July 10, 2019

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

Re: K183322
Trade/Device Name: physIQ Heart Rhythm and Respiratory Module
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 6, 2019
Received: June 10, 2019

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,

for Nicole Goodsell
External Heart Rhythm and Rate Team
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)*
K183322

Device Name
physIQ Heart Rhythm and Respiration Module (Version 2.0)

Indications for Use *(Describe)*
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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

GENERAL INFORMATION

Applicant:
physIQ Inc.
300 E. 5th Avenue
Suite 105
Naperville IL 60563
USA
Phone: (800) 561-7902

Date Prepared:
June 6, 2019

Contact Person:
George Allen Hides
Vice President, Regulatory and Clinical Affairs
physIQ Inc.
300 E. 5th Avenue
Suite 105
Naperville IL 60563
USA
Email: george.hides@physiq.com
Phone: (312) 654-1010

Trade/Proprietary Name:
physIQ Heart Rhythm and Respiration Module (Version 2.0)

Generic/Common Name:
Electrocardiograph

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

Product Code:
DPS

Predicate Device"
physIQ Heart Rhythm Module, Version 1.0 (K180234)
physIQ Inc.
HealthPatchMD/VitalPatch (K152139)
Vital Connect, Inc.

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 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 2.0) 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 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 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 2.0) 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 Module (K180234). There are no FDA-recognized consensus standards to assess the performance of respiration rate algorithms. In this submission, performance validation was performed using clinical and bench testing and results for the respiration rate algorithm were compared to internal acceptance criteria as well as to the predicate device, the Vital Connect HealthPatchMD/VitalPatch (K152139). 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 (Version 2.0) has the same intended use to the predicate devices, the physIQ Heart Rhythm Module and Vital Connect's VitalPatch (in its computational aspect). The physIQ Heart Rhythm Module calculates heart rate and heart rate variability and detects atrial fibrillation from a single-lead ECG. The Vital Connect VitalPatch calculates heart rate and heart rate variability, and determines respiration rate from a single-lead ECG plus triaxial accelerometry. The patient population for both the physIQ Heart Rhythm and Respiration Module and the predicate devices 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 and the predicate devices 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 and the physIQ Heart Rhythm Module predicate have similar safety and 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. Likewise, the physIQ Heart Rhythm and Respiration Module and the VitalPatch (in its

computational aspect) similarly require input of time-series ECG and triaxial accelerometer data. 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 meets its intended use and any differences in technological characteristics between the physIQ Heart Rhythm and Respiration Module and the predicate devices are adequately addressed. Therefore, the physIQ Heart Rhythm and Respiration Module is substantially equivalent to the predicate devices.

Device Functionality	**physIQ Heart Rhythm Module (Version 1.0)**	**HealthPatchMD/ VitalPatch**	**physIQ Heart Rhythm and Respiration Module (Version 2.0)**
Comparison	510(k) ***Predicate Device***	510(k) ***Predicate Device***	510(k) ***New Device***
Manufacturer	physIQ Inc.	Vital Connect, Inc.	physIQ Inc.
510(k) Number	K180234	K152139	TBD
Classification	Class II, 21 CFR §870.2340	Class II, 21 CFR §870.2910, §870.1025	Class II, 21 CFR §870.2340
Product Code	DPS	DRG, DSI, MHX	DPS
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	The Vital Connect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the Vital Connect Sensor for storage and analysis. The Vital Connect Platform can include the ability to notify healthcare professionals when	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

Device Functionality	physIQ Heart Rhythm Module (Version 1.0)	HealthPatchMD/ VitalPatch	physIQ Heart Rhythm and Respiration Module (Version 2.0)
	not for use in patients requiring life-supporting or life-sustaining systems or ECG Alarm devices.	physiological data fall outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the Vital Connect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.	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	Moderate
Components	Software only	Wireless data collection system comprising sensor hardware and computational firmware that computes vital signs; Relay Software Module SDK that runs on Android and iPhone; and an optional Secure Server sub-system.	Software only
Interface	Callable application programming interface (API)	Wireless offloading to smartphone via Relay Software Module.	Callable application programming interface (API)
Display	No primary display	The encrypted wireless data provided by the Sensor may be downloaded from the relay device for storage, or integrated into a Third-Party Relay Application via the APIs of the Relay Software Library	No primary display
QRS detection	YES	YES	YES

Device Functionality	physIQ Heart Rhythm Module (Version 1.0)	HealthPatchMD/ VitalPatch	physIQ Heart Rhythm and Respiration Module (Version 2.0)
Heart rate non-paced adult	YES	YES	YES
Heart rate variability	YES (deterministic based on R-to-R interval derived from QRS detection)	YES	YES (deterministic based on R-to-R interval derived from QRS detection)
Atrial fibrillation detection	YES	NO	YES
Respiration rate	NO	YES	YES
ECG morphological analysis	NO (other than QRS location and beat-to-beat analyses, no ECG morphological analyses are performed)	NO	NO (other than QRS location and beat-to-beat analyses, no ECG morphological analyses are performed)
Arrhythmia classifications (other than atrial fibrillation)	NO	NO	NO
Patient populations	Adult	Adult	Adult
Clinical setting	Subacute (non-life-supporting or life-threatening systems required)	Not intended for critical care patients.	Subacute (non-life-supporting or life-threatening systems required)
Alarm / Trigger	NO	NO	NO

Conclusion:
The physIQ Heart Rhythm and Respiration Module has the same intended use and patient population and similar technological characteristics as those of the predicate devices, the physIQ Heart Rhythm Module and the HealthPatch/VitalPatch. Differences in technological characteristics have been analyzed and addressed through performance validation testing which demonstrated that the physIQ Heart Rhythm and Respiration Module meets it intended use and that any differences between the physIQ Heart Rhythm and Respiration Module and the predicate devices dare adequately addressed. Therefore, the physIQ Heart Rhythm and Respiration Module is substantially equivalent to the predicate devices.

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