DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 11, 2015

VGBio, Inc. (DBA PhysIQ)
% Michael Billig
Regulatory Consultant
Experien Group
755 N Mathilda Avenue
Suite 100
Sunnyvale, California 94085

Re: K142512
Trade/Device Name: Personalized Physiology Analytics Engine
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: PLB (Multivariate vital signs index)
Dated: May 4, 2015
Received: May 5, 2015

Dear Michael Billig,

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. 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.

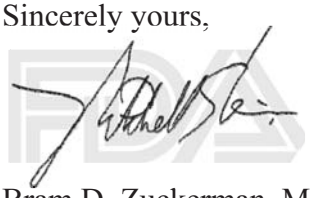
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142512

Device Name
Personalized Physiology Analytics Engine

Indications for Use *(Describe)*

The Personalized Physiology Engine (PPA Engine) is intended to be used with data from already cleared sensors measuring physiological parameters, including heart rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home. The device provides a time series Multivariate Change Index (MCI) which indicates whether the relationships among the patient's monitored vital signs change from those measured at baseline, which has been derived from measurements previously obtained during routine activities of daily living. The MCI is based on an integrated computation evaluating changes in the parameters and their relationships to each other.

The PPA Engine is an adjunct to and is not intended to replace vital signs monitoring. The MCI is intended for daily intermittent, retrospective review by a qualified practitioner. The PPA Engine is intended to provide additional information for use during routine patient monitoring. The MCI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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"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."

SECTION 5
510(k) SUMMARY

This summary of the 510(k) premarket notification for the Personalized Physiology Analytics Engine is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

510(k) SUMMARY

510(k) Notification K142512

GENERAL INFORMATION

Applicant:

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Contact Person:

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Regulatory Consultant for PhysIQ
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Date Prepared: June 10, 2015

DEVICE INFORMATION

Trade Name:

Personalized Physiology Analytics Engine

Generic/Common Name:

Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Classification:

Class II, 21 CFR§870.2300, Cardiac monitor (including cardiotachometer and rate alarm)

Product Code:

PLB

PREDICATE DEVICES

- Oxford BioSignals Ltd, BioSign™ (K053112)
- OBS Medical, Visensia® with Alert (K081140)

510(k) SUMMARY

INDICATIONS FOR USE

The Personalized Physiology Engine (PPA Engine) is intended to be used with data from already cleared sensors measuring physiological parameters, including heart rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home. The device provides a time series Multivariate Change Index (MCI) which indicates whether the relationships among the patient's monitored vital signs change from those measured at baseline, which has been derived from measurements previously obtained during routine activities of daily living. The MCI is based on an integrated computation evaluating changes in the parameters and their relationships to each other.

The PPA Engine is an adjunct to and is not intended to replace vital signs monitoring. The MCI is intended for daily intermittent, retrospective review by a qualified practitioner. The PPA Engine is intended to provide additional information for use during routine patient monitoring. The MCI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes.

PRODUCT DESCRIPTION

The PhysIQ Personalized Physiology Analytics Engine ("PPA Engine") is a computerized analysis software program that is designed for detecting change in the relationships among the patient's vital signs throughout dynamic physical activity, based on data input from multi-parameter vital sign monitoring devices. The PPA Engine first "learns" a patient's personalized baseline, defined by the relationship among the vital signs derived from measurements obtained during routine activities of daily living. Once the baseline vital sign relationships are established, it analyzes the subsequent data to assess how the relationships among the vital signs incoming during the monitoring period compare to the established baseline. The PPA Engine can analyze data collected wherever the patient is monitored, reflecting a patient's activities of daily living. The device is intended for monitoring ambulatory patients.

The PPA Engine requires vital sign inputs of Heart Rate (HR), Respiration Rate (RR) and Activity (ACT) (body motion). The PPA Engine can accept input from commercial vital sign monitors or combinations of monitors that can provide multivariate observations of these vital signs.

The PPA Engine calculates the Multivariate Change Index (MCI), a scalar index between 0 and 1, which represents the likelihood that the relationships among the patient's vital signs are different from those at baseline, which was established during routine activities of daily living. An MCI value closer to zero (0) indicates that the monitored relationships among the vital signs are similar to the learned baseline. An MCI value closer to one (1) indicates that the patient's monitored relationships among the vital signs are likely to be different from the learned baseline.

