K061046
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510(k) Summary

A. Submitter's Information

Submitter's Name: CardioMEMS, Inc.
Submitter's Address: 75 Fifth St, NW
Suite 440
Atlanta, GA 30308

OCT 12 2006

Contact Person: Carol Vierling
Telephone Number: (404) 920-6712
Fax Number: (404) 885-9974

Date of Preparation: October 3, 2006

B. Trade Name: CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System

Common Name: Pressure Sensor System

Classification Name: Implantable Intra-aneurysm Pressure Measurement System

C. Predicate Devices: CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System

D. Device Description

The CardioMEMS *EndoSure* Wireless AAA Pressure Measurement System is designed to monitor pressure within the sac of a repaired aneurysm during endovascular stent graft placement. The CardioMEMS *EndoSure* Wireless AAA Pressure Measurement System includes:

- The CardioMEMS *EndoSure* Sensor with radio-opaque markings (implant)
- A sterile Delivery System (pre-loaded with the CardioMEMS *EndoSure* Sensor)
- CardioMEMS *EndoSure* Interrogator

E. Intended Use:

The CardioMEMS EndoSure Wireless AAA Pressure Measurement System is intended for measuring intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair. It may be used as an adjunctive tool in the detection of intraoperative endoleaks.

F. Technological Characteristics Summary

The *EndoSure* Sensor is implanted in the AAA sac during the time of stent graft deployment and is left in place in the excluded portion of the aneurysm as a permanent implant. The main body of the *EndoSure* Sensor is manufactured from fused silica coated in silicone. A nitinol basket surrounds the *EndoSure* Sensor body. Radiopaque marker bands at each end of the *EndoSure* Sensor body allow visualization of the device under fluoroscopy.

Coils inside the *EndoSure* Sensor are aligned in such a way to form a capacitor (defined as an electric circuit element used to store charge temporarily, consisting in general of two metallic plates separated and insulated from each other by a dielectric). At the same time, two metal spirals form an inductor component of a miniature electrical circuit (LC circuit). It is possible to magnetically couple to the *EndoSure* Sensor and induce a current in the circuit. This allows for wireless communication with the device and the ability to operate it without the need for an internal source of energy such as a battery. Thus, if the *EndoSure* Sensor is located within the sac of an aortic aneurysm, the pressure within the sac can be determined in a simple, noninvasive procedure by remotely interrogating the *EndoSure* Sensor, recording the resonant frequency and converting this value to a pressure measurement.

The *EndoSure* Sensor is interrogated using the antenna of the *EndoSure* Interrogator. The antenna is placed over the patient's abdomen in the area of the *EndoSure* Sensor. Once the signal is acquired, a pressure waveform and numerical pressure data are displayed on the touch-screen. A printout of the data and waveform is generated from a thermal printer which is incorporated in the *EndoSure* Interrogator.

G. Performance Data

Testing has shown the *EndoSure* Wireless AAA Pressure Measurement System to be biocompatible, MRI safe, as well as compatible with ultrasound, pacemakers and defibrillators. Bench and clinical testing confirm that the device functions per its specifications and 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

OCT 12 2006

Ms. Carol Vierling
Vice President, Regulatory and Clinical Affairs
Cardiomems, Inc.
75 Fifth St., NW, Suite 440
Atlanta, GA 30308

Re: K061046
Trade/Device Name: CardioMEMS EndoSure AAA Pressure Measurement System
Regulation Number: 21 CFR 870.2855
Regulation Name: Implantable Aneurysm Pressure Sensor
Regulatory Class: Class II (Two)
Product Code: NQH
Dated: August 2, 2006
Received: August 4, 2006

Dear Ms. Vierling:

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

INDICATIONS FOR USE

510(k) Number (if known): K061046

Device Name: CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System

Indications for Use:

The CardioMEMS EndoSure Wireless AAA Pressure Measurement System is intended for measuring intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair. It may be used as an adjunctive tool in the detection of intraoperative endoleaks.

Prescription Use ___X___ (Part 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061046