June 11, 2020

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

Re: K193415
Trade/Device Name: physIQ Heart Rhythm and Respiration Module
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 8, 2020
Received: May 11, 2020

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/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 (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193415

Device Name
physIQ Heart Rhythm and Respiration Module (3.0)

Indications for Use *(Describe)*
The physIQ Heart Rhythm and Respiration Module (Version 3.0) is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability, the detection of atrial fibrillation and determination of respiration rate using ambulatory ECG and triaxial accelerometer data. The physIQ Heart Rhythm and Respiration Module is intended to be integrated by the customer organization into an end-to-end system (biosensor data collection to clinician display).

The physIQ Heart Rhythm and Respiration Module may only be used with FDA-cleared, chest-worn biosensors using "wet electrode" technology that capture single-lead digital ECG data at 125Hz or higher and integrated triaxial accelerometer data at 15Hz or higher and that are recorded in a compatible format for analysis.

The physIQ Heart Rhythm and Respiration Module is for use in adult patients in subacute clinical and nonclinical settings for remote patient monitoring. The physIQ Heart Rhythm and Respiration Module is not for use in patients requiring life-supporting or life-sustaining systems or as ECG or respiration 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.

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510(k) Notification K193415

GENERAL INFORMATION

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Trade/Proprietary Name:
physIQ Heart Rhythm and Respiration Module (Version 3.0)

Generic/Common Name:
Electrocardiograph

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

Product Code:
DPS

Predicate Device"
physIQ Heart Rhythm and Respiration Module, Version 2.0 (K183322)
physIQ Inc.

Indications for Use:
The physIQ Heart Rhythm and Respiration Module (Version 3.0) is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability, the detection of atrial fibrillation and determination of respiration rate using ambulatory ECG and triaxial accelerometer data. The physIQ Heart Rhythm and Respiration Module is intended to be integrated by the customer organization into an end-to-end system (biosensor data collection to clinician display).

The physIQ Heart Rhythm and Respiration Module may only be used with FDA-cleared, chest-worn biosensors using "wet electrode" technology that capture single-lead digital ECG data at 125Hz or higher and integrated triaxial accelerometer data at 15Hz or higher and that are recorded in a compatible format for analysis.

The physIQ Heart Rhythm and Respiration Module is for use in adult patients in subacute clinical and non-clinical settings for remote patient monitoring. The physIQ Heart Rhythm and Respiration Module is not for use in patients requiring life-supporting or life-sustaining systems or as ECG or respiration alarm devices.

Product Description:
The physIQ Heart Rhythm and Respiration Module (Version 3.0) 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 and determining respiration rate determined by automated analysis of any single electrocardiogram (ECG) channel collected by commercially-available ECG biosensor devices with triaxial accelerometers. The physIQ Heart Rhythm and Respiration Module (3.0) 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 and triaxial accelerometer 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 and Respiration Module (3.0) to input ECG and triaxial accelerometer data 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:
The physIQ Heart Rhythm and Respiration Module (Version 3.0) contains a collection of algorithms intended to be applied to ECG data collected by commercially-available ECG biosensor devices with triaxial accelerometers in an ambulatory setting. The collection consists of Heartbeat Detector, Heart Rate, Heart Rate Variability, Atrial Fibrillation and Respiration Rate algorithms. Performance testing following guidelines of *ANSI/AAMI EC572012: Testing and Reporting Performance Results of Cardiac Rhythm and ST segment Measurement Algorithms* was applied to heart rate, heart rate variability, and atrial fibrillation algorithms in a previous Traditional 510(k) submission for the physIQ Heart Rhythm and Respiration Module (K183322) predicate device. There are no FDA-recognized consensus standards to assess the performance of respiration rate algorithms. In the predicate submission for the physIQ Heart Rhythm Module (K183322), performance validation was provided for the determination of respiration rate. In this submission, performance of all algorithms including Heartbeat Detector, Heart Rate, Heart Rate Variability, Atrial Fibrillation, and Respiration Rate have been repeated and evaluated using the modified technology. The respiration rate algorithm met its corresponding acceptance criteria and performed comparably to the predicate device.

Substantial Equivalence:
The physIQ Heart Rhythm and Respiration Module (3.0) has the same intended use to the predicate device, the physIQ Heart Rhythm and Respiration Module (2.0). Both calculate heart rate and heart rate variability, detects atrial fibrillation and determine respiration rate from a single-lead ECG and triaxial accelerometry. The patient population for both the physIQ Heart Rhythm and Respiration Module (3.0) and the predicate device includes subacute adults who do not require life-supporting or life-sustaining systems or device alarms. Of note, the intended uses of the physIQ Heart Rhythm and Respiration Module (3.0) and the predicate device are to supplement standard of care and not to replace or substitute for

routine vital signs monitoring. Both the physIQ Heart Rhythm and Respiration Module (3.0) and the predicate have similar technological characteristics as both are all software medical devices and require input of time-series ECG from commercially available devices in a format acceptable for signal processing and algorithm function as well as triaxial accelerometry. Any differences in technological characteristics have been analyzed and addressed through performance validation testing and hazard analysis. Performance testing demonstrates that the physIQ Heart Rhythm and Respiration Module (3.0) meets its intended use and any differences in technological characteristics between the physIQ Heart Rhythm and Respiration Module (3.0) and the predicate device do not raise any new issues and is substantially equivalent to the predicate device.