The MCI is also presented as a time series (MCI over time) and it is intended to for retrospective review by the clinician The MCI is not intended to replace standard patient monitoring. Rather, it was designed to supplement standard monitoring of ambulatory patients.

510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the PPA Engine. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the PPA Engine is substantially equivalent to the predicate devices. A comparison of the PPA Engine to the predicate devices is provided in Table 1.

510(k) SUMMARY

Table 1: Summary Substantial Equivalence Table

Feature	PhysIQ Personalized Physiology Analytics Engine (K142512)	Oxford Biosignals Ltd. BioSign™ (K053112)	OBS Medical Visensia® with Alert (K081140)
General Characteristics			
Classification	Class II, 21CFR§870.2300	Class II, 21CFR§870.2300	Class II, 21CFR§870.1025
Product Code	MWI	MWI	MHX
Patient Environment	Ambulatory	Bedside or ambulatory	Bedside or ambulatory
Patient Population	Monitored non-pediatric patients	Monitored non-pediatric high dependency patients	Monitored non-pediatric high dependency patients
Technological Characteristics			
Components	Software only	Software only	Software only
Index Produced	Non-linear combination of vital parameters	Unknown combination of vital parameters	Non-linear combination of vital parameters
Index Meaning	Index represents how different the relationships among the patient's vital signs are with respect to normality.	Index represents how different the relationships among the patient's vital signs are with respect to normality.	Index represents how different the relationships among the patient's vital signs are with respect to normality.
Index Algorithm Normality	Normality is defined as the patient's own baseline.	Normality is defined as population normality.	Normality is defined as population normality.
Index Display	• Single numeric value of latest index • Trend graph • Table	• Trend graph	• Single numeric value of latest index • Trend graph • Table
Vital Signs Data Source	Clinical Information Systems	Physiological Patient Monitors / Clinical Information Systems	Physiological Patient Monitors / Clinical Information Systems
Alert System	No	No	Audible and Visual

510(k) SUMMARY

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and clinical testing was conducted on the PPA Engine to support a determination of substantial equivalence to the predicate devices.

Bench Testing Summary:

The PPA Engine was tested to ensure that it performs as intended per its specifications, and to verify that technological differences between the PPA Engine and the predicate devices do not raise new issues of safety or effectiveness for providing a change index. The bench testing included:

- Verification testing for the PPA Engine (to verify that the device meets its specifications)
- Validation testing of the PPA Engine's MCI output (to validate correlation of MCI with changes in the relationships among vital signs compared to baseline in order to meet its intended use), including analysis of vital sign changes in human physiological data collected:
    - Perturbed clinical data study
    - Simulator data study

The collective results of the bench testing demonstrate that the software design of the PPA Engine meets the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the PPA Engine index output correlates with changes in the relationships among vital signs compared with baseline, as do the indices of the predicate devices. Thus, the PPA Engine does not raise new questions of safety or effectiveness for vital sign monitoring when compared to the predicate devices.

Clinical Testing Summary:

To validate that the PPA Engine's MCI output correlates with changes in the relationships among vital signs compared with baseline, healthy volunteer studies were conducted under an IRB-approved non-significant risk protocol, where volunteers collected vital sign data during standard activities of daily living and during a trip with a substantial altitude change (causing natural perturbation in relationships among vital signs). Study results demonstrate the MCI correlates with change in the monitored relationships among the vital signs compared to the subject's baseline; thus, the PPA Engine meets its intended use.

CONCLUSION

The PPA Engine has a subset of the elements of intended use, patient population, as well as highly similar technological characteristics as those of the predicate devices, the BioSign and Visensia. The differences in technological characteristics have been analyzed and addressed through performance testing that demonstrates that the PPA Engine meets its intended use. Any differences between the PPA Engine and the predicate devices do not raise any new issues of safety or effectiveness. As such, the PPA Engine is substantially equivalent to the predicate devices.

510(k) SUMMARY

SUMMARY

The PPA Engine is substantially equivalent to the predicate devices.