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K001034
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510(k) Summary

March 29, 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.; Model CH 2000

510(k) Numbers: # K950018, K981697 & K983102

Product Code: 74 DPS

CFR Section: 870.2340

Indications for Use and Intended Population

The APS Alternans Processing System is intended for the measurement of T-Wave Alternans at rest and during ECG stress testing.

The presence of T-Wave alternans in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The APS Alternans Processing System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.

Device Description

The Cambridge Heart CH 2000 Cardiac Diagnostic System is a computer based ECG system which includes the optional feature for the measurement and recording of T-Wave alternans. The Cambridge Heart Model APS Alternans Processing System uses the same technology employed in the CH 2000 without the ECG functionality; it is a 'stand – alone' device for the measurement of T-wave alternans, designed for use in conjunction with a host adapter/controller for ECG functions. The host may be any ECG recording or stress test system.

The Cambridge Heart Alternans Processing System (APS) adds T-wave alternans diagnostic capabilities to standard stress test systems and ECG recording devices. The APS is intended for the measurement of T-wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing.

The Alternans Processing System is comprised of a central processing unit (the Alternans Processor), PM-3 patient module, an ink jet printer, and a mobile pole with mounting attachments for the processor, printer, and accessories.

The Alternans Processing System works in conjunction with a host standard-stress ECG controller. Attachment to the patient is through the Cambridge Heart PM-3 patient module. The Alternans Processor receives a superset of the standard stress ECG data from the PM-3 and replicates the analog standard-stress data onto a set of thirteen (13) posts (snap panel), providing the analog signals and physical interface to the host ECG system that would normally be provided at the patient.
The operator can perform standard stress tests with the APS remaining in line by using the standard-stress leadwire option on the PM-3.

The Alternans test is performed with seven standard stress test electrodes and seven proprietary multi-segment Hi-Res™ sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn PM-3, which provides digitized data to the Alternans Processor via the USB interface cable.

Standard Hardware Components

Alternans Processor	Configured for English language and U.S. lead designations
Power Supply	Modular medical-grade, in-line power supply with universal power input for Alternans Processor
PM-3 w/ Hi-Res™ Leads	with U.S. lead designations
Printer, w/ data cable	Inkjet Printer w/data cable & power cord
Line Cords	IEC 320 line cord with NEMA 5-15P hospital grade plug for Alternans Processor; printer line cord supplied with printer.
Documentation	Domestic Operator's Manual, Physicians Guide, and TWA Training Program
Shipping Containers:	Mobile pole, Processor unit and Display are shipped in a single container.

Standard Hardware Accessories

Patient Cable:	Set of 14 separately detachable lead wires which meet the requirements of 21CFR 898.12 and comply with IEC-601-1; 56.3c part 1.1, General Requirements for Safety Individual patient leads are either not detachable, or user detachable with female socket connections such that no conductive surface is exposed when unconnected.
User Manuals:	Operators manual supplied standard with every system. Physicians Guide to T-Wave Alternans processing supplied with T-wave Alternans Option. T-wave alternans Course Training Manual supplied in conjunction with training course.

Patient Electrodes: Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the CH 2000.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

Performance Standards

Both the Cambridge Heart CH 2000 and APS meet the following Performance Standards:

ANSI/AAMI EC11-1991

EN60601-1: 1988, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2

EN60601-1-1: 1993, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"

EN60601-1-2: 1993, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"

UL2601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2nd Edition, including Amendments A1 and A2

CAN/CSA C22.2 No. 601.1-M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)

Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart APS. When used in according with the directions for use, by qualified personnel, the APS Alternans Processing System 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

JUN 9 = 2000

Cambridge Heart, Inc.
C/o Mr. John Greenbaum
20310 SW 48th Street
Ft. Lauderdale, Florida 33332

Re: K001034
Cambridge Heart Model APS Alterans Processing System
Regulatory Class: II (two)
Product Code: DPS
Dated: May 13, 2000
Received: May 16, 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 control provisions of the Act. The general control 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 their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address :http.//www.fda.gov/cdrh/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): K001034

Device Name: Model APS Alternans Processing System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhous

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001034

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

(Optional Format 1-2-96)