SEP 29 2005

K042998

11. Summary of Safety and Efficacy

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 phone: (800) 729-9010 fax: (909) 839-8804
Trade Name:	RefStar RMT External Reference Patch
Common Name:	Surface Reference Device
Classification Name:	Electrode Recording Catheter
Device Classification:	Class II, 21 CFR §870.1220
Product Code	74 DRF
Predicate Device:	The RefStar RMT is substantially equivalent to the Cordis-Webster RefStar™ External Surface Reference Device, cleared for marketing under K980961.

Substantially Equivalent To:

The Biosense Webster, Inc. RefStar RMT External Reference Patch is substantially equivalent to the Cordis-Webster RefStar™ External Surface Reference Device, (cleared under K980961).

Description of the Device Subject to Premarket Notification:

The RefStar RMT is an external reference catheter designed to be placed on the patient's back in order to compensate for movement during electrophysiology mapping of the heart.

Indication for Use:

The RefStar™ RMT is indicated for use with the NAVI-STAR™ RMT catheter and the CARTO™ RMT system to provide catheter tip location as well as electrogram information.

TECHNICAL CHARACTERISTICS:

The back of the distal end of the RefStar RMT External Reference Patch has an adhesive backing, designed to be placed externally on the patient's back. The catheter contains a location sensor, that, when used together with the CARTO RMT system and the , NAVISTAR RMT Catheter provides catheter tip location information to construct a 3D electrophysiological maps of the human heart in the Stereotaxis Magnetic Navigation System magnetic field (K013484 and K021555) in real-time.

PERFORMANCE DATA:

The RefStar RMT was tested under simulated use conditions, and complies with multiple external electrical and performance standards.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The Biosense Webster, Inc. RefStar RMT External Reference Patch is substantially equivalent to the Cordis-Webster RefStar™ External Surface Reference Device, cleared for marketing under K980961. The indication for use is the same for both devices. The catheters meet the same design requirements and have similar technological characteristics. Bench testing demonstrates that the devices are functionally equivalent.

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 Mr. Mark O'Donnell
Director, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K042998
Trade Name: RefStar RMT External Reference Patch
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: September 1, 2005
Received: September 2, 2005

Dear Mr. O'Donnell:

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.

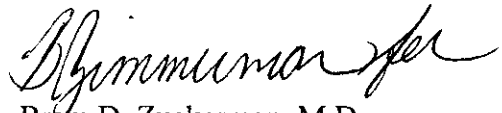
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

4. INDICATIONS FOR USE

510(k) Number (if known): K042998

Device Name: REFSTAR™ RMT External Reference Patch

Indications for Use:

The RefStar™ RMT External Reference Patch is indicated for use with the NAVI-STAR™ RMT catheter and the CARTO™ RMT system to provide catheter tip location as well as electrogram information.

Prescription Use _x_ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042998