SEP 2 9 2005

K052083 Page 1 of 2

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: NaviStar RMT Steerable Tip Diagnostic Catheter

COMMON NAME: Steerable Diagnostic EP Catheter

CLASSIFICATION NAME: Electrode Recording Catheter / Steerable Catheter

DEVICE CLASSIFICATION: Class II. 21 CFR §870.1220 and §870.1280

PRODUCT CODE: 74 DRF/DRA

PREDICATE DEVICE:
The NaviStar RMT Diagnostic Steerable Tip Catheter is substantially equivalent to the Biosense Webster STAR Catheter, cleared for marketing under K954390.

SUBSTANTIALLY EQUIVALENT TO:

The Biosense Webster, Inc. NaviStar RMT 7Fr, 4mm Steerable Tip Diagnostic Catheter is substantially equivalent to the Biosense Webster NaviStar Diagnostic Catheter, (cleared under K954390).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The NaviStar RMT Steerable Tip Diagnostic Catheter, is a 7 Fr 4mm, magnetically deflectable diagnostic catheter used in the magnetic field for catheter-based atrial and ventricular electrophysiological mapping in adults and children four (4) years of age and older.

INDICATION FOR USE:

The NAVISTAR™ RMT Steerable Tip Diagnostic Catheter, and related accessory devices are indicated for catheter-based atrial and ventricular electrophysiological mapping in adults and children four (4) years of age and older.

When used with the CARTO™ RMT EP Navigation System, the NAVISTAR™ RMT Steerable Tip Diagnostic Catheter provides location information.

TECHNICAL CHARACTERISTICS:

The NAVISTAR™ RMT Steerable Tip Diagnostic Catheter is a 7 Fr 4mm, magnetically steerable diagnostic catheter. The catheter contains a location sensor, that, when used together with the CARTO RMT system, provides location information to construct a 3D electroanatomical maps of the human heart in real-time. The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum irridium electrodes that can be used for stimulation and recording. The tip can be deflected in multiple planes.

PERFORMANCE DATA:

The NAVISTAR™ RMT Steerable Tip Diagnostic Catheter 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. NaviStar™ RMT 7Fr, 4mm Steerable Tip Diagnostic Catheter is substantially equivalent to the Biosense Webster NaviStar Diagnostic Catheter, (cleared under K954390). The indication for use is identical for both devices. The catheters meet the same design requirements and have similar technological characteristics. Bench and animal 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 2 9 2005

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

Re: K052083
Trade Name: NaviStar RMT Steerable Tip Diagnostic Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: July 29, 2005
Received: August 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.

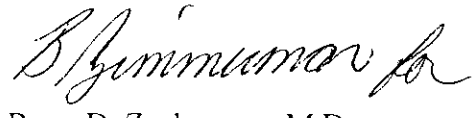
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K052083

510(k) Number (if known): _____

Device Name: NAVISTAR™ RMT Diagnostic Steerable Tip Catheter

Indications for Use:

The NAVISTAR™ RMT Steerable Tip Diagnostic Catheter and related accessory devices are indicated for catheter-based atrial and ventricular electrophysiological mapping in adults and children four (4) years of age and older. This catheter is only compatible with the Stereotaxis Magnetic Navigation Systems (MNS).

When used with the CARTO™ RMT EP Navigation System, the NAVISTAR™ RMT Steerable Tip Diagnostic Catheter provides location 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052083