K050217

MAR 3 0 2005

1/2

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Applicant:

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765 USA
Tel.: 800-729-9010
Fax: 909-839-8804

Date:_____

Contact: Wayne R. Hohman

Trade (Propreitary)Name: Flower High-Density Mapping Catheter

Common Name: Electrophysiological mapping catheter

Classification Name: Electrode recording catheter or electrode recording probe

Device Classification: Class II, 21 CFR 870.1220

Product Code: D-1245-01, D-1245-02

Equivalent Devices:

K002333	Lasso™ Deflectable Circular Mapping Catheter, Biosense Webster, Inc.
K021232	Constellation® Multiple Electrode Recording and Pacing Catheters System, Boston Scientific Corp. (EPT)
K011361	Desai VectoCath™ Mapping Catheter, CathEffects, LLC
K982740	Preface Guiding Sheath (Braided), Biosense Webster, Inc.

Substantially Equivalent To:

The Flower High-Density Mapping Catheter is substantially equivalent to the Lasso™ Deflectable Circular Mapping Catheter (Biosense Webster, Inc., K002333), Constellation® Multiple Electrode Recording and Pacing Catheters System (Boston Scientific Corp. (EPT), K021232), Desai VectoCath™ Mapping Catheter (CathEffects, LLC., K982740), and Preface Guiding Sheath (due to possessing a central lumen for heparinized saline).

Description of the Device Subject to Premarket Notification:

The Flower High-Density Mapping Catheter is a 7 Fr diagnostic, multi-electrode electrophysiological mapping catheter designed for diagnostic electrogram recording and

pacing in the heart. It has a unique distal multi-spine array of five 3 Fr 1.5 cm long spines, each containing four platinum ring electrodes for a total of 20 electrodes. Model D-1245-01 has the electrodes evenly spaced 4 mm apart on all spines, whereas Model D-1245-02 has the electrodes spaced 2, 6, and then 2 mm apart on each spine. The spines are pressed against the heart endocardium where they open into a star-like pattern that presents the 20 multiple electrodes in a two-dimensional array. This configuration of electrodes maps areas of the heart endocardium to detect various arrhythmias. A tube with a Luer connector on the proximal end provides an open lumen along the entire length of the catheter for continuous delivery of anticoagulation fluid. The catheter is controlled by a handle at the proximal end that advances or retracts the catheter, torques the catheter, and/or deflects the catheter to optimize positioning of the multi-spined tip. The catheter is connected to appropriate recording equipment.

Indications for Use:

The Biosense Webster Flower High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

Technical Characteristics:

The Flower High-Density Mapping Catheter is a typical electrophysiological catheter that is unique only in its geometrical arrangement of 20 ring electrodes on five individual spines at its distal tip. Otherwise, there are no special technical aspects of the ability of this catheter to detect electrical signals from heart endocardium and transmit this information to recording equipment for display, analysis, and interpretation in detection of various heart arrhythmias.

Performance Data:

The Flower High-Density Mapping Catheter underwent bench testing and was tested under simulated use conditions in animals and it passed all intended criteria in accordance with appropriate test criteria and standards. In addition, this catheter has been successfully evaluated in over 80 clinical cases in humans to date with no reports of patient injury or death.

Basis for Determination of Substantial Equivalence:

The Flower High-Density Mapping Catheter is substantially equivalent to other diagnostic mapping catheters such as the Biosense Webster Lasso Catheter (K002333), Boston Scientific's Constellation Multiple Electrode Recording Catheters (K021232), and CathEffects Desai VectoCath™ Mapping Catheter (K982740). The Preface Sheath was included as an example of an existing device that has a central lumen for irrigation of anti-thrombotic fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2005

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

Re: K050217
Trade Name: Flower high-density mapping catheter, models D-1245-01 and D-1245-02
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II (two)
Product Code: MTD
Dated: January 27, 2005
Received: January 31, 2005

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.

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K050217

Device Name: Flower High-Density Mapping Catheter

Indication for Use:

The Biosense Webster Flower High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

Contraindications:

- The Biosense Webster Flower High-Density Mapping Catheter has not been shown to be safe and effective for radiofrequency (RF) ablation.
- Use of this catheter may not be appropriate for use in patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.
- The transseptal approach in contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)

K050217 B Zimmerman

vision Sign-Off)
vision of Cardiovascular Devices
510(k) Number _____