



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2005

CardioMEMS, Inc.
c/o Ms. Carol Vierling
Director, Regulatory and Clinical Affairs
75 Fifth Street, NW, Suite 440
Atlanta, GA 30308

Re: K050939
CardioMEMS EndoSensor System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 870.2855
Classification: Class II (two)
Product Code: NQH

Dear Ms. Vierling,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the CardioMEMS EndoSensor System that is intended for use as follows:

The CardioMEMS EndoSensor™ 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.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the CardioMEMS EndoSensor System, and substantially equivalent devices of this generic type into class II under the generic name, Implantable Intra-aneurysm Pressure Measurement System. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as:

A device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to

as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On August 9, 2005, FDA filed your petition requesting classification of the CardioMEMS EndoSensor System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on August 4, 2005, automatically classifying the CardioMEMS EndoSensor System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the CardioMEMS EndoSensor System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition, FDA has determined that the CardioMEMS EndoSensor System is intended for use as follows:

The CardioMEMS EndoSensor™ 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.

FDA concludes that this device can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

The potential risks presented by this device type include: adverse tissue reactions; migration of the implanted sensor; inaccurate sensor information; failure of the implanted sensor; failure of the sensor delivery system; failure of the electronic monitor; electromagnetic interference or other electrical hazards; incompatibility with magnetic resonance or ultrasound imaging devices; incompatibility with external defibrillators; and, failure of the device to detect and/or diagnose an endoleak that

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requires medical intervention. FDA has concluded that these risks can be adequately mitigated by means of the pre-clinical and clinical testing delineated in special controls, in combination with the general controls of the act.

In addition to the general controls of the act, the CardioMEMS EndoSensor System is subject to the following special controls: the guidance document entitled, "Implantable Intra-Aneurysm Pressure Measurement System." Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the implantable intra-aneurysm pressure sensor they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Nels Anderson at (301)443-8262 ext. 171.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and Radiological Health