August 10, 2018

physIQ Inc.
George Hides
Vice President, Regulatory and Clinical Affairs
300 E. 5th Avenue, Suite 105
Naperville, Illinois 60563

Re: K180234
Trade/Device Name: physIQ Heart Rhythm Module (Version 1.0)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 13, 2018
Received: July 17, 2018

Dear George Hides:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180234

Device Name

physIQ Heart Rhythm Module (Version 1.0)

Indications for Use *(Describe)*

The physIQ Heart Rhythm Module is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability and the detection of atrial fibrillation using ambulatory ECG data. The physIQ Heart Rhythm Module supports receiving and analyzing single-lead ECG signals recorded in a compatible format from FDA-cleared ECG biosensor devices using "wet" electrode technology when assessment of rhythm is desired. The physIQ Heart Rhythm Module is for use in subacute clinical and non-clinical settings for remote patient monitoring. The physIQ Heart Rhythm Module is not for use in patients requiring life-supporting or life-sustaining systems or ECG Alarm devices,

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) Notification K180234

GENERAL INFORMATION

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Trade/Proprietary Name:
physIQ Heart Rhythm Module (Version 1.0)

Generic/Common Name:
Electrocardiograph

Classification:
Class II, 21 CFR§870.2340 (Electrocardiograph)

Product Code:
DPS

Predicate Device"
Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0 (K062282)
Monebo Technologies Inc.

Indications for Use:
The physIQ Heart Rhythm Module (Version 1.0) is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability and the detection of atrial fibrillation using ambulatory ECG data. The physIQ Heart Rhythm Module supports receiving and analyzing single-lead ECG signals recorded in a compatible format from

FDA-cleared ECG biosensor devices using "wet" electrode technology when assessment of rhythm is desired. The physIQ Heart Rhythm Module is for use in subacute clinical and non-clinical settings for remote patient monitoring. The physIQ Heart Rhythm Module is not for use in patients requiring life-supporting or life-sustaining systems or ECG Alarm devices.

Product Description:
The physIQ Heart Rhythm Module (Version 1.0) is a computerized all-software callable function library in the Python programming language that is designed for calculating heart rate and heart rate variability and for detecting atrial fibrillation determined by automated analysis of any single electrocardiogram (ECG) channel collected by commercially-available ECG biosensor devices. This Heart Rhythm Module will be integrated by the customer organization into an end-to-end system (biosensor data collection to clinician display) that makes calls into the product, most typically via a Python middleware script. The "middleware" accesses the source ECG data from a customer's data collection system, most likely via its own application programming interface (API), and makes calls to the physIQ Heart Rhythm Module to input ECG for processing into the vital sign outputs of the product. These outputs are returned to the middleware, which may insert these results into a downstream monitoring system for clinical use.

Performance Testing:
physIQ's Heart Rhythm Module (Version 1.0) contains a collection of algorithms intended to be applied to ECG data collected by commercially-available ECG biosensor devices in an ambulatory setting. The collection consists of Heartbeat Detector, and Heart Rate, Heart Rate Variability and Atrial Fibrillation Detector algorithms. Performance testing following guidelines of *ANSI/AAMI EC572012: Testing and Reporting Performance Results of Cardiac Rhythm and ST segment Measurement Algorithms* has been applied to each of the algorithms. The performance testing results for all algorithms were compared to physIQ's defined acceptance criteria for performance testing. All algorithms met their corresponding acceptance criteria.

In addition, further supportive clinical validation testing of the physIQ Heart Rhythm Module was performed using electrocardiography (ECG) signals captured from ambulatory patients using a wearable single-lead biosensor device which were annotated by medical experts in cardiology. This testing did not use any patch-generated vitals, but instead compared physIQ Heart Rhythm Module outputs to annotations by cardiology experts using ECG captured from two commercially-available patches: HealthPatch (K152139) manufactured by VitalConnect Inc. and BodyGuardian (K121197; K151188) manufactured by Preventice Inc. All algorithms met acceptance criteria.

