AUG 1 8 2000

K002230

510(k) Summary

July 19, 2000

Submitter: Cambridge Heart, Inc
1 Oak Park
Bedford, Ma 01730
(781) 271-1200
(781) 275-8431

Contact: Jeffrey Arnold

510(k) Numbers and Product Codes of equivalent devices.

Cambridge Heart, Inc.; Hi-Res™ Electrode

510(k) Number: #K962115

Product Code: 74 DRX

CFR Section: 870.2360

Cambridge Heart, Inc.

Indications for Use and Intended Population

The Cambridge Heart Micro-V Alternans™ Sensor is intended for short term use to measure electrocardiograph/vectorcardiograph and T-wave alternans signals at rest and during stress testing with the Cambridge Heart Model CH 2000 Cardiac Diagnostic System, HeartWave™ Alternans Processing System and successor systems.

Device Description

The Cambridge Heart Micro-V Alternans™ Sensor is a self adhesive, non-sterile, single use disposable ECG electrode designed specifically for use in conjunction with the Cambridge Heart Model CH 2000 Cardiac Diagnostic System and the Cambridge Heart, HeartWave™ Alternans Processing System. Both the Micro-V Alternans Sensor and the predicate (Cambridge Heart Hi-Res™ Electrode) include a silver/silver chloride sensing element, proprietary lead contacts for connection to electrode wires and a conductive Gel. These elements are held in place to the patient's skin by a foam tape coated with a medical grade adhesive.

Physical/Technical Characteristics

The Micro-V Alternans™ Sensor is equivalent to the His-Res™ Electrodes. Physical and technical characteristics, including design, materials used, safety and efficacy characteristics and intended use of the Micro-V Alternans™ Sensor and the predicate are either identical or comparable.

Performance Standards

Both the Cambridge Heart Micro-V Alternans™ Sensor and the Hi-Res™ Electrode have been tested to and meet the following Performance Standards:

- ANSI/AAMI EC12-1991
- ISO 10993-1 " Biological Evaluation of Medical Devices – Part I: Guidance on Selection of Tests"
- FDA Guidance on Electrocardiograph Electrodes; 2/11/1997

Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart Micro-V Alternans™ Sensor. When used in according with the directions for use, by qualified personnel, the Cambridge Heart Micro-V Alternans™ Sensor is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Cambridge Heart
c/o Mr. John D. Greenbaum
Generic Devices Consultant
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K002230
Cambridge Heart Micro-V Alternans™ Sensor, Model 20327-002
Regulatory Class: II (two)
Product Code: DRX
Dated: July 19, 2000
Received: July 24, 2000

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k)Number(if known): K002230

Device Name: Micro-V Alternans Sensor

Indications For Use:

The Cambridge Heart Micro-V Alternans™ Sensor is intended for short term use to measure electrocardiograph/vectorcardiograph and T-wave alternans signals at rest and during stress testing with the Cambridge Heart Model CH 2000 Cardiac Diagnostic System, HeartWave™ Alternans Processing System and successor systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

Division of Cardiovascular & Respiratory Devices
510(k) Number K002230

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

(Optional Format 1-2-96)