# 13 510(k) Summary

## 13.1 SPONSOR'S NAME & ADDRESS

AUG 14 2006

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

## 13.2 OFFICIAL CORRESPONDENT

Natalie Bennington
Project Manager, Regulatory Affairs
Phone: 909-839-7272
Fax: 909-839-8804
Email: nbenning@bwius.jnj.com

## 13.3 SUBMISSION DATE

May 26, 2006

## 13.4 TRADE NAME

RefStar External Reference Patch

## 13.5 COMMON NAME

Surface Reference Device

## 13.6 CLASSIFICATION NAME

Electrode Recording Catheter

## 13.7 CLASSIFICATION

Class II

## 13.8 PREDICATE DEVICE

RefStar External Reference Device, K982415, August 10, 1998

## 13.9 DESCRIPTION OF DEVICE

The Biosense Webster RefStar External Reference Patch is an integral part of a non-fluoroscopic catheter tip location and electrogram capture technology called CARTO and NOGA. When used with the CARTO and NOGA systems, the location of the navigation catheter tip is compared to the location of this reference patch. This reference device consists of a sensor embedded in an adhesive patch, which is connected to a handle that houses the printed circuit board.

## 13.10 INTENDED USE

The intended use of the RefStar External Reference Device is to provide a reference location relative to the mapping/diagnostic catheter when used in conjunction with the CARTO and NOGA equipment.

## 13.11 INDICATIONS FOR USE

The Biosense Webster RefStar External Reference Patch is indicated for use with Biosense Webster navigation catheters and the CARTO and NOGA Systems to provide a reference point for catheter tip location.

## 13.12 DESCRIPTION OF MODIFICATION

The modified RefStar External Reference Device is physically ***identical*** to the predicate device in terms of design, manufacturing methods, materials and performance. There are absolutely no changes to the device what so ever. The only modification is to the labeling for the device to indicate that the device is indicated for use with Biosense Webster navigation catheters, specifically adding the use of the EsophaStar Esophageal Mapping Catheter.

## 13.13 SUMMARY OF NONCLINICAL TESTS

All testing previously submitted for the RefStar External Reference Patch still applies to the modified device as there were no changes to the design, materials, manufacturing methods or performance of the device. Therefore, no additional testing is submitted in this Premarket Notification.

## 13.14 SUBSTANTIAL EQUIVALENCE

The modified RefStar External Reference Device is identical to the previously cleared RefStar External Reference Device in that the devices:

- have the same intended use,
- use the same operating principle,
- use the same fundamental scientific technology,
- incorporate the same design,
- incorporate the same materials and construction,
- have the same shelf life, and
- are packaged using the same materials and processes.

In summary, the RefStar External Reference Device described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2006

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

Re: K061468
Trade/Device Name: Refstar External Reference Patch
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: DRF
Dated: May 26, 2006
Received: May 26, 2006

Dear Ms. Bennington:

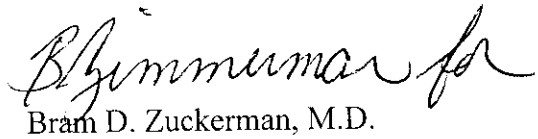
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 6 Indications for Use

**510(k) No (if known):** K061468

**Device Name:** RefStar™ External Reference Patch

**Indications for Use:**

The Biosense Webster RefStar External Reference Patch is indicated for use with Biosense Webster navigation catheters and the CARTO and NOGA Systems to provide a reference point for catheter tip location.

Prescription Use √ (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)



510(k) Number K061468

Division of Cardiovascular Devices
(Division Sign-Off)