May 27, 2025

Medicalgorithmics S.A.
Agnieszka Romowicz
Product Compliance Manager
Aleje Jerozolimskie 81
Warsaw, 02-001
Poland

Re: K250932
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: March 28, 2025
Received: March 28, 2025

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 (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) 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
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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)*
K250932

Device Name
DeepRhythmAI

Indications for Use *(Describe)*
DeepRhythmAI is a cloud-based software that utilizes AI algorithms to assess cardiac arrhythmias using a single- or two-lead ECG data from 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 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.

March 28, 2025

510(k) Summary

I. Submitter's name and address:

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Aleje Jerozolimskie 81,
02-001 Warsaw, Poland

Contact Person:
Agnieszka Romowicz
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Date Prepared: 2025-03-28

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, K241197 (Predicate Device)

No reference devices were used in this submission.

IV. Device description

The DeepRhythmAI is a cloud-based software utilizing CNN and transformer models 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 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 that utilizes AI algorithms to assess cardiac arrhythmias using a single- or two-lead ECG data from 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 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 (-)**	**Predicate device (K241197)**
	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 (Ventricular ectopic beats, Supraventricular ectopic beats)	YES	YES
Patient populations	Adult	Adult

Device comparison:

Device functionality	**Subject device**	**Predicate device**	**Similarities/ Differences**
	DeepRhythmAI (DRAI)	**DeepRhythmAI (DRAI)**	
Manufacturer	Medicalgorithmics S.A.	Medicalgorithmics S.A.	N/A
510(k) Number	---	K241197	N/A
Classification	Class II	Class II	Equivalent
Regulation Number(s)	21 CFR §870.1425 21 CFR §870.2340 21 CFR §870.1025	21 CFR §870.1425 21 CFR §870.2340 21 CFR §870.1025	Equivalent
Classification name	Programmable Diagnostic Computer,	Programmable Diagnostic Computer,	Equivalent

Device functionality	Subject device	Predicate device	Similarities/ Differences
	DeepRhythmAI (DRAI)	**DeepRhythmAI (DRAI)**	
	Electrocardiograph. Outpatient Cardiac Telemetry	Electrocardiograph, Outpatient Cardiac Telemetry	
Product Code	DQK, DPS, QYX	DQK, DPS, QYX	Equivalent
Indications for Use	DeepRhythmAI is a cloud-based software that utilizes AI algorithms to assess cardiac arrhythmias using a single- or two-lead ECG data from 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 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	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	Similar, DRAI's ECG analysis capabilities were expanded to include single-lead patch recorders placed on the upper mid/left chest.

Device functionality	Subject device	Predicate device	Similarities/ Differences
	DeepRhythmAI (DRAI)	**DeepRhythmAI (DRAI)**	
	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.	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.	
Documentation Level Evaluation	Enhanced Documentation Level	Enhanced Documentation Level	Equivalent
Components	Software only: 1) A web API 2) An automated proprietary algorithm.	Software only: 1) A web API 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 modified, so that it can process two-lead and single-lead ECG recordings 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 including two-leads recorders and single lead patch recorders located on the upper, mid/left chest.

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. Unit, integration and system level testing conducted identified no residual anomalies during verification software tests. Cybersecurity testing was conducted in which no vulnerabilities were identified and all software requirements were satisfied. Overall, the software verification & validation testing was completed successfully and met all requirements. Testing demonstrated that the subject device performance was deemed to be acceptable.

VIII. Conclusion

In conclusion, DeepRythmAI has extended the intended use compared to the predicate device as it allows for two-lead and single-lead data processing but it can be still concluded that any differences in technological characteristics do not raise different questions of safety or effectiveness. compared to the predicate device. Therefore, DRAI is substantially equivalent to the predicate device.