K090898

SEP 04 2009

## 510(K) SUMMARY

**Applicant:**

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765,
USA
Phone: 800-839-8599
Fax: 909-839-8804

**Date:**

September 2, 2009

**Contact Person:**

Natalie Bennington, Regulatory Affairs Manager

**Proprietary Device Name / Manufacturing Part Number:**

- Coronary Sinus Deflectable Mapping Catheters (D-1263-01-S & D-1263-02-S)
- Webster CS Catheter with EZ Steer Technology (D-1263-04-S & D-1263-05-S)
- Webster CS Catheter with EZ Steer Technology and Auto ID (D-1263-06-S & D-1263-07-S)

**Common Device Name:**

Electrophysiology Mapping Catheter

**Classification Name:**

Electrode Recording Catheter (per 21 CFR 870.1220, Product code DRF)

**Predicate Device:**

Biosense Webster Coronary Sinus Deflectable Mapping Catheters (D-1263-01-S & D-1263-02-S), originally cleared via 510(k) K050877 on June 24, 2005.

**Manufacturing Facilities:**

- Biosense Webster, Inc.
  Circuito Interior Norte #1820
  Parque Industrial Salvacar
  Juarez, Chihuahua Mexico, Mexico
  32599

- Biosense Webster, Inc.
  15715 Arrow Highway
  Irwindale, CA 91706

**Device Description**

**The Webster Coronary Sinus Catheter (D-1263-01-S & D-1263-02-S)**

The Coronary Sinus Deflectable Mapping Catheters (D-1263-01-S & D-1263-02-S) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-5-2 mm or 2-8-2 mm electrode spacing, have uni-directional deflection with an MZ curve, and are 115 cm long. The catheters include a handle with a thumb knob, which allows deflection of the distal end of the catheter. The handle also has a 10-pin connector for interfacing to a recording system though a standard catheter cable. The braided, bendable/conformable shaft allows torque and contact force to be transmitted from the handle to the distal end. The distal tip is unbraided and soft. These two predicate models are identical except that the electrode spacing is 2-5-2 mm for D-1263-01-S and 2-8-2 mm for D-1263-02-S. The following cables are used to provide a means for interface of the catheters with the appropriate equipment:

- D-1221-21-S
- D-1221-26-S
- D-1221-25-S

**The Webster Coronary Sinus Catheter with EZ Steer Technology (D-1263-04-S & D-1263-05-S)**

The Webster CS Catheters with EZ Steer Technology (D-1263-04-S & D-1263-05-S) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bi-directional deflection and are 115 cm long. These

catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180° opposed single plane curves. Currently, the available curves for the Webster CS Catheters with EZ Steer Technology include FJ (D-1263-04-S) and DF (D-1263-05-S). These catheters include a handle with a Rocker Lever, which is used to deflect the tip. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. The following cables are used to provide a means for interface of the catheters with the appropriate equipment:

- D-1221-21-S
- D-1221-25-S
- D-1221-26-S

**The Webster Coronary Sinus Catheter with EZ Steer Technology (D-1263-06-S & D-1263-07-S)**

The Webster CS Catheters with EZ Steer Technology (D-1263-06-S & D-1263-07-S) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bi-directional deflection and are 115 cm long. These catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180° opposed single plane curves. Currently, the available curves for the modified Webster CS Catheters include FJ (D-1263-06-S) and DF (D-1263-07-S). These catheters include a handle with a Rocker Lever which is used to deflect the tip. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. The catheters are equipped with Electronically Erasable Programable Read Only Memory (EEPROM) which is used to store unique catheter identification information. Carto EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information.

The catheters interface with Carto EP Navigation Systems via an interface cable (D-1286-16-S) with the appropriate connectors.

**Indications for Use**

The Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

**Summary of Testing**

The Webster CS Catheters have been subjected to performance testing to validate the integrity of the catheters and the performance of the catheters with the ancillary equipment.

**Substantial Equivalence**

The Webster CS Catheters (D-1263-01-S, D-1263-02-S, D-1263-04-S, D-1263-05-S, D-1263-06-S & D-1263-07-S) are substantially equivalent to the Biosense Webster Coronary Sinus Deflectable Mapping Catheters (D-1263-01 & D-1263-02), originally cleared via 510(k) K050877 on June 24, 2005.

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

SEP 04 2009

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

Re: K090898
Trade/Device Name:
- Webster CS Catheter (D-1263-01-S and D-1263-02-S);
- Webster CS Catheter with EZ Steer Technology (D-1263-04-S and D-1263-05-S); and
- Webster CS Catheter with EZ Steer Technology and Auto ID (D-1263-06-S and D-1263-07-S).

Regulatory Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (Two)
Product Code: DRF
Dated: July 28, 2009
Received: August 5, 2009

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.

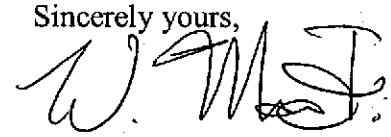
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

## INDICATIONS FOR USE

**510(k) No (if known):** K090898

**Device Name:**

- Webster CS Catheter
  D-1263-01-S
  D-1263-02-S

- Webster CS Catheter with EZ Steer Technology
  D-1263-04-S
  D-1263-05-S

- Webster CS Catheter with EZ Steer Technology and Auto ID
  D-1263-06-S
  D-1263-07-S

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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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090898