MRI structural images with CARTO Maps physiological information and real-time catheter navigation. CARTO® XP System with CARTOXPRESS™ Module (V10) also allows the integration of intracardiac echo (ICE) 2D images to provide 3D combined maps.

CARTO® XP System with CARTOXPRESS™ Module (V10)includes Fast Anatomical Mapping (FAM) that is a method for quick creation of cardiac anatomical volumes using catheters with magnetic location sensors, supports the LASSO® NAV Catheter with location sensors, displays Complex Fractionated Atrial Electrograms (CFAE), and adds Pace-Mapping Software (PaSo) ECG signal correlation tool.

5.4 PERFORMANCE DATA

The CARTO® XP V10 System was subjected to extensive Bench and Animal Testing. New algorithms were properly validated and new functionalities were subjected to rigorous Proof of Design. The performed bench testing included software verification of new features and regression tests for functionalities maintained from the CARTO XP V9 System.

Tests demonstrated system compatibility and support for the visualization, mapping, and pacing with the fixed loop LASSO® NAV Catheter. This catheter has been submitted to FDA in pending 510(k) K093376.

The CARTO® XP System with CARTOXPRESS™ Module (V10) passed all acceptance criteria in accordance with appropriate test criteria and standards and did not raise any new questions of safety or effectiveness

5.5 OVERALL PERFORMANCE CONCLUSIONS

Bench and Animal Studies demonstrated that the CARTO® XP System with CARTOXPRESS™ Module (V10) is safe and effective for anatomic navigation and mapping of the human heart and is substantially equivalent to two predicate systems, the CARTO® XP EP Navigation System, Version 9, and the CARTO® 3 EP Navigation System, Version 1.0.

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

JUN 18 2010

Biosense Webster, Inc.
c/o Mr. Wayne Hohman
Project Manager Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K093566
Trade/Device Name: CARTO® XP System with CARTOXPRESS™ Module (V10)
Regulation Number: 21 CFR §870.1425
Regulation Name: Programmable Diagnostic Computer.
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 2, 2010
Received: June 4, 2010

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.

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

K093566

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K093566

Device Name: CARTO® XP System with CARTOXPRESS™ Module (V10)

Indications for Use:

The intended use of the CARTO® XP System with CARTOXPRESS™ Module (V10) is catheter-based atrial and ventricular mapping.

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093566

Concurrence of CDRH, Office of Device Evaluation (ODE)