510(k) Summary December 1, 2008

K090037
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1. Submitter Name and Address

Medicalgorithmics LLC	245 West 107th St., Suite 11A New York, NY 10025, USA
Contact Person	Martin Jasinski, phone (917) 9419581, fax (817) 5829527

2. Device

Trade name:	PocketECG – Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector
Classification name:	Arrhythmia Detector and Alarm
Product code:	DSI
Regulation no:	870.1025
Class:	Class II, Special Controls

3. Substantial Equivalence

The selected predicate devices are:

1. CardioNet's Ambulatory ECG Monitor, K072558 (Reg. Number 870.1025 Product Code DSI)
2. Card Guard's CG-6108 Continuous ECG Monitor and Arrhythmia Detector, K071995 (Reg. Number 870.1025, Product Code DSI)

4. Device Description

PocketECG – Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector is an ambulatory ECG monitor which analyzes electrographic signal, classifies all detected heart beats and recognizes rhythm abnormalities. All detection results, including annotations for every detected heart beat and ECG signal are transmitted via cellular telephony network to a remote server accessible by a Monitoring Center for reviewing by trained medical staff. The data transmission is automatically triggered when abnormalities are detected, or periodically in case of normal ECG.

The patient worn transmitter streams via Bluetooth link the ECG signal to a Windows Mobile operated PDA (Personal Digital Assistant) device with mobile phone capabilities. The PDA runs Medicalgorithmics proprietary software which detects the ECG annotations and manages the data transmission. The PDA device stores entire ECG on its storage card.

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5. Indications for Use and contradictions

The indications for use for the PocketECG monitor 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 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. 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.

Contradictions:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

6. Technological comparison to predicate devices

The first technology difference between the subject device is that the predicate devices use customized PDA size monitors, while the subject device uses of-the-shelf PDA with the following minimum requirements:

1. Windows Mobile 5.x or 6.x Operating System,
2. built in GSM/CDMA modem,
3. built in Bluetooth module for communication with the ECG Transmitter,
4. replaceable Storage Card slot for cards of minimum 1 GB capacity,
5. USB port

Example PDAs meeting the above criteria are:
HTC Touch:
http://www.htc.com/www/product.aspx?id=362

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Hewlett Packard iPAQ hw6940
http://h10010.www1.hp.com/wwpc/us/en/sm/WF06a/215348-215348-64929-314903-215381-1822489.html

The second technological difference between the subject device and the predicate devices is that the subject device uses an arrhythmia analysis algorithm developed by Medicalgorithmics while the predicate devices use arrhythmia analysis algorithm licensed from Mortara (K072558) or their proprietary algorithms (K071995).

The third technological difference between the subject device and the predicate devices is that the subject device uses its own ECG sensor and transmitter, while the predicate devices use their own manufactured ECG sensors.

7. Referenced standards

The Medicalgorithmics ECG Monitor and Arrhythmia Detector, PocketECG meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- IEC 60601-1:1999 "Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995"
- IEC 60601-1-2:2001/A1:2004 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests" Class B
- AAMI/ANSI EC38:2007 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- AAMI / ANSI EC57:1998/(R)2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms

Quality management system - Medical devices is in conformance with the standards: PN-EN ISO 9001:2001 and PN-EN ISO 13485:2005.

8. Substantial Equivalence Conclusion

Medicalgorithmics ECG Monitor and Arrhythmia Detector, PocketECG is safe, effective and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing. The subject device is composed of off-the-shelf, certified devices and components fully complying with the US safety and EMC standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

MedicAlgorithmics, Sp. Z O.O.
c/o Mr. Martin Jasinski
MedicAlgorithmics, LLC
245 West 107th St, Suite 11A
New York, NY 10025

Re: K090037
Trade/Device Name: MedicAlgorithmics Real-Time ECG Monitor and Arrhythmia Detector, Model PocketECG
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (special controls)
Product Code: DSI, MLO
Dated: March 31, 2009
Received: May 8, 2009

Dear Mr. Jasinski:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

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): K090037

Device Name: PocketECG-Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector

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

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)

Susana R. Cruz

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090037

4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
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Contradictions:

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number_____