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5 510(K) SUMMARY

MAY - 4 2007

Applicant:

Biosense Webster, Inc.
3333 Diamond Canyon Rd,
Diamond Bar, CA 91765
USA
Phone: +1-800-729-9010
Fax: +1-909-839-8804

Date:

January 24, 2007

Contact Person:

Neelu Medhekar
Manager, Regulatory Affairs

Proprietary Device Name:

CARTO® XP EP Navigation System, Version 9

Common Device Name:
Classification Name:

Cardiac mapping system
Programmable diagnostic computer
(per 21 CFR 870.1425, Product Code DQK)
Class II Device

Predicate Devices:

CARTO® XP EP Navigation System, Version 8
510(k) K042999

Manufacturer:

Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel 39120
Israel

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5.1 SUBSTANTIALLY EQUIVALENT TO

The Biosense Webster, Inc., CARTO® XP EP Navigation System, Version 9, is substantially equivalent to the CARTO® XP EP Navigation System, Version 8, cleared under 510(k) K042999 on March 21, 2005.

5.2 INTENDED USE

The intended use of the CARTO® XP EP Navigation System, Version 9, is catheter-based atrial and ventricular mapping.

The CARTO® XP EP Navigation System, Version 9, 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 display screen.

CARTO® XP EP Navigation System, Version 9, 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 EP Navigation System, Version 9 also allows the integration of intracardiac echo (ICE) visualization to provide 3D combined maps.

5.3 GENERAL DEVICE DESCRIPTION

The CARTO® XP EP Navigation System, Version 9, is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The 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 EP Navigation System, Version 9, includes the following capabilities:

- The CARTOMERGE™ Module, released with the CARTO® XP EP Navigation System, Version 8 under 510(k) K042999. This module enables the integration of pre-acquired Computed Tomography (CT) and Magnetic Resonance (MR) images.
- The new CARTOSOUND™ Image Integration Module. This module, when used on the CARTO® XP EP Navigation System, Version 9, with a SOUNDSTAR™ 3D Ultrasound Catheter (510(k) bundled with the

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CARTO™ XP EP Navigation System Version 9 System submission) enables interfacing with intracardiac ultrasound devices, providing for real-time integration of ultrasound (U/S) images with CARTO electromagnetic acquired maps.

The Biosense Webster SOUNDSTAR 3D™ Ultrasound Catheter is a 90 cm 10F IntraCardiac Echo (ICE) catheter with an acoustic array embedded in the catheter tip that allows the acquisition of real time ultrasound images. The catheter also contains a location sensor that enables the accurate location of the U/S-observed intracardiac anatomies in the CARTO® XP EP Navigation System Version 9 spatial coordinates.

5.4 PERFORMANCE DATA AND CONCLUSION

The CARTO® XP EP Navigation System, Version 9, 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 did not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2007

Biosense Webster
c/o Neelu Medhekar
Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K070240
Trade/Device Name: Carto XP EP Navigation System, Version 9
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: April 6, 2007
Received: April 9, 2007

Dear Mr. Medhekar:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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4 INDICATIONS FOR USE STATEMENT

510(k) No (if known): K070240

Device Name: CARTO® XP EP Navigation System, Version 9

Indications for Use:

The intended use of the CARTO® XP EP Navigation System, Version 9 is catheter-based atrial and ventricular mapping.

The CARTO® XP EP Navigation System, Version 9 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 display screen.

CARTO® XP EP Navigation System, Version 9 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 EP Navigation System, Version 9 also allows the integration of intracardiac echo (ICE) visualization to provide 3D combined maps.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ 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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Donna R. Volkmann

(Division Sign-Off)
Division of Cardiovascular Devices

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