December 7, 2020

B-Secur Ltd.
% Paul Dryden
Consultant
B-Secur Ltd. c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K200884
Trade/Device Name: B-Secur HeartKey Software Library
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: October 30, 2020
Received: November 2, 2020

Dear Paul Dryden:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K200884

Device Name

B-Secur HeartKey Software Library

Indications for Use *(Describe)*

The B-Secur HeartKey Software Library is intended to be used by medical device manufacturers in medical devices to assess a single lead ECG spot checks from adult patients. The product allows the processing and extraction of beats from an ECG signal to provide a heart rate reading and ECG rhythm analysis. The library will classify a 30 second ECG spot check recording as normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia, unreadable or inconclusive.

The library is intended to be integrated into other device software. All interpretations must be reviewed by a medical professional for clinical decision making, and the user of the device should not make changes to their medication without consulting a physician.

The library is not intended for use in life supporting or sustaining systems, or cardiac alarm systems.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 7-Dec-20

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Sponsor Contact: David Brown, Head of Operations

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: HeartKey Software Library

Common/Usual Name: Electrocardiograph

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

Classification Name: Electrocardiograph
Product Classification: DPS
Regulation: 21CFR 870.2340
Class: Class II

Predicate Device: K181823 – AliveCor, Inc. - KardiAI

Device Description:
The B-Secur HeartKey Software Library is an "object library". An object library is a collection of callable functions that have been compiled into native machine code of the computer on which they will execute. The HeartKey Software Library includes a basic application for viewing and analyzing electrocardiogram (ECG) data. The source code for the library is not available and cannot be modified by the end user.

The B-Secur HeartKey Software Library provides ECG signal processing and QRS detection for a single lead ECG 30s spot check. System input lead is configurable based on the application, but the typical application is arrhythmia screening from a Lead I stainless steel dry electrode device capable of carrying out periodic spot checks.

The software library is designed to accept a digital ECG stream and produce several metrics.

Feature	Description
Signal filtering	The removal of noise from the input ECG
QRS detection	Identification of QRS complexes
Heart rate	Report calculated heart rate (40 bpm – 200 bpm) from the input ECG
RR interval	Report of time between QRS complexes

Feature	Description
Signal Quality	Analysis and output of the quality of incoming signal
Arrhythmia analysis	Normal Sinus Rhythm Bradycardia Tachycardia Atrial Fibrillation Inconclusive Unreadable

All features are accessed via an application programming interface (API).

The device is only intended to analyze ECG from:

(1) "wet" lead I-or II electrodes, or
(2) lead I handheld stainless-steel dry electrodes from devices intended for automated ECG analysis.

B-Secur will compile the HeartKey library for the ECG device manufacturer. An object library will be created and delivered to the device manufacturer, who can then integrate it into their product for their ECG analysis.

It is the responsibility of the device manufacturer to integrate HeartKey correctly and to obtain the necessary regulatory approval/clearance for the final device integrating the HeartKey. It is also the responsibility of the device manufacturer to ensure their ECG device has the correct regulatory approvals and meets the required standards for their intended use; any regulatory clearance and tests that HeartKey has does not apply to an ECG device integrating HeartKey, and these processes and tests should be repeated at the system level.

Principle of Operation:
It is intended that the library is integrated into other device software. An application software program is written that calls some or all of the available functions within the software library. The application which forms the device software could be written to run on a PC, server or embedded microcontroller. All features are accessed via a documented application programming interface (API).

Indications for Use:
The B-Secur HeartKey Software Library is intended to be used by medical device manufacturers in medical devices to assess a single lead ECG spot checks from adult patients. The product allows the processing and extraction of beats from an ECG signal to provide a heart rate reading and ECG rhythm analysis. The library will classify a 30 second ECG spot check recording as normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia, unreadable or inconclusive.

The library is intended to be integrated into other device software. All interpretations must be reviewed by a medical professional for clinical decision making, and the user of the device should not make changes to their medication without consulting a physician.

The library is not intended for use in life supporting or sustaining systems, or cardiac alarm systems.

Patient Population:
Adults (over 18)

Environments of use:
Home or healthcare environment

We present the proposed device vs. the predicate in **Table 1**.

As part of the comparison we will present and discuss the:

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

Table 1 is a comparison – Subject Device vs. the Predicate, K181823 – AliveCor, Inc. - KardiAI. Note that the comparison to the predicate is based upon available technical specifications vs. comparative testing.

