B-Secur Limited
Cameron Moore
Quality Assurance Manager
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Belfast, BT1 3FE
United Kingdom

Re: K233755
Trade/Device Name: HeartKey® Rhythm
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: July 19, 2024
Received: July 22, 2024

Dear Cameron Moore:

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,

Kimberly N. Crowley -S

For: 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)*
K233755

Device Name
HeartKey® Rhythm

Indications for Use *(Describe)*
HeartKey Rhythm is intended for use by qualified healthcare professionals for analysing ECG data from adults. HeartKey Rhythm analyses a single ECG lead recorded from compatible devices used for arrhythmia diagnostics such as Holters, Extended Holters, ECG Patches, Event Recorders, or other similar devices when assessment of the rhythm is necessary.

The HeartKey Rhythm application program interface (API) is intended to be integrated into other device software to provide the following capabilities:

- ECG signal conditioning,
- ECG signal quality assessment,
- QRS beat detection,
- Ventricular ectopic beat detection,
- ECG rhythm analysis

HeartKey Rhythm is not intended for use in life supporting, or sustaining systems, or real-time ECG monitors, or cardiac alarm devices, or OTC-use only devices. HeartKey Rhythm analysis 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.

510(k) Summary

Date Prepared: 19 July 2024

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Proprietary or Trade Name: HeartKey® Rhythm

Common/Usual Name: Electrocardiograph

Classification Name:
21CFR 870.1425
DQK – Programmable diagnostic computer
Class II

Predicate Device: K210822 – Medicalgorithmics S.A. - DeepRhythmAI

Device Description:
HeartKey Rhythm is intended to automatically analyse ECG data and provide ECG signal processing and assessment of cardiac arrhythmias. The software processes the following types of ambulatory ECGs:

- Standard Holter: Lead I, II, III electrode configuration using gel electrodes e.g., Ag/AgCl,
- Patch: Modified Lead II, Lead III, sternum using gel electrodes e.g., Ag/AgCl

HeartKey Rhythm is capable of analysing both continuous ECGs as well as event recorders. The device provides the following analysis:

Feature	Description
ECG Signal Processing Engine (SPE)	Signal Conditioning (SC): Reduce the noise artefact present in the input ECG signal for physician review of NSR, AF and VE beats. Beat Detector (BD): Detect the QRS complexes of the input ECG signal. Signal Quality (SQ): Identify and classify the ECG segments' signal quality from the input ECG signal.
ECG Arrhythmia Analysis (AA)	Rhythm Analysis: Normal Sinus Rhythm Atrial Fibrillation Cardiac Pause Tachycardia Bradycardia Inconclusive Unreadable Beat Analysis: Normal (N) Ventricular (V) Ectopic Beat Clustering: Beat Cluster Template Beat Cluster Count QRS Location Beat Classification Heart Rate

The Software Library may be integrated into ECG management systems, ECG analysis platforms or remote patient monitoring platforms. The filtered and enhanced ECG is not intended to be used by other automated analysis algorithms.

Principle of Operation:
It is intended that the library is integrated into other software such as ECG management systems, ECG analysis platforms or remote patient monitoring platforms. Such applications could be written to run on a PC or server. All features are accessed via a documented rest application programming interface (API).

HeartKey Rhythm analyses the input ECG using a combination of rules-based calculations and AI / ML technology. The software is compiled and remains static, with no further modification of the code carried out once deployed.

Indications for Use:
HeartKey Rhythm is intended for use by qualified healthcare professionals for analysing ECG data from adults. HeartKey Rhythm analyses a single ECG lead recorded from compatible

devices used for arrhythmia diagnostics such as Holters, Extended Holters, ECG Patches, Event Recorders, or other similar devices when assessment of the rhythm is necessary.

The HeartKey Rhythm application program interface (API) is intended to be integrated into other device software to provide the following capabilities:

- ECG signal conditioning,
- ECG signal quality assessment,
- QRS beat detection,
- Ventricular ectopic beat detection,
- ECG rhythm analysis

HeartKey Rhythm is not intended for use in life supporting, or sustaining systems, or real-time ECG monitors, or cardiac alarm devices, or OTC-use only devices. HeartKey Rhythm analysis 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.

Patient Population:
Adults.

Environments of use:
Home or hospital environment.

Table 3.1. outlines the proposed device vs. the predicate.

As part of the comparison, the following shall be presented & discussed:

- Indications for Use
- Technology and Principle of Operation
- Performance and Specifications

Table 3.1 is a comparison – Subject Device vs. the Predicate, K210822 – Medicalgorithmics S.A. - DeepRhythmAI.

Note: The comparison to the predicate is based upon available technical specifications vs. comparative testing.

