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K093376

5. 510(k) Summary

Applicant:
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765 USA
Telephone: 800-729-8597
Fax: 909-839-8804

JUN 18 2010

Date:
October 27, 2009

Contact Person:
Wayne R. Hohman
Project Manager Regulatory Affairs

Trade or Proprietary Name:
LASSO® NAV Catheter

Common or Usual Name of Device:
Electrophysiological Mapping Catheter

Classification Name:
Electrode Recording Catheter
(per 21 CFR 870.1220; Product Code: DRF)

Predicate Devices:
LASSO® Deflectable Circular Mapping Catheter
510(k) K002333

LASSO® 2515 NAV Variable Circular Mapping Catheter
510(k) K081258

Manufacturer:
Biosense Webster
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Manufacturing Sites:
Biosense Webster, Inc
15715 Arrow Highway
Irwindale, CA 91706

Biosense Webster, Inc.
Cordis de Mexico
Circuito Interior Norte #1820
Parque Industrial Salvarcar 32599
Juarez, Chihuahua, Mexico

Sterilization Site:
Steris Isomedix
7685 St. Andrews Avenue
San Diego, CA 92154

5.1 Substantially Equivalent To:

The Biosense Webster LASSO® NAV Catheter is substantially equivalent to the Biosense Webster LASSO® Deflectable Circular Mapping Catheter (510(k) K002333 cleared August 31, 2000) and the Biosense Webster LASSO® 2515 NAV Variable Circular Mapping Catheter (510(k) K081258, cleared January 6, 2009).

5.2 Description of the Device Subject to Premarket Notification:

The LASSO® NAV Catheter has been designed to facilitate electrophysiological mapping of the atria of the human heart. It is deployed in the right or left atrium through an 8 Fr guiding sheath. This deflectable catheter consists of a 4.5 Fr circular spine on its distal tip with platinum/iridium electrodes that can be used for stimulation and recording. The purpose of this Premarket Notification is to add location sensors to provide location/visualization when used with CARTO Electrophysiological (EP) Navigation Systems and a reference device.

The LASSO® NAV Catheter will be manufactured in three fixed loop sizes (15, 20, and 25 mm loop diameters) designed to diagnose veins with different sizes. There will be10 or 20 ring electrodes available on each of the three loop sizes for a total of six new models.

The proposed catheter will interface with standard recording equipment via interface cables with appropriate connectors.

5.3 Indications for Use:

The LASSO® NAV Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. This catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® NAV Catheter provides location information when used with compatible CARTO EP Navigation Systems.

5.4 Performance Data:

The LASSO® NAV Catheter was subjected to extensive Bench and Animal Testing. This catheter passed all intended criteria in accordance with appropriate standards and test criteria.

5.5 Overall Performance Conclusions:

The nonclinical studies demonstrated that the LASSO® NAV Catheter with location sensors is safe and effective for anatomic mapping of the human heart and established equivalence to the predicate devices, the LASSO® Deflectable Circular Mapping Catheter and the LASSO® 2515 NAV Variable Circular Mapping Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Biosense Webster, Inc.
c/o Mr. Wayne R. Hohman
Project Manager, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765-8597

Re: K093376
Trade/Device Name: Lasso NAV Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: June 17, 2010
Received: June 18, 2010

Dear Mr. Hohman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

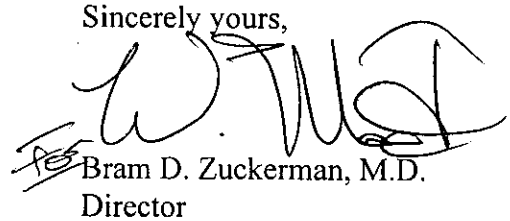
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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): K093376

Device Name: LASSO® NAV Catheter

Indications for Use:
The LASSO® NAV Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. This catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® NAV Catheter provides location information when used with compatible CARTO EP Navigation Systems.

Prescription Use √ AND/OR Over-The-Counter Use
(Part 2 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093376