June 20, 2024

Medicalgorithmics S.A.
℅ Joanna Dabala
Product Compliance Leader
Medicalgorithmics US Holding Corporation
Corporation Service Company 251 Little Falls Drive
Wilmington, Delaware 19808

Re: K232161
Trade/Device Name: DeepRhythm Platform
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: February 29, 2024
Received: February 29, 2024

Dear Joanna Dabala:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232161

Device Name
DeepRhythm Platform

Indications for Use *(Describe)*
The DeepRhythm Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in adult patients.
The product supports downloading and analyzing data recorded in compatible formats from 1-channel and 2-channel ambulatory ECG recording devices used for the arrhythmia diagnostics such as Holter, event recorder or other similar devices when retrospective assessment of the rhythm is necessary.
The DeepRhythm Platform is intended for the storage, analysis, visualization, review and reporting of arrhythmias.
The DeepRhythm Platform utilizes DeepRhythmAI (FDA-cleared device) for QRS and arrhythmia detection on the received signal. The DeepRhythm Platform provides further ECG signal annotations processing on a beat-by-beat basis, heart rate measurement and rhythm analysis, for both symptomatic and asymptomatic events.
The DeepRhythm Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.
The product can be integrated with computerized ECG monitoring devices compatible with DeepRhythmAI.
The DeepRhythm Platform 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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510(k) Summary

1 Submitter's name and address

Medicalgorithmics S.A.
Aleje Jerozolimskie 81,
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Contact Person:
Joanna Dąbała
Phone: (+48) 733888448
Email: j.dabala@medicalgorithmics.com

Date Prepared: June 14, 2024

2 Device

Trade name	DeepRhythm Platform
Common name	DR Platform, DRP
Classification name	Electrocardiograph Programmable Diagnostic Computer
Regulation number	21 CFR § 870.2340 21 CFR § 870.1425
Regulatory Class	Class II
Product Codes:	DPS, DQK

3 Predicate device

The selected predicate device is:

- **Cardiologs Holter Platform (K212112)**

4 Device description

The DeepRhythm Platform system is a cloud-based software with microservice architecture and browser-based user interface. It provides arrhythmia diagnosis process and monitoring session management capabilities.

The DeepRhythm Platform's functionality consists of:

- enrolling a patient for an ECG monitoring session in a medical facility (performed by Healthcare Professionals users),
- receiving the signal from a compatible monitoring device worn by the patient,
- using an external AI service for signal analysis and classification (not a part of the subject device),
- processing signal and annotations received from the external AI service, including statistics computation,
- reviewing the signal and annotations by an ECG Technician user,
- generating and publishing a report for a single ECG episode (Urgent report) and for the entire monitoring session (End of Study report), performed by an ECG Technician user,
- reviewing a published report back at the medical facility that ordered the monitoring session in the first place (performed by a Physician user).

5 Indications for use

The DeepRhythm Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in adult patients.

The product supports downloading and analyzing data recorded in compatible formats from 1-channel and 2-channel ambulatory ECG recording devices used for the arrhythmia diagnostics such as Holter, event recorder, or other similar devices when retrospective assessment of the rhythm is necessary.

The DeepRhythm Platform is intended for the storage, analysis, visualization, review and reporting of arrhythmias.

The DeepRhythm Platform utilizes DeepRhythmAI (FDA-cleared device) for QRS and arrhythmia detection on the received signal. The DeepRhythm Platform provides further ECG signal annotations processing on a beat-by-beat basis, heart rate measurement and rhythm analysis, for both symptomatic and asymptomatic events.

The DeepRhythm Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated with computerized ECG monitoring devices compatible with DeepRhythmAI.

The DeepRhythm Platform 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.

6 Guidance documents

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

1. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff (July 28, 2014);
2. Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (May 11, 2005);
3. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (October 2, 2014);
4. Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act., March 30,2023
5. Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (September 27, 2019);
6. Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Guidance for Industry and Food and Drug Administration Staff (September 6, 2017);
7. General Principles of Software Validation, Guidance for Industry and Food and Drug Administration Staff (January 11, 2002);
8. Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (February 3, 2016);
9. Multiple Function Device Products: Policy and Considerations, Guidance for Industry and Food and Drug Administration Staff (July 29, 2020),
10. Postmarket Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (December 28, 2016);

7 Referenced standards

The DeepRhythm Platform meet the requirements of the following performance standards in accordance with FDA recognized consensus standards:

1. AAMI/ANSI/IEC 60601-2-47:2012 /(R)2016, Medical Electrical Equipment – Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems;
2. IEC EN 60601-2-25 Edition 2.0 2011-10, Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs;
3. ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)];

4. ANSI AAMI ISO 14971 :2019 Medical devices - Applications of risk management to medical devices;
5. ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices - Part 1: Application of usability engineering to medical devices.

