SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765
OFFICIAL CORRESPONDENT	Diana Thorson Director, Regulatory Affairs Tel: (800)-729-9010 Fax: (909) 839-8804
TRADE NAME	CARTO™ RMT EP Navigation System v8
COMMON NAME	Cardiac mapping system
DEVICE CLASSIFICATION	Class II, 21 CFR § 870.1425 Programmable diagnostic computer
PRODUCT CODES	DQK - Programmable diagnostic computer
PREDICATE DEVICE	CARTO™ RMT EP Navigation System v8
MANUFACTURER	Biosense Webster (Israel), Ltd. POB 2009 Tirat HaCarmel 39120 Israel

OCT - 1 2009

SUBSTANTIALLY EQUIVALENT TO:

The CARTO™ RMT EP Navigation System v8 is substantially equivalent in design and intended use to the CARTO™ RMT EP Navigation System v8 (K060047). The indications for use have been expanded to include operation in magnetic environments of up to 0.1 Tesla.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CARTO™ RMT EP Navigation System v8 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,

SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.

The CARTO™ RMT System v8 enables cardiac mapping using CARTO™ RMT compatible catheters utilizing the magnetic navigation capabilities of the Stereotaxis Niobe Systems. In this way the system seamlessly combines the benefits of cardiac 3D mapping with remote catheter navigation and may further reduce the hospital staff exposure to dangerous ionizing radiation.

The CARTO™ RMT EP Navigation System v8 includes the CARTOMERGE™ module. The CARTOMERGE module provides for the import, visualization and processing of pre-acquired cardiac images. These images are then registered and superimposed to the CARTO RMT EP maps. CARTOMERGE supports import of Computed Tomography (CT) and Magnetic Resonance (MRI) images in DICOM format.

INDICATIONS FOR USE:

The CARTO™ RMT EP Navigation System v8 is intended to acquire real time catheter based cardiac electrophysiological maps in patients who are eligible for a conventional electrophysiological study. The CARTO™ RMT EP Navigation System v8 is restricted for use by licensed medical practitioners who participate in a CARTO™ training course. There are no special contraindications when using the CARTO™ RMT EP Navigation System v8.

TECHNICAL CHARACTERISTICS:

The CARTO™ RMT EP Navigation System v8 is a programmable diagnostic computer.

PERFORMANCE DATA:

Bench testing confirms that the Carto™ RMT EP Navigation System v8 can be used according to its intended use.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and bench testing demonstrates that the CARTO™ RMT EP NAVIGATION SYSTEM V8 is substantially equivalent to the predicate device.

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. Diana Thorson
Director, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

OCT - 1 2009

Re: K091789
Trade/Device Name: Carto RMT EP Navigation System, v8
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 3, 2009
Received: September 4, 2009

Dear Ms. Thorson:

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) Number (if known): K091789

Device Name: CARTO™ RMT EP Navigation System v8

Indications for Use:

The intended use of the CARTO™ RMT EP Navigation System v8 is catheter-based atrial and ventricular mapping.

The CARTO RMT System v8 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.

The CARTO RMT System v8 is intended to support EP procedures in the presence of the high metallic environment presented by the NIOBE 1 (PM3.0) and NIOBE 2 (PM3.1 and PM3.2) Stereotaxis Magnetic Navigation Systems (MNS) in magnetic environments of up to 0.1 Tesla.

Although the CARTO™ RMT system requires the use of a magnetic steerable catheter, i.e. the NAVISTAR RMT, when used in conjunction with the Stereotaxis Niobe MNS, it also enables the use of the standard NAVISTAR and QWIKSTAR catheters when the Stereotaxis magnets are stowed away or when used in a conventional EP lab, maintaining full CARTO™ XP capabilities.

CARTO RMT System v8 includes the CARTOMERGE™ capability to import, register and merge CT or MRI structural images with CARTO maps physiological information and real time catheter navigation.

Prescription Use __x____ (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)

(Division Sign-Off)
Division of Cardiovascular Devices

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510(k) Number K091789