Table 1 – Comparison – Subject vs. Predicate

	Predicate - KardiAI	Subject device - HeartKey® Software Library	Comparison
K#	**K181823**	**K200884**	**-**
Product Code	**DQK and DPS**	**DQK and DPS**	Same
CFR	870.1425 / 870.2340	870.1425 / 870.2340	Same
Classification	Programmable Diagnostic Computer	Programmable Diagnostic Computer	Same
Indications for Use	KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects. The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software. The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices. KardiaAI provides the following capabilities: ● ECG noise filtering, ● heart rate measurement from ECGs, ● detection of noisy ECGs, and ● ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).	The B-Secur HeartKey Software Library is intended to be used by medical device manufacturers in medical devices to assess a single lead ECG spot checks from adult patients. The product allows the processing and extraction of beats from an ECG signal to provide a heart rate reading and ECG rhythm analysis. The library will classify a 30 second ECG spot check recording as normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia, unreadable or inconclusive. The library is intended to be integrated into other device software. All interpretations must be reviewed by a medical professional for clinical decision making, and the user of the device should not make changes to their medication without consulting a physician. The library is not intended for use in life supporting or sustaining systems, or cardiac alarm systems.	Similar The predicate device may be implemented in a device with OTC and/or prescriptive use. The medical device manufacturer integrating the library, or select features of the library, into an ECG monitoring device will determine the type of use for their specific application.
Target Population	Adults (over 18)	Adults (over 18)	Same
Components	Software only	Software only	Same

	Predicate - KardiAI	Subject device - HeartKey® Software Library	Comparison
Software Functional Comparisons	An interface that provides tools to process and analyze ECGs through various algorithms The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the KardiaAI's Application Programming Interface	An interface that provides tools to process and analyze ECGs through various algorithms. An application software library can be written to invoke some or all of the functions in an object library. The library can be accessed by directly calling the HeartKey Application Programming Interface.	Similar An object library is a collection of callable functions that have been compiled into native machine code of the computer on which they will execute. It is intended that an application software program is written that calls some or all of the available functions within the library.
Parameters measured	ECG Signal Processing Beat Detection Heart Rate determination for non-paced adults Arrhythmia determination for adults including Atrial Fibrillation, Tachycardia and Bradycardia	ECG Signal Processing Beat Detection Heart Rate determination for non-paced adults Arrhythmia determination for adults including Atrial Fibrillation, Tachycardia and Bradycardia	Same
Performance Testing	Algorithm performance testing was assessed using ECG databases from ANSI/AAMI EC57:2012 and other proprietary datasets	Algorithm performance testing was assessed using ECG databases from ANSI/AAMI EC57:2012 and other proprietary datasets	Same
Biocompatibility	No patient contact materials	No patient contact materials	Same

Substantial Equivalence Discussion

The HeartKey® Software Library has the same general intended use and similar indications, technological characteristics, and principles of operation as the predicate AliveCor KardiaAI, K181823.

Intended Use/ Indications for Use
The indications for use for the B-Secur HeartKey® Software Library and the predicate AliveCor KardiaAI, K181823 both are software libraries which are intended to be integrated into medical devices. Both devices allow for the processing and extraction of beats from an ECG signal, providing an accurate heart rate measurement, in either an ambulatory or non-ambulatory environment.

Both the proposed and the predicate allow for ECG rhythm analysis in order to detect Sinus Rhythm, Atrial Fibrillation, Tachycardia and Bradycardia. The indications for use are similar.

Environment of Use and Target Population
The HeartKey® Software Library is intended for prescriptive and for adults over 18. The predicate KardiaAI library has the same environment of use and population.

Both the HeartKey® Software Library and the KardiaAI library are intended for home use.

Technological Characteristics and Principles of Operation
The HeartKey® Software Library is an "object library" – a collection of callable functions that have been compiled to native machine code of the computer on which they will execute. The HeartKey® Software Library is intended to be implemented into medical devices by medical device manufacturers. The HeartKey® library has the same intended use and users as the predicate.

The HeartKey® Software Library provides the medical devices it is intended to be used in, with real time ECG signal processing and beat extraction in order to provide a heart rate reading and arrhythmia analysis to the device user. The predicate KardiaAI (K181823) software analysis library assesses ambulatory electrocardiogram (ECG) rhythms from adult subjects.
The HeartKey® Software Library and KardiaAI are based on the following technological characteristics:

- Process ECG signals
- Detect peaks in ECG signals
- Output heart rate measurements to the user
- Rhythm analysis to detect Sinus Rhythm, Atrial Fibrillation, Bradycardia and Tachycardia

The HeartKey® Software Library and the predicate are substantially equivalent in relation to their technological characteristics.

Non-clinical Testing
Non-clinical testing was conducted to assess algorithm performance and to verify that the HeartKey® Software Library performs as intended including Heart Rate Validation, Tachycardia and Bradycardia Validation, Atrial Fibrillation Validation and Arrhythmia Detection Validation assessed using ECG databases from the ANSI/AAMI EC57:2012 standard as well as B-Secur

proprietary databases. The results of the testing demonstrate that the HeartKey® Software Library performs to its specifications and meets its intended use, which is substantially equivalent to that of the predicate device.

Differences and Substantial Equivalence Conclusion

The results of nonclinical testing demonstrate that the HeartKey® Software Library meets its intended use which is equivalent to that of the predicate device. Testing also ensured that differences in technological characteristics perform as intended and do not raise different questions of safety or effectiveness.