K042681

SEP 29 2005

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# C. 510(K) SUMMARY

The 510(k) summary for the CARTO RMT Mapping System is provided below.

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

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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 M. Thorson<br>Project Manager, Regulatory Affairs |
| Proprietary Device Name: | CARTO™ RMT EP Navigation System |
| Classification Name: | Programmable diagnostic computer<br>(per 21 CFR 870.1425) |
| Common Device Name: | Cardiac mapping system |
| Predicate Device: | CARTO™ XP QWIKMAP EP Navigation System |
| Manufacturer: | Biosense Webster (Israel) Ltd.<br>POB 2009<br>Tirat HaCarmel, 39120<br>Israel |

**Indications For Use**

The CARTO™ RMT EP Navigation System 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 is restricted for use by licensed medical practitioner who participated in a CARTO™ training course. There are no special contraindications when using the CARTO™ RMT EP Navigation System.

**General Device Description**

The CARTO™ RMT EP Navigation system 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 locations. Maps may be displayed as electrical activation maps, electrical propagation maps, electrical potential 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 ionizing radiation during the course of the procedure. The CARTO™ RMT mapping system enables cardiac mapping using CARTO™ RMT compatible catheters utilizing the enhanced magnetic navigation capabilities of the Stereotaxis Magnetic Navigation System (remote catheter navigation). In this way the system seamlessly combines the benefits of cardiac 3D mapping with remote catheter navigation and may further reduce the exposure to dangerous ionizing radiation.

The CARTO™ RMT EP Navigation System complies with the following safety standards:
UL 2601-1:97/CSA C22.2 NO.601.1
IEC 60601-2-25:93 and Al(99)
IEC 60601-2-27:94

The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed device 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

SEP 29 2005

Biosense Webster, Inc.
c/o Ms. Diana M. Thorson
Project Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K042681
Trade Name: CARTO™ RMT EP Navigation System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: September 1, 2005
Received: September 2, 2005

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.

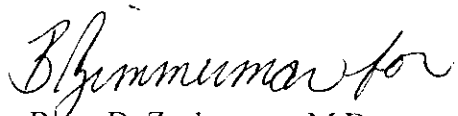
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0295. 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 (301) 443-6597 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

# D. INDICATIONS FOR USE STATEMENT

**510(k) No (if known):** K042681

**Device Name:** CARTO™ RMT EP Navigation System

**Indication for Use:**

The intended use of the CARTO™ RMT mapping system is catheter-based atrial and ventricular mapping.

The CARTO XP RMT mapping system 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, and cardiac chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed on the Stereotaxis Magnetic Navigation System in real time on the display screen.

The CARTO™ RMT System is intended to support EP procedures in the presence of the high metallic environment created by the Stereotaxis Magnetic Navigation System, as well as in a regular EP lab.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042681