Substantial Equivalence:
The intended use and indications for use for the physIQ Heart Rhythm Module (Version 1.0) are the same as the predicate device, the Monebo Automated ECG Analysis and Interpretation Software Library Version 3.0 (K062282). Patient populations and monitoring environments for the physIQ Heart Rhythm Module are similar to the predicate device. Performance testing on the physIQ Heart Rhythm Module demonstrates comparable performance to the predicate device using international standard *ANSI/AAMI EC57:2012*. Any differences in the technological characteristics between the physIQ Heart Rhythm Module and the predicate device do not raise any new issues of safety or effectiveness. Therefore, the physIQ Heart Rhythm Module is substantially equivalent to the predicate device.

Device Functionality	**Monebo Automated ECG Analysis and Interpretation Software Library Version 3.0**	**physIQ Heart Rhythm Module (Version 1.0)**
Manufacturer	Monebo Technologies Inc.	physIQ Inc.
510(k) Number	K062282	K180234
Classification	Class II, 21 CFR §870.2340	Class II, 21 CFR §870.2340
Product Code	DPS	DPS
Indications for Use	The Automatic Analysis and Interpretation Software Library is intended for use by qualified medical professionals for the assessment of arrhythmias using historic ambulatory ECG data. The product supports downloading and analyzing data recorded incompatible formats from any device used for the arrhythmia diagnostics such as Holter, Event Monitor, 12 lead ambulatory or resting ECG devices, or other similar devices when assessment of the rhythm is necessary. The Automatic Analysis and Interpretation Software Library can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. The Automatic Analysis and Interpretation Software Library provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for up to sixteen (16) leads of captured data. The library is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices. The product can be integrated into computerized ECG monitoring devices. In this case the medical device manufacturer will identify the indication for use depending on the application of their device.	The physIQ Heart Rhythm Module is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability and the detection of atrial fibrillation using ambulatory ECG data. The physIQ Heart Rhythm Module supports receiving and analyzing single-lead ECG signals recorded in a compatible format from FDA-cleared ECG biosensor devices using “wet” electrode technology when assessment of rhythm is desired. The physIQ Heart Rhythm Module is for use in subacute clinical and non-clinical settings for remote patient monitoring. The physIQ Heart Rhythm Module is not for use in patients requiring life-supporting or life-sustaining systems or ECG Alarm devices.
Level of Concern	Moderate	Moderate
Components	Software only	Software only

Device Functionality	**Monebo Automated ECG Analysis and Interpretation Software Library Version 3.0**	**physIQ Heart Rhythm Module (Version 1.0)**
Interface	Callable application programming interface (API)	Callable application programming interface (API)
Display	No primary display	No primary display
QRS detection	YES	YES
Heart rate non-paced adult	YES	YES
Heart rate variability	YES (deterministic based on R-to-R interval derived from QRS detection which may be analyzed using spectral and time-domain approaches)	YES (deterministic based on R-to-R interval derived from QRS detection which is analyzed using a time-domain approach)
Atrial fibrillation detection	YES (classification)	YES (classification)
ECG morphological analysis	YES (including PR and QT intervals, and QRS duration	NO (other than QRS location and beat-to-beat analyses, no ECG morphological analyses are performed)
Arrhythmia classifications (other than atrial fibrillation)	YES (normal sinus rhythm, ventricular tachycardia, bradycardia, tachycardia, AV block, BBB, ventricular bigeminy, ventricular trigeminy, AIVR, pause, ventricular flutter)	NO
Patient populations	Adult	Adult
Clinical setting	Subacute (non-life-supporting or life-threatening systems required)	Subacute (non-life-supporting or life-threatening systems required)
Alarm / Trigger	NO	NO

Conclusion:
The physIQ Heart Rhythm Module (Version 1.0) has the same intended use and patient population and similar technological characteristics as those of the predicate device, the Monebo Automated ECG Analysis and Interpretation Software Library. Any differences in technological characteristics have been analyzed and addressed through performance testing which demonstrated that the physIQ Heart Rhythm Module meets it intended use and that any differences between the physIQ Heart Rhythm Module and the predicate device do not raise any new issues of safety or effectiveness. As such, the physIQ Heart Rhythm Module is substantially equivalent to the predicate device.

Summary:
Based on the information provided and the testing conducted, the physIQ Heart Rhythm Module (Version 1.0) is substantially equivalent to the predicate device.