July 27, 2022

Medicalgorithmics S.A.
% Agnieszka Romowicz
Operations & Product Compliance Director
Medicalgorithmics US Holding Corporation
2711 Centerville Road, Suite 400
Wilmington, DE 19808

Re: K210822
Trade/Device Name: DeepRhythmAI
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: June 24, 2022
Received: June 27, 2022

Dear Agnieszka Romowicz:

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 Kozen
Assistant Director
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)*
K210822

Device Name
DeepRhythmAI

Indications for Use *(Describe)*
DeepRhythmAI is a cloud-based software for the assessment of cardiac arrhythmias using two lead ECG data in adult patients.
It is intended for use by a healthcare solution integrator to build web, mobile or another types of applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry or other similar devices when the assessment of the rhythm is necessary.
The product can be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. DeepRhythmAI can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

DeepRhythmAI is not for use in life-supporting or sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.

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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June 24, 2022

510(k) Summary

I. Submitter's name and address:

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

Contact Person:
Agnieszka Romowicz
Phone: (+48) 733 888 448
Email: a.romowicz@medicalgorithmics.com

Date Prepared: 2022-06-24

II. Device

Trade name:	DeepRhythmAI
Common name:	ECG Analysis System
Classification name:	Programmable Diagnostic Computer/ Electrocardiograph
Regulation number:	870.1425 870.2340
Regulatory Class:	Class II
Classification Product code:	DQK, DPS

III. Substantial Equivalence

The selected predicate and reference devices are:

1. RhythmAnalytics, K182344 (Predicate Device),
2. Zio AT ECG Monitoring System, K181502 (Reference Device).

IV. Device description

The DeepRhythmAI is a cloud-based software for automated analysis of ECG data. It uses a scalable Application Programming Interface (API) to enable easy integration with other medical products. The main component of DeepRhythmAI is an automated proprietary deep-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information for review.

DeepRhythmAI can be integrated into medical devices. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry or other similar devices when the assessment of the rhythm is necessary. DeepRhythmAI can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. DeepRhythmAI doesn't have a User Interface therefore it should be integrated with the external visualization software used by the ECG technicians for the ECG visualization and analysis reporting.

It is intended for use by a healthcare solution integrator to build web, mobile or another types of applications to let qualified healthcare professionals review and confirm the analytic result. .

DeepRhythmAI algorithm detects cardiac beats/arrythmias and intervals including:

- QRS
- Heart rate determination
- RR Interval measurements
- Non-paced arrhythmias
- Non-paced ventricular arrhythmia calls
- Ventricular ectopic beats
- Supraventricular ectopic beats

DeepRhythmAI returns the interpretation result to be reviewed by a qualified healthcare professional. DeepRhythmAI when integrated with the other computer-based ECG systems, creates a semi-autonomous system for analysis of ECG recordings. All algorithm annotations must be analyzed and confirmed by a qualified healthcare professional. The subject device can only be integrated with the display product used by the monitoring center that allows for verification of the algorithm output, its correction and confirmation.

DeepRhythmAI is not for use in life-supporting or sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.

V. Indications for use

DeepRhythmAI is a cloud-based software for the assessment of cardiac arrhythmias using two lead ECG data in adult patients.

It is intended for use by a healthcare solution integrator to build web, mobile or another types of applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry or other similar devices when the assessment of the rhythm is necessary.

The product can be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. DeepRhythmAI can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

DeepRhythmAI is not for use in life-supporting or sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.

VI. Comparison to predicate device

The following tables provide a comparison of the detection features and device comparison of DeepRhythmAI and the predicate devices.

Detection Features comparison:

Device functionality	DeepRhythmAI	RhythmAnalytics	Zio AT ECG Monitoring System
QRS detection	YES	YES	No information
Heart rate determination for non-paced adult	YES	YES	YES
R-R interval detection	YES	YES	No information
Non-paced arrhythmias interpretation	YES	YES	YES
Non-paced ventricular arrhythmias calls	YES	YES	YES
Atrial fibrillation detection	YES	No information	YES
Cardiac beats detection (Ventricular ectopic beats, Supraventricular ectopic beats)	YES	YES (Ventricular ectopic beats)	YES
Patient populations	Adult	Min 18 years old	Min 18 years old

Device comparison:

Device functionality	**Subject device**	**Predicate device**	**Reference device**
	DeepRhythmAI	**RhythmAnalytics**	**Zio AT ECG Monitoring System**
Manufacturer	Medicalgorithmics S.A.	Biofourmis Singapore Pte. Ltd.	iRhythm Technologies, Inc.
510(k) Number	K210822	K182344	K181502
Classification	Class II	Class II	Class II
Regulation Number(s)	21 CFR §870.1425 21 CFR §870.2340	21 CFR §870.1425 21 CFR §870.2340	21 CFR §870.1425 21 CFR §870.2800 21 CFR §870.2920 21 CFR §870.1025

