August 15, 2019

Biofourmis Singapore Pte. Ltd
% Rakesh Lal
Consultant
Rakesh Lal
7 Courtyard Pl
Lexington, Massachusetts 02420

Re: K183282
Trade/Device Name: Biovitals Analytics Engine
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: PLB
Dated: July 18, 2019
Received: July 19, 2019

Dear Rakesh Lal:

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,

Stephen Browning
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183282

Device Name
Biovitals Analytics Engine

Indications for Use *(Describe)*
The Biovitals Analytic Engine (BA Engine) is intended to be used with continuous biometric data from already cleared sensors measuring heart rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home, during periods of minimal activity. The device learns the correlation between multiple vital signs during the patient's daily activity and builds an individualized biometric signature which is dynamically updated based on incoming data. The device computes a time series Biovitals Index (BI), which reflects changes in the patient's measured vital signs from their measured baseline, which is derived from the individualized biometric signature of the patient.

The BA Engine is a cloud-based software engine, intended to be an adjunct to and is not intended to replace vital signs monitoring. The BI is intended for daily intermittent, retrospective review by a qualified practitioner. The BA Engine is intended to provide additional information for use during routine patient monitoring. The BI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes.

The device is intended for an adult population.

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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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:

Date Prepared:	July 16, 2019
Name:	Biofourmis Singapore Pte. Ltd.
Address:	Vision Exchange, #07-15 2 Venture Drive Singapore 608526
Contact Person:	Rakesh M. Lal, Consultant rakesh.m.lal@gmail.com
Phone:	(817) 734-8303

Device Information:

Trade Name:	Biovitals Analytics Engine
Common Names:	BA Engine
Classification Name(s):	Cardiovascular
Product Code/ Regulation:	PLB/21 CFR 870.2300
Classification:	Class II

Predicate Device:

- PhysIQ PPA Engine – K142512

Device Description:

Biovitals Analytics Engine consists of:

- An automated proprietary algorithm to analyze data and generate Biovitals Index.
- A cloud-based database to store the input, intermedium output and the final output
- A web application programming interface (API) which handle the continuous physiology data.
- A web application programming interface (API) query the databases and get output.
- A web dashboard to render the BA Engine output in a continuous graph format, which can help intended users to monitor a patient's Biovitals Index.

Biovitals Analytics Engine works in the following sequence:

- Accept input data via secure API;
- Analyze the input data using Biovitals Analytics Engine proprietary algorithm, which generate Biovitals Index:

    - Personal physiology signature data base initialization (at the early stage on the algorithm when the engine learns the patients and builds the personal baseline)
    - Biovitals Index calculation
- Biovitals Analytics engine generates the Biovitals Index which is a time series scalar value from 0 to 1.
- The output of BA Engine is stored in a cloud-based database.
- The output API queries the databases and gets the output, and the output shall be reviewed by the qualified practitioner via a dashboard.

Interpretation of Biovitals Index:

The BA Engine computes a time series Biovitals Index (BI), which reflects changes in the patient's measured vital signs from their measured baseline, which is derived from the individualized biometric signature of the patient. The BI is displayed in 30-minute segments and ranges from 0 to 1. The BI is intended for daily intermittent, retrospective review by a qualified practitioner.

A BI closer to 0 indicates that the relationships among the patient's vital signs are similar to the baseline. A BI value closer to 1 indicates that the relationships among the patient's vital signs are different from the baseline. The baseline is initially established using data from the first 24 hours and updated periodically as new data is received. The initial baseline comprises 3 to 13 hours of data and the updated baseline usually comprises the last 9 to 45 hours of data with low change in the relationship among the vital signs, depending on the monitoring duration.

To aid in understanding the magnitude of changes in the relationship among the patient's vital signs as compared to the baseline, the BI is divided into three categories. A BI less than or equal to 0.3 indicates that there has been little or no change in the relationship among the patient's vital signs as compared to baseline. A BI value greater than 0.3 and less than or equal to 0.7 reflects moderate change, and a BI value greater than 0.7 reflects significant change in the relationship among the patient's vital signs as compared to baseline.

The expected within-subject variability for each of the three ranges of the BI are shown in the table below.

BI Category	**Expected within-subject variability**
Low ($BI \leq 0.3$)	0.11
Moderate ($0.3 < BI \leq 0.7$)	0.27
Significant ($BI > 0.7$)	0.17

The expected within-subject variability was computed using data from a clinical study involving 50 emergency department patients that were deemed appropriate for home monitoring.

Indications for Use:

The Biovitals Analytic Engine (BA Engine) is intended to be used with continuous biometric data from already cleared sensors measuring heart rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home, during periods of minimal activity. The device learns the correlation between multiple vital signs during the patient's daily activity and builds an individualized biometric signature which is dynamically updated based on incoming data. The device computes a time series Biovitals Index (BI), which reflects changes in the patient's measured vital signs from their measured baseline, which is derived from the individualized biometric signature of the patient.

The BA Engine is a cloud-based software engine, intended to be an adjunct to and is not intended to replace vital signs monitoring. The BI is intended for daily intermittent, retrospective review by a qualified practitioner. The BA Engine is intended to provide additional information for use during routine patient monitoring. The BI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes.

