APR 25 2006

510(k) Summary Date: 11/21/2005

Submitter Name and Address
CardioNet, Inc.
1010 2nd Avenue, Suite 700
San Diego, CA 92101

Contact Person:
Jack Gaikwad
619-243-7527

Name of Device

Trade/Proprietary Name:	Model 1003 - CardioNet ECG Monitor with Arrhythmia Detection
Common/Usual Name:	Arrhythmia detector and alarm
Classification Name:	CFR §870.1025 Procode DSI 'Arrhythmia Detector and Alarm'
Class:	Class II, Special Controls

Predicate Device
The predicate devices selected are as follows:

1. **CardioNet Ambulatory ECG Monitor,** cleared by FDA under 510(k) number K052240; 870.1025 Procode DSI "Arrhythmia Detector and Alarm"
2. **Century Series ™ Holter Scanner System, Model C3000/C2000/C1000** manufactured by Biomedical Systems Corporation cleared by FDA under 510(k) number K024323; 870:2800 Product Code MLO 'Medical Magnetic Tape Recorder'

Device Description

The CardioNet ECG Monitor with Arrhythmia Detection is an ambulatory ECG monitor with capability to detect cardiac arrhythmias and transmit ECG data to a CardioNet staffed monitoring center.

The subject device is comprised of three (3) main components: 1) a patient-worn Sensor, 2) a Monitor and 3) a charging Base.

A Sensor acquires the ECG signal from the patient's body and transmits the signal to PDA sized monitor where the data is stored and analyzed by an automated arrhythmia analysis algorithm. When an arrhythmic event is detected the monitor can transmit the ECG data to the monitoring center utilizing a cellular modem or telephone data line. The patient can also initiate the recording and transmission of ECG data if symptoms are felt. The data is received and reviewed by trained technicians using the Monitoring Services Application.

Indications for Use and Contraindications

The indications for use for the subject device are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease

2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) monitoring of therapeutic and potential proarrhythmic effects (e.g. QT prolongation) of membrane active drugs b) monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias

7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter

8. Patients requiring measurement, analysis and reporting of the QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.

2. Patients who the attending physician thinks should be hospitalized.

3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.

Technological comparison to predicate devices

With the exception of the QT measurement capability, the technological characteristics of the subject device are identical to the CardioNet predicate device. The design of the QT measurement algorithm contained in the subject device is different from the design of the BioMedical predicate device. The subject device determines the Q and end of T wave points using a method similar to that used to determine the R point and beat morphology used in the CardioNet predicate device. The subject device also analyzes data directly on the acquisition device whereas the BioMedical predicate device performs the analysis after uploading the data from an acquisition device.

Summary of Performance Testing

Performance testing was performed in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm. The CardioNet Ambulatory ECG Monitor meets or intends to conform to the applicable standards suggested in the guidance document including:

- ANSI/AAMI EC 38: 1998 – Ambulatory Electrocardiographs
- ANSI/AAMI EC 57: 1998 – Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety

The performance of the QT detection algorithm was assessed by comparing the performance of both the subject and predicate devices against human annotated ECG data.

Substantial Equivalence Conclusion

CardioNet ECG Monitor with Arrhythmia Detection, Model 1003 is safe, effective, and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing, and will comply with appropriate medical device standards and FDA special controls guidance prior to market release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardionet, Inc.
c/o Mr. Jack Gaikwad
Director, Quality and Regulatory
1010 2nd Avenue, Suite 700
San Diego, CA 92101

APR 25 2006

Re: K053263
Trade Name: Cardionet Ambulatory ECG Monitor with Arrhythmia Detection
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (special controls)
Product Code: DSI
Dated: March 21, 2006
Received: March 24, 2006

Dear Mr. Gaikwad:

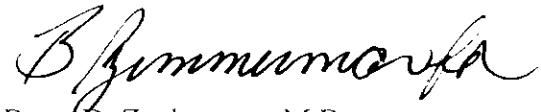
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K053263

Device Name: CardioNet Ambulatory ECG Monitor with Arrhythmia Detection

Indications for Use:

The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease

2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs b) monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias

7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter

8. Patients requiring measurement, analysis and reporting of the QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.

2. Patients who the attending physician thinks should be hospitalized.

3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.

4. The device does not replace QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. The device is not intended to sound any alarms for QT interval changes.

5. The device does not annotate QT interval for QRS durations ≥ 160 ms or for T wave amplitudes ≤ to 5% of the peak QRS amplitude.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053263