



Food and Drug Administration  
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October 8, 2015

Medicalgorithmics S.A.  
% Martin Jasinski  
Vice President  
Medicalgorithmics LLC  
245 West 107th Street  
Suite 11 A  
New York, New York 10025

Re: K152550

Trade/Device Name: PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIIV

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)

Regulatory Class: Class II

Product Code: DSI

Dated: August 5, 2015

Received: September 8, 2015

Dear Martin 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. 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**Kenneth J. Cavanaugh -S**

for 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): K152550 Device Name: PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIV

### Indications For Use:

The indications for use for the PocketECG III 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.

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
(CONTINUE ON A SEPARATE PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Summary****August 4, 2015****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 III – Medicalgorithmics Unified Arrhythmia  
 Diagnostic System  
 Type                                      PECGT-IIIIV  
 Classification name:              Arrhythmia Detector and Alarm  
 Product code:                      DSI  
 Regulation no:                      870.1025  
 Class:                                      Class II, Special Controls

**3. Substantial Equivalence**

The PocketECG III – Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIIV is a modification of a legally marked Medicalgorithmics predicate device:

- PocketECG v3 – Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-III; K124060 (Reg. no. 870.1025)

Note: For commercial reasons Medicalgorithmics S.A. launched the medical device onto the U.S. market under the name of PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, and has continued to distribute the device under the same name. The modified device is the latest evolution of this predicate one.

**4. Device Description**

PocketECG III – Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIIV 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 the entire ECG signal are transmitted via cellular telephony network to a remote server accessible by a Monitoring Center for reviewing by trained medical staff.

**5. Indications for Use and contradictions**

The indications for use for the PocketECG III, type PECGT-IIIIV 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. Predicate Device Information**

To K124060 - PocketECG v3 - Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECT-III

- Similarities:
  - o The subject device and the predicate device have the same fundamental scientific technology and intended use;
  - o The subject device and the predicate device have the same components: transmitter, lithium-ion rechargeable batteries, AC plug-in battery charger and PC application;
  - o The subject device and the predicate device analyze electrographic signal, classify all detected heart beats and recognize rhythm abnormalities;
  - o The subject device and the predicate device send all detection results, including annotations for every detected heart beat and the entire ECG signal via cellular telephony network to a remote server;
- Differences:

- The predicate device uses a Global System for Mobile Communication (GSM) protocol, whereas the subject device uses Code Division Multiple Access protocol (CDMA) for data transmission to a remote server.

### **7. Referenced standards**

The PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIIV meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm like the predicate device.

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance", with National Differences for United States (US) ANSI/AAMI ES 60601-1:2005/A2:2010 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance",
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,
- IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment,
- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems,
- AAMI / ANSI EC57:2012 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms.

Quality management system - Medical devices is in conformance with the standards: EN ISO 13485:2012 + EN ISO 13485:2012/AC:2012, ISO 13485:2003 under CMDCAS and EN ISO 9001:2008.

### **8. Substantial Equivalence Conclusion**

PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, type PECGT-IIIIV is safe, effective and substantially equivalent to the predicate device 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.