OCT 1 2 2001 K012206

# 510(k) Summary

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

**Contact: David Chazanovitz**

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

**Cambridge Heart, Inc.; Model CH 2000 Cardiac Diagnostic System**

510(k) Number: #K983102

Product Code: 74 DPS

CFR Section: 870.2340

**Spacelabs/Burdick, Inc.; Quest Exercise Stress system**

510(k) Number: #K952417

Product Code: 74 DSI

CFR Section: 870.1025

**Indications for Use and Intended Population**

**Indications for use**

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

The presence of Microvolt T-wave Alternans as measured by the Analytic Spectral Method of the Alternans Processing System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Alternans Processing System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests. The interpretive results of the Alternans Processing System should be reviewed by a qualified physician.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations

greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

## Description of Device

The Cambridge Heart Alternans Processing System is intended for use with computer-based ECG systems which include the feature for the measurement and recording of T-Wave alternans at rest and during treadmill, ergometer, electrophysiological, and pharmacologic stress testing. The Alternans Processing System uses the Analytic Spectral Method which consists of several computational steps that combine to form a unique analytical process. The Microvolt T-wave Alternans measurement, the output of this specific process, has been shown to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death. The alternans levels reported in K983102 were measured using the Analytic Spectral Method.

The Alternans Processing System is embodied in software and can be incorporated into a device for the measurement of T-Wave alternans. The Cambridge Heart Alternans Processing System adds T-wave alternans diagnostic capabilities to standard stress test systems and ECG recording devices.

The Alternans Processing System is embodied in two legally marketed products, the Model CH2000 Cardiac Diagnostic System (K983102) and the Heartwave Alternans Processing System (K001034). It is designed for use in conjunction with a host adapter/controller for ECG functions. The host may be any ECG recording or stress test system. In the case of the Model CH 2000 Cardiac Diagnostic System the host controller is an integral part of the device (K983102).

Attachment to the patient is through the Cambridge Heart patient module(s). Digitized signals from the patient module are used as inputs to the Alternans Processing System.

The Alternans test using the Alternans Processing System is performed with seven standard stress test electrodes and seven proprietary multi-segment Micro-V Alternans™ Sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn Patient module, which provides digitized data to the Alternans Processor.

The Alternans Processing System uses interpretive Alternans Report Classifier software that provides an assessment of the alternans report data to assist the physician in diagnosis. The computerized assessment is printed at the bottom of the alternans report and indicates that the result is consistent with a Positive, Negative, or Indeterminate finding. This assessment should be considered preliminary and should be reviewed by a qualified physician. Alternans results should always be used as an adjunct to clinical history and the results of other non-invasive or invasive tests.

**Patient Electrodes:** Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with Alternans Processing Systems.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) or The Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

**Performance Standards**

The Analytic Spectral Method of Alternans Processing is incorporated into the Cambridge Heart HeartWave™ Alternans Processing System and the Cambridge Heart Model CH 2000 Cardiac Diagnostic System which 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 Alternans Processing System. The predicate devices use the Analytic Spectral Method of Alternans Processing and/or an interpretive algorithm for assessing ECG data. When used in accordance with the directions for use, by qualified personnel, the 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

OCT 12 2001

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

Re: K012206
Trade Name: Cambridge Heart Alternans Processing System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: July 6, 2001
Received: July 13, 2001

Dear Mr. Greenbaum:

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.

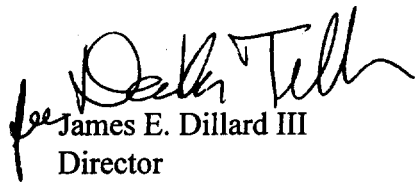
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



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): K012206

Device Name: 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)

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

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012206