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Biosense Webster
a Johnson & Johnson company

510(k) Summary for the LASSO™ 2515 Variable Circular Mapping Catheter

510(k) Notification submitted by:	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765 USA Phone: +1-800-729-9010 Fax: +1-909-839-8804
Contact person:	William Welch Regulatory Affairs Project Manager
Proprietary device name:	LASSO 2515 Mapping Catheter
Classification name:	Electrode Recording Catheter (per 21 CFR 870.1220)
Common device name:	Deflectable Electrophysiologic Mapping Catheter
Predicate device:	LASSO Deflectable Circular Mapping Catheter 510(k) No. K002333
Manufacturer:	Biosense Webster Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765

Overview

The LASSO 2515 Variable mapping catheter when used in conjunction with electrophysiological pacing and recording equipment is designed to acquire, analyze and display electrical activity in the human heart. In particular the device is targeted for use in the atrial chambers of the heart and is particularly well-suited for placement in or near the pulmonary veins in the left atrium. The catheter transmits electrical pulses from the pacing equipment and intracardiac electrical signals to the recording equipment for display as electrograms (ECG traces). Trained physicians interpret the electrograms in diagnosing cardiac arrhythmias.

Design

The Variable LASSO™ 2515 electrophysiologic mapping catheter now incorporates a tip with a variable radius mechanism that allows selection of radii in a range from 15 –25 mm. The LASSO predicate device cleared in K002333 is marketed with fixed radii of 10, 15, 20 and 25 mm. The subject device will allow the user to select a continuum of radii from 10- 25 mm. To facilitate user selection of this range of radii, design changes were

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required in the handle of the catheter. The Variable Lasso handle mechanism now has two independently operating deflecting mechanisms that control tip deflection and circular spine expansion and contraction. Tip deflection is controlled with a thumbknob attached to the distal end of a piston mechanism enclosed in the handle barrel. The spine contraction and expansion mechanism is also controlled by the movement of a puller wire attached to a cam assembly mechanism in the catheter handle that when rotated either contracts or expands the distal loop in a diameter range from 15 to 25 mm.

Testing

Various non - clinical bench tests were conducted to verify conformance of Variable Lasso catheter to design and performance specifications. Mechanical, dimensional, and reliability tests were performed and all requirements were met prior to submission of the 510k. No new questions of safety and effectiveness were raised as a result of these tests.

Biocompatibility and sterilization validation testing were not repeated since patient - contact materials identical to the predicate device are used and since the described design changes do not affect the ability to sterilize the product.

Indications and Contraindications for Use

The intended use of this device is identical to the predicate Lasso device, namely:

The catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording and stimulation only. The LASSO 2515 Variable Circular Mapping catheter is designed to obtain electrograms in the atrial regions of the heart.

Contraindications – No new contraindications have been introduced as a result of implementing the design changes necessary to operate a Variable Lasso catheter.

Packaging and Shelf Life

The catheter is packaged in a thermoformed tray and sealed in a nylon/Tyvek breather pouch. The pouch is placed in a preprinted unit box, labeled, and with other units, is placed in an outer shipping box prior to sterilization. Testing has been conducted to establish the expiration date of the product which is printed on the pouch and unit box labels as a "Use By" date.

Risks

An additional risk to patient safety involves failure of the handle rotation mechanism and associated components which may require the catheter to be replaced with another catheter. This is a standard practice for any catheter when one or more performance features of the catheter are compromised and thus this is not viewed as a new risk but

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instead an additional cause for the risk. All risks have been mitigated by appropriate means.

Summary of Substantial Equivalence

The design differences between the Variable Lasso 2515 and Lasso predicate device do not raise new questions of safety and effectiveness. The devices use the same fundamental technology, energy source, patient contact materials, and have the same the intended use as the predicate device. Finally, verification testing has raised no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Biosense Webster, Inc.
c/o Mr. William Welch
Regulatory Affairs Project Manager
3333 Diamond Canyon Road
Diamond Bar, CA 92128

Re: K031161
Trade Name: Lasso 2515 Variable Circular Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: July 17, 2003
Received: July 18, 2003

Dear Mr. Welch:

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) 594-4646. 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

Indications for Use Statement

K031161

510(k) No: ____Unknown_____

Device Name: Variable LASSO™ 2515 Circular Mapping Catheter

Indications For Use:

The catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording and stimulation only. The LASSO 2515 Variable Circular Mapping catheter is designed to obtain electrograms in the atrial regions of the heart.

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices

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