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510(k) Summary

A. Submitter's Information

Submitter's Name: CardioMEMS, Inc.
Submitter's Address: 387 Technology Circle NW
Suite 500
Atlanta, GA 30313

AUG 19 2008

Contact Person: Grace Powers
Telephone Number: (678) 651-2323
Fax Number: (678) 651-2400

Date of Preparation: July 31, 2008

B. Trade Name: CardioMEMS EndoSure s2 Wireless AAA Pressure Measurement System

Common Name: AAA Pressure Measurement System

Classification Name: Implantable Intra-aneurysm Pressure Measurement System

C. Predicate Devices: CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System and
CardioMEMS EndoSure s2 Wireless AAA Pressure Measurement System

D. Device Description

The CardioMEMS EndoSure s2 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 s2 Wireless AAA Pressure Measurement System includes:

- The CardioMEMS EndoSure™ s2 Sensor with radio-opaque markings (implant)
- A sterile Delivery System (pre-loaded with the CardioMEMS EndoSure™ s2 Sensor)
- CardioMEMS EndoSure™ Electronics System

E. Intended Use:

The CardioMEMS EndoSure s2 Wireless AAA Pressure Measurement System is intended for measuring intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair and may be used as an adjunctive tool in the detection of intraoperative endoleaks. It also may be used for measuring intrasac pressure during thoracic aortic aneurysm (TAA) repair.

F. Technological Characteristics Summary

The Sensor is implanted in the aneurysm 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 Sensor is manufactured from fused silica coated in silicone. Nitinol loops extend from and surround the Sensor body. Radiopaque marker bands at each end of the Sensor body allow visualization of the device under fluoroscopy.

The Sensor is interrogated using the antenna of the EndoSure Electronics System. The antenna is placed over the patient's abdomen in the area of the 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 Electronics.

G. Performance Data

Testing has shown the EndoSure Sensor with Delivery System to be biocompatible and compatible with MRI, ultrasound, pacemakers and external defibrillators. Bench testing confirms that the device functions per its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2008

CardioMEMS, Inc.
c/o Ms. Grace Powers
Regulatory Affairs Specialist
387 Technology Circle NW, Suite 500
Atlanta, GA 30313

Re: K082191
EndoSure s2 Wireless AAA Pressure Measurement System
Regulation Number: 21 CFR 870.2855
Regulation Name: Implantable Intra-aneurysm Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: NQH
Dated: July 31, 2008
Received: August 4, 2008

Dear Ms. Powers:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): Not known K082191

Device Name: CardioMEMS EndoSure s2 Wireless AAA Pressure Measurement System

Indications for Use:

The CardioMEMS EndoSure s2 Wireless AAA Pressure Measurement System is intended for measuring intrasac pressure during endovascular abdominal aortic aneurysm (AAA) repair and may be used as an adjunctive tool in the detection of intraoperative endoleaks. It also may be used for measuring intrasac pressure during thoracic aortic aneurysm (TAA) repair.

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

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082191