8 Performance data

8.1 Software Verification and Validation Testing

Software verification and validation testing were conducted and documented.

The DeepRhythm Platform has been subjected to evaluation according to the applicable clauses of recognized consensus standard, ANSI/AAMI/IEC 60601-2-47:2012 /(R)2016 and IEC EN 60601-2-25 Edition 2.0 2011-10.

The Medicalgorithmics S.A. 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 DeepRhythm Platform to support a determination of substantial equivalence to the predicate device. Test results confirm that DeepRhythm Platform meets its intended use.

The software was considered an Enhanced Level of Documentation as a design flaw or failure could directly or indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of care provider.

8.2 Usability Engineering

The DeepRhythm Platform went under the usability engineering study. It was performed according to the FDA guidance and standards: Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (February 3, 2016) and ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices - Part 1: Application of usability engineering to medical devices.

8.3 Substantial Equivalence Conclusion

The DeepRhythm Platform is substantially equivalent to the marketed predicate device – Cardiologs Holter Platform, which already has the 510(k) clearance – K212112.

Both devices – DeepRhythm Platform and Cardiologs Technologies are software products intended for use by a qualified and trained professionals for assessment of arrhythmias. Differences between the proposed device and predicate device are minor and have no impact on the safety and the effectiveness of the product. Descriptive characteristics and performance testing were used to demonstrate substantial equivalence.

In the tables below are demonstrated similarities and differences between the proposed and predicate device.

Table 1 Similarities – between proposed and predicate device

Characteristics	DeepRhythm Platform (Proposed device)	Cardiologs Holter Platform (Predicate device)
Manufacturer	Medicalgorithmics S.A.	Cardiologs Technologies
510(k) number	K232161	K212112
Classification	Class II	Class II
Regulation Number(s)	21 CFR 870.2340 21 CFR § 870.1425	21 CFR 870.2340 21 CFR § 870.1425
Classification name	Electrocardiograph Programmable Diagnostic Computer	Electrocardiograph Programmable Diagnostic Computer
Product code	DPS, DQK	DPS, DQK
Components	Software only	Software only
Display Options	Computer	Computer
Algorithm	Proprietary algorithm	Proprietary algorithm
Multiple monitoring mode options	Holter, Event recorder	Holter, event recorder, 12 lead ECG device
Intended users	Qualified and trained healthcare professionals	Qualified healthcare professionals
Alarm function	No	No

Table 2 Differences – between proposed and predicate device

Characteristics	DeepRhythm Platform (Proposed device)	Cardiologs Holter Platform (Predicate device)
Manufacturer	Medicalgorithmics S.A.	Cardiologs Technologies
Level of concern	Major	Moderate
Patient population	Adult	Adult and Pediatric
Fundamental scientific technology	DeepRhythm Platform consists of: A software interface intended for analysis, review, assessment and reporting of arrhythmias using ECG data acquired from a compatible device, coded in C# and Typescript languages, under the React and .NET frameworks. DeepRhythm Platform is compatible with an external AI service for ECG analysis, Medicalgorithmics' DeepRhythmAI, which performs QRS complexes and arrhythmia detection on the ECG signal. Additionally, DeepRhythm Platform performs statistical processing of results of data analysis received from DeepRhythmAI.	The Cardiologs Holter Platform consists of: An interface which provides tools to measure, analyze and review numerous ECGs coded in java language under the Angular and D3.js frameworks; An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide supportive information for ECG diagnosis, written in Python language. This application can be accessed through an Internet connection and a web browser, or is directly connected to the Cardiologs' Application Programming Interface (API).

Characteristics	DeepRhythm Platform (Proposed device)	Cardiologs Holter Platform (Predicate device)
Compatible devices	The DeepRhythm Platform supports downloading and analyzing data recorded in compatible formats from 1-channel and 2-channel ambulatory ECG recording devices used for the arrhythmia diagnostics such as Holter, event recorder, or other similar devices when assessment of the rhythm is necessary.	The product supports data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary.

9 Conclusion

The DeepRhythm Platform is substantially equivalent to the predicate device as supported by the descriptive information and the performance testing. The non-clinical data support the safety of the device and software verification and validation demonstrate that the DeepRhythm Platform should perform as intended in the specified use conditions.