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Attachment I – Revised 510k Summary MTWA OEM Module

APR 14 2010

5. 510K Summary

Submitter: Cambridge Heart, Inc
100 Ames Pond
Tewksbury MA,
(978) 654-7600
(978) 654-4501

Contact: Ali Haghighi-Mood

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

Cambridge Heart, Inc.; HearTwave II Cardiac Diagnostic System
510(k) Number: # K050225
Product Code: 74 DPS
CFR Section: 870.2340

Indications for Use and Intended Population

The MTWA OEM Module is intended for the recording of electrocardiograms, vector cardiograms and 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 MTWA OEM Module in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The MTWA OEM Module 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 MTWA OEM Module 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.

Device Description

The MTWA OEM Module consist of a patient module and an analysis software operating on a PC platform meeting the technical requirement specified in Product Requirement Document (PRD) for the module. The MTWA OEM Module is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing. The alternans levels reported in K983012, K001034, K003492 and K022149, K050225 were measured using the Analytic Spectral Method. This method 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 Cambridge Heart MTWA OEM Module provides T-wave alternans diagnostic capabilities to standard stress labs. The Analytic Spectral Method of Alternans Processing used in the Cambridge Heart MTWEA OEM Module is intended for the measurement of microvolt T-Wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing.

The Alternans test using the Cambridge Heart MTWA OEM Module 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 MTWA OEM Module.

Patient Electrodes:

Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Cambridge Heart MTWA OEM Module.
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 Cambridge Heart MTWA OEM Module is designed to work with FDA cleared computerized electrocardiographic devices that meet the following or equivalent voluntary Performance Standards:

- AAMI/ANSI EC11 - 1991(R)2007 – "Diagnostic electrocardiographic devices" (Cardiovascular)
- AAMI/ANSI EC 13 – 2002/(R)2007 – "Cardiac monitors, heartrate meters, and alarms (Cardiovascular)"

- AAMI EC53 – 2001 – "ECG Cables and Leadwires"
- IEC 60601-1: , "Medical Electrical Equipment, Part 1: General Requirements for Safety, 1998; Amendment 2. 1995. (general)"
- IEC60601-1-1: 2000, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Collateral standard: Safety requirements for medical electrical systems"
- IEC60601-1-2: 2001, "Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests"
- IEC60601-1-4: edition 1.1 2000, "Medical Electrical Equipment Part 1-4: General Requirement for Safety – Collateral Standard, Programmable Electrical Medical Systems"
- IEC 60601-2-25: 1999, ""Medical Electrical Equipment, Part 2: Particular requirements for the safety of electrocardiographs (Cardiovascular"
- FDA Diagnostic ECG Guidance: 1998, Version 1.0
- FDA Electrocardiograph Lead Switching Adaptor Guidance: 1997, Version 1.0
- FDA Guidance For Industry: 2000 " General Principles of Software Validation"
- FDA Guidance For Industry: 1999 " Guidance for Off-The –Shelf Software for use in Medical Devices"
- ISO 14971: 2007 " Application of risk management to medical devices"

Similarities and Differences to Predicates

The MTWA OEM Module (new) is essentially the same device as in K050225 with the exception of the modification described in this pre-market submission, which essentially allows a user to apply the module as a "plug in" to a compatible electrocardiograph or similar device. The MTWA OEM Module uses the same patient interface, the same data acquisition module (PM3), and the same application software and analysis method (Analytic Spectral Method)as the HearTwave II Cardiac Diagnostic System (K050225) for measuring T-Wave Alternans. The MTWA OEM Module and the predicate device have the same indications for use and utilize the same software to process analytical results.

The Cambridge Heart MTWA OEM Module was validated for specific use with the Cardiac Science Q-Stress System (K082173). Both design and process validations were conducted using the OEM Module incorporated into the Q-stress system. Validation parameters verified that all compatibility requirements are met and that the performance of the Cambridge Heart TWA OEM module is identical to its predicate device, HearTwave II Cardiac Diagnostic System (K050025). Validations and compatibility testing of the OEM Module included, but were not limited to: Data Management, Main Application and Processing

Screens, Printing, System Setup,& Configuration, MTWA Algorithm , ECG Processing and Overall System Performance.

Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart MTWA OEM Module. Both devices use the same patient interface the Analytic Spectral Method of Alternans Processing. When used in accordance with the directions for use, by qualified personnel, the Cambridge Heart MTWA OEM Module is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 14 2010

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

Re: K100362
Device Name: MWTA OEM Module
Regulation Number: 21 CFR 870.2340
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK
Dated: March 12, 2010
Received: March 17, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

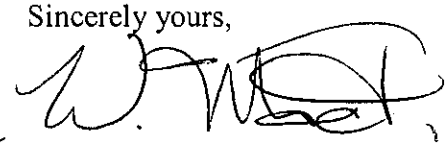
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K100362

Device Name: MTWA OEM Module

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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 Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100362