Device functionality	Subject device	Predicate device	Reference device
	DeepRhythmAI	**RhythmAnalytics**	**Zio AT ECG Monitoring System**
Classification name	Programmable Diagnostic Computer, Electrocardiograph	Programmable Diagnostic Computer, Electrocardiograph	Programmable Diagnostic Computer; Medical Magnetic Tape Recorder; Telephone electrocardiograph transmitter and receiver; Arrhythmia detector and alarm
Product Code	DQK, DPS	DQK, DPS	DQK, DSH, DXH, DSI
Indications for Use	DeepRhythmAI is a cloud-based software for the assessment of cardiac arrhythmias using two lead ECG data in adult patients. It is intended for use by a healthcare solution integrator to build web, mobile or another types of applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry or other similar devices when the assessment of the rhythm is necessary. The product can be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. DeepRhythmAI can be integrated into medical	RhythmAnalytics is a software application for the assessment of cardiac arrhythmias using single-lead ECG data in subjects over 18 years of age. It is intended for use by a healthcare solution integrator to build web or mobile applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in compatible formats from any FDA cleared device used for the arrhythmia diagnostics such as Holter, event recorder, or other similar devices when assessment of the rhythm is necessary. RhythmAnalytics can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. RhythmAnalytics provides ECG signal	The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. While continuously recording patient ECG, both patient triggered and automatically-detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on the beat-to-beat information from the entire ECG recording. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic. The reports are provided for review by the intended user to render a diagnosis based on

Device functionality	Subject device	Predicate device	Reference device
	DeepRhythmAI	**RhythmAnalytics**	**Zio AT ECG Monitoring System**
	devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. DeepRhythmAI is not for use in life-supporting or sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.	processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. RhythmAnalytics is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices. The product can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. RhythmAnalytics interpretation results are not intended to be the sole means of diagnosis. Itis offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.	clinical judgment and experience. It is not intended for use on critical care patients.
Level of Concern	Moderate	Major	No information
Components	Software only: 1) A web API 2) An automated proprietary algorithm.	Software only: 1) A web API 2) An automated proprietary algorithm.	1) Zio AT Patch Recorder Device 2) Zio AT Wireless Gateway Device with Bluetooth and Cellular Technology 3) ZEUS System for analysis and reporting.
Interface	Web application programming interface (API)	Web application programming interface (API)	PC / Server Mix to Clinician & Patient Websites
Part responsible for ECG signal analysis	The automated proprietary deep-learning algorithm, which measures and analyzes	The automated proprietary algorithm, i.e., cardiac beats/arrhythmias	The ZEUS System (component of the Zio AT ECG Monitoring System) is an

Device functionality	Subject device	Predicate device	Reference device
	DeepRhythmAI	**RhythmAnalytics**	**Zio AT ECG Monitoring System**
	ECG data to provide qualified healthcare professional with supportive information for review.	detection which measures and analyzes ECG data to provide qualified healthcare professional supportive information for review.	electrocardiogram (ECG) analysis and reporting software, designed to process continuously recorded single-lead ECG data. The ZEUS Software downloads, stores, analyzes and sorts the ECG data to allow iRhythm's Certified Cardiographic Technicians (CCTs) to generate and distribute a report of the findings contained within the data, thereby enabling the provision of a complete ECG processing and analysis service. The ZEUS Software contains a rhythm classification algorithm utilizing deep-learning technology.
Number of leads for a received ECG signal	two lead ECG data	single-lead ECG data	single-lead ECG data
Display or Graphical User Interface (GUI)	No primary display or GUI	No primary display, it has a GUI	Has display and GUI

Device comparison summary:

- Similarities:
  1. The subject device, predicate and reference devices have the same fundamental scientific technology and intended use.
  2. The subject device, predicate and reference devices analyze ECG signals, detect and classify arrhythmias for compatible formats from FDA -cleared devices.
  3. The subject device and predicate device are software only with callable Application Programming Interface (API) used for interaction with clients.
  4. The subject device and the predicate device are not for use in patients requiring life-supporting or life-sustaining systems or ECG Alarm devices.
  5. The subject device and the predicate device provide arrhythmia analysis that are not intended to be the sole means of diagnosis. In both devices, the ECG analytics results are returned to be reviewed and interpreted by a physician or other qualified healthcare professional to make a diagnosis.
  6. The subject device, predicate and reference devices have the same patient population.
- Differences:
  1. The predicate and reference devices have Graphical User Interface (GUI), while DeepRhythmAI doesn't have GUI. This is minor difference, and it does not impact either safety or effectiveness of the product. Analysis results are made available for the user through GUI of the third-party software integrated with DeepRhythmAI, but it does not cause neither safety nor effectiveness impact. GUI just makes it easier for users.
  2. The predicate device and reference device have different Levels of Concern . The Level of Concern of the subject device has been determined according to the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medica Devices, May 11, 2005

VII. Summary of performance data

The DeepRhythmAI software for arrhythmia detection and automated analysis of ECG data has been subjected to performance testing according to the recognized consensus standards, ANSI/AAMI/IEC 60601-2-47:2012/(R)2016 and AAMI/ANSI/EC57:2012.

Medicalgorithmics followed ANSI/AAMI/IEC 62304 and the FDA Guidance Document, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January, 2002) with respect to software development and validation.

All necessary testing was conducted on the DeepRhythmAI to support a determination of substantial equivalence to the predicate and reference devices. Test results confirm that DeepRhythmAI meets its intended use.

VIII. Conclusion

The Medicalgorithmics' DeepRhythmAI is substantially equivalent to the predicate and reference devices as supported by the descriptive information and the performance testing. The subject device complies with all applicable FDA requirements, recognized consensus standards and guidance documents. Any differences in technological characteristics have been analyzed and addressed through performance testing that demonstrated that the DeepRhythmAI meets its intended use and that any differences between the subject device and the predicate and reference devices do not raise any new issues of safety or effectiveness.