



December 4, 2024

Medicalgorithmics S.A.  
Joanna Dabala  
Product Compliance Leader  
Aleje Jerozolimskie 81  
Warsaw, 02-001  
Poland

Re: K241197  
Trade/Device Name: DeepRhythmAI  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II  
Product Code: DQK, DPS, QYX  
Dated: November 7, 2024  
Received: November 7, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer 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

## Indications for Use

Submission Number (if known)

K241197

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, Outpatient Cardiac Telemetry devices or other similar recorders 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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## 510(k) Summary

### I. Submitter's name and address:

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

Contact Person:

Joanna Dąbala

Phone: (+48) 733 888 448

Email: j.dabala@medicalgorithmics.com

Date Prepared: 2024-11-07

### II. Device

Trade name: DeepRhythmAI

Common name: ECG Analysis System

Classification name: Programmable Diagnostic Computer/  
Electrocardiograph/ Outpatient Cardiac Telemetry

Regulation number: 870.1425  
870.2340  
870.1025

Regulatory Class: Class II

Classification Product code: DQK, DPS, QYX

### III. Substantial Equivalence

The selected predicate device is:

1. DeepRhythmAI, K210822 (Predicate 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 compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Outpatient Cardiac Telemetry devices or other similar recorders used when assessment of the rhythm is necessary. The DRAI 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 User Interface therefore it should be integrated with the external visualization software used by the ECG technicians for the ECG visualization and analysis reporting.

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, Outpatient Cardiac Telemetry devices or other similar recorders 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 device.

Detection Features comparison:

| Device functionality                                                                      | Subject device<br>(K241197) | Predicate device<br>( K182344) |
|-------------------------------------------------------------------------------------------|-----------------------------|--------------------------------|
|                                                                                           | DeepRhythmAI                | DeepRhythmAI                   |
| QRS detection                                                                             | YES                         | YES                            |
| Heart rate determination for non-paced adult                                              | YES                         | YES                            |
| R-R interval detection                                                                    | YES                         | YES                            |
| Non-paced arrhythmias interpretation                                                      | YES                         | YES                            |
| Non-paced ventricular arrhythmias calls                                                   | YES                         | YES                            |
| Atrial fibrillation detection                                                             | YES                         | YES                            |
| Cardiac beats detection<br>(Ventricular ectopic beats,<br>Supraventricular ectopic beats) | YES                         | YES                            |
| Patient populations                                                                       | Adult                       | Adult                          |

Device comparison:

| Device functionality | Subject device                                                                     | Predicate device                                     | Similarities/<br>Differences |
|----------------------|------------------------------------------------------------------------------------|------------------------------------------------------|------------------------------|
|                      | DeepRhythmAI<br>(DRAI)                                                             | DeepRhythmAI<br>(DRAI)                               |                              |
| Manufacturer         | Medicalgorithmics S.A.                                                             | Medicalgorithmics S.A.                               | N/A                          |
| 510(k) Number        | K241197                                                                            | K182344                                              | N/A                          |
| Classification       | Class II                                                                           | Class II                                             | Equivalent                   |
| Regulation Number(s) | 21 CFR §870.1425<br>21 CFR §870.2340<br>21 CFR §870.1025                           | 21 CFR §870.1425<br>21 CFR §870.2340                 | Equivalent                   |
| Classification name  | Programmable Diagnostic Computer, Electrocardiograph. Outpatient Cardiac Telemetry | Programmable Diagnostic Computer, Electrocardiograph | Equivalent                   |
| Product Code         | DQK, DPS, QYX                                                                      | DQK, DPS                                             | Equivalent                   |



| Device<br>functionality | Subject device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Predicate device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Similarities/<br>Differences |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|                         | DeepRhythmAI<br>(DRAI)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | DeepRhythmAI<br>(DRAI)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                              |
| Indications for<br>Use  | <p>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, Outpatient Cardiac Telemetry devices or other similar recorders 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.</p> | <p>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.</p> | Equivalent                   |



| Device functionality                      | Subject device                                                                                                                                                                                                                                                                                                                                                                             | Predicate device                                                                                                                                                                                                                                                                                                                                                                           | Similarities/<br>Differences |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
|                                           | DeepRhythmAI (DRAI)                                                                                                                                                                                                                                                                                                                                                                        | DeepRhythmAI (DRAI)                                                                                                                                                                                                                                                                                                                                                                        |                              |
|                                           | 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. | 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. |                              |
| Level of Concern                          | Moderate                                                                                                                                                                                                                                                                                                                                                                                   | Moderate                                                                                                                                                                                                                                                                                                                                                                                   | Equivalent                   |
| Components                                | Software only:<br>1) A web API<br>2) An automated proprietary algorithm.                                                                                                                                                                                                                                                                                                                   | Software only:<br>1) A web API<br>2) An automated proprietary algorithm.                                                                                                                                                                                                                                                                                                                   | Equivalent                   |
| Interface                                 | Web application programming interface (API)                                                                                                                                                                                                                                                                                                                                                | Web application programming interface (API)                                                                                                                                                                                                                                                                                                                                                | Equivalent                   |
| Part responsible for ECG signal analysis  | The automated proprietary deep-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information for review.                                                                                                                                                                                                               | The automated proprietary deep-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information for review.                                                                                                                                                                                                               | Equivalent                   |
| Display or Graphical User Interface (GUI) | No primary display or GUI                                                                                                                                                                                                                                                                                                                                                                  | No primary display or GUI                                                                                                                                                                                                                                                                                                                                                                  | Equivalent                   |

Device comparison summary:

The algorithm responsible for arrhythmia detection has been changed. Performance data was evaluated on the same requirements according to the

international standards ANSI/AAMI EC57:2012 and ANSI/AAMI/IEC 60601-2-47:2012/(R)2016 as the predicate device. Patient population and monitoring environments for devices are equivalent.

The subject device is considered substantially equivalent to the predicate devices.

## **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. Moreover, to enable robust device validation, the algorithm was tested against the proprietary database (MDG validation db) that includes a large number of recordings captured among the intended patient population. MDG validation database allowed for validation of additional compatible hardware configurations (MLII and MLIII leads)

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**

In conclusion, DeepRhythmAI has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, DRAI is substantially equivalent to the predicate device.