K012241

FEB 01 2002

510(k) Summary Date: 10/30/2001

Submitter Information

CardioNet, Inc.
Attn: Mr. Donald V. Canal
Vice President RAQA
510 Market Street
San Diego, Ca 92101

1. Name of Device

Trade/Proprietary Name:	Model 1001 - CardioNet ECG Monitor with Arrhythmia Detection.
Common/Usual Name:	Ambulatory ECG Monitor and Arrhythmia detector and alarm.
Classification Name:	CFR §870.2920 'Telephone Electrocardiograph Transmitter and Receiver', CFR §870.2800 'Medical Magnetic Tape Recorder'. CFR §870.1025 Procode DSI 'Arrhythmia Detector and Alarm'.
Class:	Class III Preamendments Device for which FDA has not yet called for PMAs.

2. Predicate Devices

The predicate devices selected are as follows:

1. **CardioNet Ambulatory ECG Monitor,** cleared by FDA under 510(k) number K003707; 870.2800 "Medical Magnetic Tape Recorder". Procode: MWJ "Electrocardiograph, Ambulatory (Without analysis)".
2. **Cardiac Telecom Cardiac TeleCom HeartLink II ECG Arrhythmia detector and Alarm System**– Manufactured by Cardiac Telecom, Inc., cleared by FDA under 510(k) number K982803; 870.1025 Procode DSI 'ECG Arrhythmia detector and alarm".

3. Device Description

The CardioNet Arrhythmia Detector which is also referred to as the subject device, is a modification to the CardioNet Ambulatory ECG monitor cleared by FDA under 510(k) number K003707, in May 2001. The subject device includes the addition of an ECG analysis capability that allows detection of cardiac arrhythmia.

As described in the previous 510(k) the subject device is comprised of three components: 1) a patient-worn Sensor, 2) a Monitor and 3) a charging Base.

The Sensor acquires the ECG signal from the patient's body. It is connected to electrodes attached to the patient's skin. It is suspended in place by a neck strap. The ECG signal is conditioned, filtered, digitized and transmitted to the Monitor via Radio Frequency bi-directional communications. The Sensor utilizes a disposable AAA battery.

The Monitor receives, analyzes, stores and transmits the ECG data. The Monitor has an LCD display and handles the user interaction for the system. The Monitor has an integrated cellular modem to allow communications with and without physical connection to a phone line. The Monitor has a re-chargeable battery. When an ECG threshold is exceeded or if the patient initiates a call, the ECG data is transmitted to the CardioNet Monitoring Center where trained clinical personnel review the data. The Monitor Center can also request data from the Monitor, the Monitor will transmit ECG data are requested. All ECG data for the past 24 hours is resident on the Monitor and can be transmitted to the Monitoring Center as requested by Monitoring Center Personnel. The subject device utilizes the proven Mortara ECG analysis algorithm that is currently used in the Quinton Q-tel telemetry system, 510(k) number K003576, 807.1025, Procode DSI, Class III; and the Datex-Ohmeda CS/3 telemetry system, 510(k) number K000882, 807.1025, Procode DSI, Class III. The Quinton Q-tel telemetry system and the Datex-Ohmeda telemetry system are both Class III Preamendments devices for which FDA has not yet requested PMAs.

The Base provides power, RS232, and telephone communication connectivity to allow telephone transmission of ECG data when in the Monitor is charging. The Base does not include any software; it is a passive component that provides input to the Monitor.

4. Indications For Use

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

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
2. Patients with dizziness or lightheadedness
3. Patients with palpitations
4. Patients with syncope of unknown etiology
5. Patients who require monitoring for non life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block. This includes post operative monitoring for these rhythms
6. Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias
7. Patients requiring monitoring for arrhythmias inducing co-morbid conditions such as hyperthyroidism or chronic lung disease
8. Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias

9. Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation
10. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT changes.

5. Comparison to Predicate Devices

	CardioNet Arrhythmia Detector (Subject device)	**CardioNet Ambulatory ECG Monitor**	**Cardiac Telecom HeartLink II**
Manufacturer	CardioNet, Inc.	CardioNet, Inc.	Cardiac Telecom, Inc.
510k number	Subject Device Class III DSI 870.1025	K003707 Class II MWJ	K982803 Class III Preamendments device, DSI 870.1025
Maximum storage capacity.	24 hours	24 hours	Last 30 minutes of data
Includes transtelephonic capability	Yes	Yes	Yes
Event Recording time.	Marker inserted into full disclosure data. All data is available for 24 hours at the request of Monitoring Center.	+/- 5 minutes from Patient Marker in event mode. Patient Marker inserted into full disclosure data in Holter mode.	Marker inserted into full disclosure data. All data is available for 30 minutes at the request of the Monitoring Center.
Pacer Pulse Detection and reporting	Yes	Yes	Yes
Leads off detection	Yes	Yes	Yes
Power input/ Battery Type	Sensor – 1 AAA, Monitor – Li Ion, rechargeable Base – 6 volts	Sensor – 1 AAA, Monitor – Li Ion, rechargeable Base – 6 volts	Sensor – NiCad Tower PC - 120 V AC
Enclosure	Sensor – Molded TPE, Monitor – Molded Plastic	Sensor – Molded TPE, Monitor – Molded Plastic	Molded plastic
A to D sampling rate (samples/sec)	250	250	Not Specified in available literature
Resolution (A/D conversion bits)	12 bit	12 bit	Not Specified in available literature
Number of channels	3	3	1
Number of Electrodes	3	3	3
Storage Type (digital or Tape)	Digital flash non-removable	Digital flash non-removable	Hard disk