The following 510(k) Summary is identical in terms of the characterization of device functionality, with the exception of the updated software version number.

Device Functionality	**physIQ Heart Rhythm and Respiration Module (Version 2.0)**	**physIQ Heart Rhythm and Respiration Module (Version 3.0)**
Comparison	510(k) ***Predicate Device***	510(k) ***Candidate Device***
Manufacturer	physIQ Inc.	physIQ Inc.
510(k) Number	K183322	K193415
Classification	Class II, 21 CFR §870.2340	Class II, 21 CFR §870.2340
Product Code	DPS	DPS
Indications for Use	The physIQ Heart Rhythm and Respiration Module (Version 2.0) is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability, the detection of atrial fibrillation and determination of respiration rate using ambulatory ECG and triaxial accelerometer data. The physIQ Heart Rhythm and Respiration Module supports receiving and analyzing single-lead ECG signals recorded in a compatible format from FDA-cleared ECG biosensor devices using “wet” electrode technology and triaxial accelerometers when assessment of rhythm and respiration rate is desired. The physIQ Heart Rhythm and Respiration Module is for use in adult patients in subacute clinical and non-clinical settings for	The physIQ Heart Rhythm and Respiration Module (Version 3.0) is intended for use by a physician or other qualified medical professionals for the calculation of heart rate and heart rate variability, the detection of atrial fibrillation and determination of respiration rate using ambulatory ECG and triaxial accelerometer data. The physIQ Heart Rhythm and Respiration Module is intended to be integrated by the customer organization into an end-to-end system (biosensor data collection to clinician display). The physIQ Heart Rhythm and Respiration may only be used with FDA-cleared, chest-worn biosensors using “wet electrode” technology that capture single-lead digital ECG data at 125Hz or

Device Functionality	physIQ Heart Rhythm and Respiration Module (Version 2.0)	physIQ Heart Rhythm and Respiration Module (Version 3.0)
	remote patient monitoring. The physIQ Heart Rhythm and Respiration Module is not for use in patients requiring life-supporting or life-sustaining systems or as ECG or respiration alarm devices.	higher and integrated triaxial accelerometer data at 15Hz or higher and that are recorded in a compatible format for analysis. The physIQ Heart Rhythm and Respiration Module is for use in adult patients in subacute clinical and non-clinical settings for remote patient monitoring. The physIQ Heart Rhythm and Respiration Module is not for use in patients requiring life-supporting or life-sustaining systems or as ECG or respiration alarm devices.
Level of Concern	Moderate	Moderate
Components	Software only	Software only
Interface	Callable application programming interface (API)	Callable application programming interface (API)
Biosensor requirements	---	FDA-cleared, chest-worn, "wet electrode" technology Single-lead digital ECG data at 125Hz or higher Triaxial accelerometer data at 15Hz or higher
Display	Compatible medical device data system (MDDS) display	Compatible medical device data system (MDDS) 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)	YES (deterministic based on R-to-R interval derived from QRS detection)
Atrial fibrillation detection	YES	YES
Respiration rate	YES	YES
ECG morphological analysis	NO (other than QRS location and beat-to-beat analyses, no ECG morphological analyses are performed)	NO (other than QRS location and beat-to-beat analyses, no ECG morphological analyses are performed)
Arrhythmia classifications (other than atrial fibrillation)	NO	NO
Patient populations	Adult	Adult

Device Functionality	physIQ Heart Rhythm and Respiration Module (Version 2.0)	physIQ Heart Rhythm and Respiration Module (Version 3.0)
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 and Respiration Module (3.0) has the same intended use and patient population and similar technological characteristics as those of the predicate device, the physIQ Heart Rhythm and Respiration Module (2.0). Differences in technological characteristics have been analyzed and addressed through performance validation testing which demonstrated that the physIQ Heart Rhythm and Respiration Module (3.0) meets it intended use and that any differences between the physIQ Heart Rhythm and Respiration Module (3.0) and the predicate devices do not raise any new issues.

Summary:
Based on the information provided and the testing conducted, the physIQ Heart Rhythm and Respiration Module (3.0) is substantially equivalent to the predicate device.

Date: 9 June 2020