April 9, 2020

Medicalgorithmics S.A.
% Przemyslaw Tadla
Strategy Director
Medicalgorithmics US Holding Corporation
Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808

Re: K193104
Trade/Device Name: Unified Arrhythmia Diagnostic System PocketECG IV
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: March 6, 2020
Received: March 11, 2020

Dear Przemyslaw Tadla:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director (Acting)
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193104

Device Name
Unified Arrhythmia Diagnostic System PocketECG IV

Indications for Use *(Describe)*
The PocketECG IV is intended to be used by:
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 a correlation of rhythm with symptoms.
4. Patients who require monitoring of the 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.

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.

Contraindications:
The PocketECG IV is not intended to be used by:
1. Patients who have been diagnosed with life-threatening arrhythmias and require hospitalization.
2. Patients who require inpatient monitoring using a life-saving device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Submitter's name and address:

Medicalgorithmics S.A. Aleje Jerozolimskie 81,
02-001 Warsaw, Poland

Contact Person: Przemysław Tadla
Phone: (+1) 302 2615184
Email: p.tadla@medicalgorithmics.com

Date Prepared: 2019-10-28

II. Device

Trade name:	Unified Arrhythmia Diagnostic System PocketECG IV
Type:	P4TR-AA-ADS
Regulation number:	870.1025
Classification name:	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class:	Class II, Special Controls
Classification:	Detector And Alarm, Arrhythmia; DSI

III. Substantial Equivalence

The selected predicate device is:

1. Medicalgorithmics Unified Arrhythmia Diagnostic System PocketECG III, type PECGT-IIIV K152550 (Predicate Device)

IV. Device description

The Medicalgorithmics Unified Arrhythmia Diagnostic System PocketECG IV, type P4TR-AA-ADS 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.

V. Indications for use

The PocketECG IV is intended to be used by:

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 a correlation of rhythm with symptoms.
4. Patients who require monitoring of the 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.

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.

Contraindications:

The PocketECG IV is not intended to be used by:

1. Patients who have been diagnosed with life-threatening arrhythmias and require hospitalization.
2. Patients who require inpatient monitoring using a life-saving device.

VI. Technological comparison to predicate device

Predicate Device (K152550):

- Similarities:
  - The subject device and the predicate device have the same fundamental scientific technology and intended use.
  - The subject device and the predicate device have the same components: transmitter, lithium-ion rechargeable batteries, AC plug-in battery charger and PC application.
  - The subject device and the predicate device analyze electrographic signal, classify all detected heart beats and recognize rhythm abnormalities.
  - 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 Code Division Multiple Access protocol (CDMA), whereas the subject device uses Verizon Wireless Long-Term Evolution (LTE) for data transmission to a remote server.

VII. Guidance documents

The following guidance documents have been taken into account during preparation of this submission:

- Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003;
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005;
- Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and FDA Staff, August 14, 2013;
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, October 2, 2014;
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, June 16, 2016.

VIII. Referenced standards

The Medicalgorithmics Arrhythmia Diagnostic System PocketECG IV, type P4TR-AA-ADS meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document Arrhythmia Detector and Alarm.

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod);
- IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability;
- AAMI / ANSI / IEC 62366:2007/(R)2013, Medical Devices - Application Of Usability Engineering To Medical Devices;
- AAMI / ANSI HA60601-1-11:2015, Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment (IEC 60601-1-11:2015 Mod);
- AAMI / ANSI / IEC 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems;
- ANSI/AAMI/IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 4).

Medicalgorithmics has assessed the PocketECG IV for wireless coexistence in accordance with the FDA guidance document Radio Frequency Wireless Technology in Medical Devices (August 14, 2013). This include FCC & Verizon Open Development performance testing.

IX. Performance data

Arrhythmia detection algorithms implemented in PocketECG IV have been subject for performance testing according to IEC 60601-2-47:2012 (AAMI / ANSI / IEC 60601-2-47:2012) Test results were considered to be in complaint with standard requirements.

Wireless transmission performance has been tested according to Verizon Open Development (based on CTIA) requirements for LTE data transmissions.

X. Substantial Equivalence Conclusion

The Medicalgorithmics Unified Arrhythmia Diagnostic System PocketECG IV, type P4TR-AA-ADS is 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 electrical safety and EMC standards.