JUN 19 2006

K060047

# 5. 510(K) SUMMARY

**510(k) Summary for the CARTO™ RMT EP Navigation System v8**

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| 510(k) Notification Submitted by: | Biosense Webster, Inc.<br>3333 Diamond Canyon Rd.<br>Diamond Bar, CA 91765<br>USA<br>Phone: +1-800-729-9010<br>Fax: +1-909-839-8804 |
| Contact Person: | Diana Thorson<br>Manager, Regulatory Affairs |
| Proprietary Device Name: | CARTO™ RMT EP Navigation System v8 |
| Classification Name: | Programmable diagnostic computer<br>(per 21 CFR 870.1425) |
| Common Device Name: | Cardiac mapping system |
| Predicate Devices: | 1. CARTO™ XP EP Navigation System v8<br>2. CARTO™ RMT EP Navigation System v7 |
| Manufacturer: | Biosense Webster (Israel) Ltd.<br>POB 2009<br>Tirat HaCarmel, 39120<br>Israel |

## Intended Use

The CARTO™ RMT EP Navigation System v8 is intended to acquire real time catheter based cardiac electrophysiogical 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.

## General Device Description

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

In the conventional procedure both the patient and the physician are exposed to X-Ray radiation during the course of the procedure. 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.

The non-clinical bench tests and the location accuracy tests performed under the Niobe environment show that the device is as safe and as effective as the previously marketed devices to which it is being compared and does 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

JUN 19 2006

Ms. Diana M. Thorson
Acting Director, Regulatory Affairs
Biosense Webster, Inc.
3333 Diamond Canyon Rd
Diamond Bar, CA 91765

Re: K060047
Trade/Device Name: CARTO™ RMT EP Navigation System v8
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: II (two)
Product Code: DRF
Dated: May 18, 2006
Received: June 2, 2006

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 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 (see bottom for #s). 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,

B Zuckerman 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):** K060047

**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 0.08 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.

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| Prescription Use<br>(Part 21 CFR 801 Subpart D) | X | AND/OR | Over-The-Counter Use<br>(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)

Page 1_ of _1_

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060047