Table 3.1 – Comparison – Subject vs. Predicate

	Predicate DeepRhythmAl	**Subject device HeartKey® Rhythm**
K#	**K210822**	**K233755**
Product Code	**DQK and DPS**	**DQK and DPS**
CFR	870.1425	870.1425
Classification	Class II	Class II
Regulation Number(s)	21 CFR §870.1425 21 CFR §870.2340	21 CFR §870.1425 21 CFR §870.2340
Classification name	Programmable Diagnostic Computer, Electrocardiograph	Programmable Diagnostic Computer, Electrocardiograph
Intended 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.	HeartKey Rhythm is intended for use for signal processing and analysis of ambulatory ECGs. It is intended for non-active patient monitoring or for non-urgent clinical decision making.
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	HeartKey Rhythm is intended for use by qualified healthcare professionals for analysing ECG data from adults. HeartKey Rhythm analyses a single ECG lead recorded from compatible devices used for arrhythmia diagnostics such as Holters, Extended Holters, ECG Patches, Event Recorders, or other similar devices when assessment of the rhythm is necessary. The HeartKey Rhythm application program interface (API) is intended to be integrated into other device software to provide the following capabilities: ECG signal conditioning, ECG signal quality assessment, QRS beat detection, Ventricular ectopic

	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.	beat detection, ECG rhythm analysis. HeartKey Rhythm is not intended for use in life supporting, or sustaining systems, or real-time ECG monitors, or cardiac alarm devices, or OTC-use only devices. HeartKey Rhythm analysis 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/Documentation Level	Moderate	Enhanced
Components	Software only: 1) A web API 2) An automated proprietary algorithm.	Software only: 1) A web API 2) An automated proprietary algorithm.
Interface	Web application programming interface (API)	Web application programming interface (API)
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	The automated proprietary machine-learning algorithm, which measures and analyzes ECG data to provide qualified healthcare professional with supportive information

	for review.	for review.
Number of leads for a received ECG signal	Two lead ECG data	A single lead from one of the following leads: Wet Electrode Lead I, II, and III Wet Electrode Modified Leads II and III Wet Electrode Sternum Lead
Display or Graphical User Interface (GUI)	No primary display or GUI	No primary display or GUI

Substantial Equivalence Discussion
HeartKey Rhythm has the same general intended use and similar indications, technological characteristics, and principles of operation as the predicate Medicalgorithmics DeepRhythmAI, K210822.

Intended Use/ Indications for Use
The indications for use for HeartKey Rhythm and the predicate Medicalgorithmics DeepRhythmAI, K210822 both are rest API based software libraries which are intended to be integrated into computer-based ECG systems. Both devices allow for the processing and extraction of beats from an ECG signal, providing an accurate heart rate measurement, in an ambulatory environment.

Both the proposed and the predicate allow for ECG rhythm analysis and beat classification. The indications for use are substantially equivalent.

Environment of Use and Target Population
HeartKey Rhythm is intended for prescriptive use and for adults over 18. The predicate DeepRhythmAl has the same environment of use and population.

Both HeartKey Rhythm and DeepRhythmAl are intended for use in a home or hospital environment.

Technological Characteristics and Principles of Operation

HeartKey Rhythm is a library collection of callable functions that have been compiled into native machine code of the computer on which they will execute. A rest application programming interface (API) calls some or all the available functions within the library to securely exchange information. This can be deployed to a variety of cloud platforms or to a virtual or physical machine.

HeartKey Rhythm is intended to be integrated into different ECG platforms such as ECG management systems, ECG analysis platforms or remote patient monitoring platforms. Medicalgorithmics DeepRhythmAl software has the same intended use and users as the predicate.

HeartKey Rhythm provides the applications/platforms it is intended to be deployed in, with ECG signal processing and beat extraction in order to provide a heart rate reading and arrhythmia analysis to the device user. The predicate DeepRhythmAI (K210822) software assesses ambulatory electrocardiogram (ECG) rhythms from adult subjects.

HeartKey Rhythm and DeepRhythmAI are based on the following technological characteristics:

- Process ECG signals
- Detect peaks in ECG signals
- Output heart rate measurements to the user
- Rhythm analysis
- Beat classification

HeartKey Rhythm and the predicate are substantially equivalent in relation to their technological characteristics.

Non-clinical Testing

Nonclinical performance testing was conducted in compliance with the appropriate recognised consensus standards, to demonstrate that HeartKey Rhythm satisfies its design and software requirements as well as demonstrate that the ECG analysis performance is substantially equivalent to the predicate device (DeepRhythmAI, K210822). Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. B-Secur evaluated HeartKey Rhythm against a large independent proprietary set of ECGs and standard databases, comparing its analysis output against a known reference. The proprietary dataset included more than 1200 ECGs with approximately 25% females, 25% males and 50% gender unknown, approximately 16% whites, 24% non-whites, and 60% race unknown, and approximately 66% of ECGs recorded in the US. Performance testing included the evaluation of metrics such as sensitivity, specificity, and positive predictive values. These outputs were evaluated against a clinically relevant acceptance criteria to demonstrate HeartKey Rhythm's effectiveness. 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.

Verification and validation testing was completed in compliance with the following standards and guidance documents:

- ANSI/AAMI EC57:2012, Testing and Reporting Performance Results of Cardiac Rhythm And ST-Segment Measurement Algorithms.
- ANSI/AAMI/IEC 60601-2-47:2012, Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 62304:2006+A1:2015, Medical device software – Software life cycle processes.

- IEC 81001-5-1:2022, Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle.
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January, 2002)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Final Guidance for Industry and FDA Staff (September, 2023)

Substantial Equivalence Conclusion

In conclusion, HeartKey Rhythm has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness. Differences between the subject device and the predicate have been tested to ensure that the device meets its intended use. Therefore, HeartKey Rhythm is substantially equivalent to the predicate device.