	CardioNet Arrhythmia Detector (Subject device)	CardioNet Ambulatory ECG Monitor	Cardiac Telecom HeartLink II
Input impedance	>1 Mohm	>1 Mohm	2.5 Mohm @10 Hz
Frequency Response	0.5 Hz up to 40 Hz	0.5 Hz up to 40 Hz	Not Specified in available literature
Communication Means	Cellular Phone, PSTN phone, RS232, audio Coupled	Cellular Phone, PSTN phone, RS232, audio Coupled	PSTN telephone connection
Operating temperature range	Sensor: 20°C to 45°C Monitor: 0°C to 45°C	Sensor: 20°C to 45°C Monitor: 0°C to 45°C	25+/- 10 degrees C
Storage temperature range	-20°C to 65°C	-20°C to 65°C	Not Specified in available literature
Relative Humidity	5% to 95%	5% to 95%	50%+/-30%
Dimensions	Sensor –2" x 12" x 0.5" Monitor – 4.5" x 3.5" x 1.5"	Sensor –2" x 12" x 0.5" Monitor – 4.5" x 3.5" x 1.5"	Sensor - 3. 5" x 1.25" x 4.5 " Tower PC – 17" x 5" x 12"
Weight	Sensor 1.8 ounces Monitor 10 ounces	Sensor 1.8 ounces Monitor 10 ounces	Sensor 10.5 ounces Monitor 10 lbs.
RF Modulation	902 - 928 MHz with frequency hopping (30 foot range)	902 - 928 MHz with frequency hopping (30 foot range)	908-928 MHz No frequency hopping (300 foot range)
LCD display	Yes with touch screen	Yes	Yes on the Tower PC

6. Non-Clinical Performance Test Summary

There are no applicable device-specific guidance documents for the subject device. The CardioNet Ambulatory ECG Monitor meets or exceeds the applicable requirements in ANSI/AAMI/ISO EC38 'Ambulatory electrocardiographs', 1998. The ECG analysis algorithm and the ECG viewing station meets the requirements of ANSI/AAMI EC57:1998 "Testing and reporting performance results of cardiac rhythm and ST segment algorithms". Note: the CardioNet Arrhythmia detector does not generate alarms for ST segment changes.

Several other ECG related standards have also been considered as design inputs for the CardioNet Ambulatory ECG Monitor: ANSI/AAMI EC13:'Cardiac Monitors, Heart rate meters and alarms', 1992; ANSI/AAMI EC11 "Diagnostic Electrocardiographic devices", 1991; and ANSI/AAMI EC53-1995 "ECG Cable and Lead wires".

The Sensor skin contact materials will be tested to meet the requirements for surface devices, skin contact > 30 days as required in ISO10993 'FDA modified Biocompatibility' table.

The Sensor, Monitor and Base comply with the applicable requirements in UL2601, and ANSI/AAMI EC1-1993, "Safe Current Limits for electromechanical Apparatus: December", 1993.

The applicable communications for the Monitor will meet the applicable requirements in FCC part 15, subpart C, and part 68.

7. Substantial Equivalence Conclusion

The CardioNet Arrhythmia detector is equivalent to the predicate devices as supported by the descriptive information and the performance testing demonstrates that it meets the applicable requirements of ANSI/AAMI EC38:1998 'Ambulatory electrocardiographs', the ECG analysis algorithm and the ECG viewing station meet the requirements of ANSI/AAMI EC57:1998 "Testing and reporting performance results of cardiac rhythm and ST segment algorithms".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2002

Mr. Jerry Kalieta
Director Quality Assurance
CardioNet, Inc.
510 Market Street
San Diego, CA 92101

Re: K012241
Trade Name: CardioNet Ambulatory ECG Monitor with Arrhythmia Detection
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: October 31, 2001
Received: November 5, 2001

Dear Mr. Kalieta:

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.

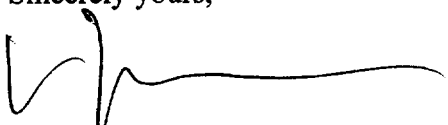
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K01224, 1

Device Name: CardioNet Ambulatory Monitor with Arrhythmia Detection

Indications for Use:

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia.
2. Patients with dizziness or lightheadedness
3. Patients with palpitations
4. Patients with syncope of unknown etiology
5. Patients who require monitoring for non life-threatening arrhythmias, such as atrial fibrillation, other supra-ventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block. This includes post operative monitoring for these rhythms
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8. Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias
9. Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation
10. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

[redacted]

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Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular
510(k) Number K012241