July 11, 2018

Medicalgorithmics S.A.
% Przemyslaw Tadla
Strategy Director
Medicalgorithmics US Holding Corporation
2711 Centerville Rd Ste 400
Wilmington, Delaware 19808

Re: K173969
Trade/Device Name: Unified Cardiac Rehabilitation System PocketECG CRS
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, MHX
Dated: June 13, 2018
Received: June 15, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Deborah Castillo

For

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173969

Device Name
Unified Cardiac Rehabilitation System PocketECG CRS

Indications for Use *(Describe)*
PocketECG CRS is intended to be used for:
1. Cardiac monitoring of patients undergoing a cardiac rehabilitation program. Its main feature is patient monitoring during previously planned training sessions and training assistance to achieve desired intensity and duration of workout. Training session parameters such as heart rate threshold, session duration (time intervals and number of repetitions) are defined by the physician for each patient individually. Additionally, the transmitter allows continuous ECG monitoring between trainings, during patient daily activities.
2. All patients hospitalized with a primary diagnosis of an acute myocardial infarction (MI) or chronic stable angina (CSA), or who during hospitalization have undergone coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, referred to an early outpatient cardiac rehabilitation or secondary prevention (CR) program.
3. All patients evaluated in an outpatient setting who within the past 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation or secondary prevention (CR) program for the qualifying event or diagnosis, referred to such a program.
4. 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;
5. PocketECG CRS can be used to monitor the training session in hospital, rehabilitation center or physicians office under supervision of qualified staff.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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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)*
K173969

Device Name
Unified Cardiac Rehabilitation System PocketECG CRS

Indications for Use *(Describe)*
Contraindications:
1. Patients with recent change in the resting ECG suggesting significant ischemia, recent MI, or other acute cardiac event,
2. Patients with: unstable angina, symptomatic severe aortic stenosis or other valvular disease, decompensated symptomatic heart failure, acute pulmonary embolus or pulmonary infarction, acute myocarditis or pericarditis, or acute thrombophlebitis
3. Patients with potentially life-threatening arrhythmias who require inpatient monitoring,
4. Patients with physical disability that would preclude safe and adequate exercise performance, or with acute noncardiac disorder that may affect exercise performance or may be aggravated by exercise (e.g., infec¬tion, thyrotoxicosis),
5. The PocketECG CRS is not intended for use in surgical rooms, intensive care units, and emergency vehicles. The transmitter is MR unsafe and should not be used in any magnetic resonance environment.

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)

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June 11, 2018 - K173969

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: 2018-02-28

II. Device

Trade name: Unified Cardiac Rehabilitation System PocketECG CRS
Regulation number: 870.1025
Classification name: Arrhythmia detector and alarm (including ST-segment measurement and alarm) Regulatory
Class: Class II, Special Controls
Procode: DSI
Other: MHX

III. Substantial Equivalence

The selected predicate devices are:

1. Medicalgorithmics Unified Arrhythmia Diagnostic System, K124060 (Primary Predicate Device);
2. Mortara Instruments Inc., Quinton Q-TEL RMS, K041607.

IV. Device description

Medicalgorithmics Unified Cardiac Rehabilitation System PocketECG CRS is an ambulatory system which can be used for patient monitoring during previously planned cardiac rehabilitation training sessions and training assistance to achieve desired intensity and duration of workout. The system measures patient's physical activity and ECG signal, classifies all detected heart beats and recognizes rhythm abnormalities. PocketECG CRS can be also used for patient's monitoring between training sessions as 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 beats and the entire ECG signal are transmitted via cellular network to a remote server accessible by a Monitoring Center for review by trained medical staff.

V. Indications for use

PocketECG CRS is intended to be used for:

1. Cardiac monitoring of patients undergoing a cardiac rehabilitation program. Its main feature is patient monitoring during previously planned training sessions and training assistance to achieve desired intensity and duration of workout. Training session parameters such as heart rate threshold, session duration (time intervals and number of repetitions) are defined by the physician for each patient individually. Additionally, the transmitter allows continuous ECG monitoring between trainings, during patient daily activities.
2. All patients hospitalized with a primary diagnosis of an acute myocardial infarction (MI) or chronic stable angina (CSA), or who during hospitalization have undergone coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, referred to an early outpatient cardiac rehabilitation or secondary prevention (CR) program.
3. All patients evaluated in an outpatient setting who within the past 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation or secondary prevention (CR) program for the qualifying event or diagnosis, referred to such a program.
4. 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;
5. PocketECG CRS can be used to monitor the training session in hospital, rehabilitation center or physician’s office under supervision of qualified staff.

Contraindications:

1. Patients with recent change in the resting ECG suggesting significant ischemia, recent MI, or other acute cardiac event,
2. Patients with: unstable angina, symptomatic severe aortic stenosis or other valvular disease, decompensated symptomatic heart failure, acute pulmonary embolus or pulmonary infarction, acute myocarditis or pericarditis, or acute thrombophlebitis
3. Patients with potentially life-threatening arrhythmias who require inpatient monitoring,
4. Patients with physical disability that would preclude safe and adequate exercise performance, or with acute noncardiac disorder that may affect exercise performance or may be aggravated by exercise (e.g., infection, thyrotoxicosis),
5. The PocketECG CRS is not intended for use in surgical rooms, intensive care units, and emergency vehicles. The transmitter is MR unsafe and should not be used in any magnetic resonance environment.

VI. Technological comparison to predicate devices

Primary Predicate Device (K124060):

- Similarities
  - 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 network to a remote server.
  - The subject and predicate device utilize the same hardware.
  - Software of subject device has additional features used during monitoring of training sessions, however its architecture, software requirements, and basic features remains the same.
  - The subject device meets the same electrical safety, performance, EMC and wireless requirements as the predicate device.
- Differences
  - The predicate device is intended to be used for ambulatory diagnostic monitoring of cardiac arrhythmias, while the subject device is intended to be used for cardiac monitoring of patients undergoing a cardiac rehabilitation program.
  - User interfaces of the predicate device and the subject device differs according to their intended use.

Predicate Device (K041607):

- Similarities
  - The subject device and the predicate device are both telemetric systems used for monitoring patients undergoing cardiac rehabilitation.
  - The subject device and the predicate device use individual patient monitors to acquire and transmit ECG data using wireless transmission to central monitoring unit. Central monitoring units (PCs with proprietary software) allow display of full ECG waveforms along with arrhythmia annotations.
  - The subject device does not have technological differences in comparison to the predicate device which can influence its safety and effectiveness.
- Differences:
  - The predicate device uses short range wireless communication (e.g. Bluetooth) which limits it use only to trainings held in rehabilitation facilities within short distance from the transmitter, while the subject device uses cellular network, which allows to perform trainings in rehabilitation facilities without above mentioned limitation.
  - The predicate device monitors only patient's ECG, while the subject device monitors ECG with corresponding level of patient's physical activity (through the use of accelerometer).

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 Unified Cardiac Rehabilitation System PocketECG CRS 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
- AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3).

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

IX. Performance data

Arrhythmia detection algorithms implemented in PocketECG CRS (PECGT-III) and PocketECG III (PECGT-IIIR) 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 PTCRB and CTIA requirements for GSM and WCDMA transmissions.

X. Substantial Equivalence Conclusion

Medicalgorithmics Unified Cardiac Rehabilitation System PocketECG CRS 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 electrical safety and EMC standards.