The device is intended for an adult population.

Summary Comparison to Predicate:

The following tables provide a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use and substantially equivalent characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate Device:
The following table provides a comparison of the detection features of Biovitals Analytics Engine and the predicate device:

Features	Biofourmis Biovitals Analytics Engine	PhysIQ PPA Engine (K142512)	Comparison
General Characteristics			
Classification	Class II, 21 CFR 870.2300	Class II, 21 CFR 870.2300	Equivalent
Product Code	PLB	PLB	Equivalent
Intended Use	Patient Monitor (without alarms)	Patient Monitor (without alarms)	Equivalent
Indications for Use	The Biovitals Analytic Engine (BA Engine) is intended to be used with continuous biometric data from already cleared sensors measuring heart	The Personalized Physiology Engine (PPA Engine) is intended to be used with data from already cleared sensors measuring physiological	Equivalent – both devices are intended to provide an index to a physician based a patient's on vital signs, to provide additional information during routine

Features	Biofourmis Biovitals Analytics Engine	PhysIQ PPA Engine (K142512)	Comparison
	rate, respiratory rate, and activity in ambulatory patients being monitored in a healthcare facility or at home, during periods of minimal activity. The device learns the correlation between multiple vital signs during the patient's daily activity and builds an individualized biometric signature which is dynamically updated based on incoming data. The device computes a time series Biovitals Index (BI), which reflects changes in the patient's measured vital signs from their measured baseline, which is derived from the individualized biometric signature of the patient. The BA Engine is a cloud-based software engine, intended to be an adjunct to and is not intended to replace vital signs monitoring. The BI is intended for daily intermittent, retrospective review by a qualified practitioner. The BA Engine is intended to provide additional information for use during routine patient monitoring. The BI is not intended for making clinical decisions regarding patient treatment or for diagnostic purposes. The device is intended for an adult population.	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.	patient monitoring. Neither device is intended to replace vital signs monitoring, nor is either device intended to provide a diagnosis to the physician.

Features	Biofourmis Biovitals Analytics Engine	PhysIQ PPA Engine (K142512)	Comparison
Patient Population & Environment	Ambulatory | Non-pediatric	Ambulatory | Non-pediatric	Equivalent
Technological Characteristics			
Components	Cloud-based Software only	Software only	Equivalent – the only differences arise with regard to the specific implementation (software architecture, programming languages, etc.). These minor differences do not raise new questions of safety and effectiveness.
Index Produced	Non-linear combination of vital parameters	Non-linear combination of vital parameters	Equivalent – while the specific combination of the index may be different, the general approach, meaning of the index and use of baseline information are the same.
Index Meaning	Index represents how different the relationships among the patient's vital signs are with respect to normality. A BI less than or equal to 0.3 indicates that there has been little or no change in the relationship among the patient's vital signs as compared to baseline. A BI value greater than 0.3 and less than or equal to 0.7 reflects moderate change, and a BI value greater than 0.7 reflects significant change in the relationship among the patient's vital signs as compared to baseline.	Index represents how different the relationships among the patient's vital signs are with respect to normality. 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.	Equivalent – the devices have a different interpretation of the index specific to its software implementation, but the interpretation is conceptually similar, and this difference does not raise new questions of safety and effectiveness.
Index Algorithm Normality	Normality is defined as the patient's own baseline. The baseline is initially established using data from the first 24 hours and	Normality is defined as the patient's own baseline	Equivalent – the subject device's baseline is periodically updated but still reflects the same relationship among vital

Features	Biofourmis Biovitals Analytics Engine	PhysIQ PPA Engine (K142512)	Comparison
	updated periodically as new data is received.		signs as initially established in the first 24 hours. This difference does not raise new questions of safety and effectiveness.
Index Display	Single numeric value of latest index Trend graphs	Single numeric value of latest index Trend graphs Table	Equivalent – specific differences in the user interface do not raise different questions of safety and effectiveness.
Vital Signs Data Source	FDA cleared Patient Monitors and Clinical Information Systems	Clinical Information Systems	Equivalent – the subject device enables use of data captured directly from FDA cleared patient monitors. The predicate device also uses data from FDA cleared devices but obtains the data through integration with Clinical Information Systems. Since the actual sensor data is the same, this difference does not raise new questions of safety and effectiveness.
Alarm System	No	No	Equivalent

Summary of Performance Testing

Tests have been performed in compliance with the appropriate recognized consensus standards. Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. No residual anomalies appeared during verification and software validation tests. General usability tests, analyzing the users' ability to login, upload, review and download were performed and met all requirements. All software validation testing was completed successfully and met all requirements.

Summary of Clinical Testing

Clinical testing was performed with the BA Engine to evaluate the performance of the Biovitals Index. The testing was performed on a total of 50 subjects presenting at an Emergency Department,

who were deemed appropriate for home monitoring, and compared the performance of the BI against a panel of three physicians evaluating the changes in the relationship among the patients' vital sign parameters. The testing showed that the BI was correlated to the changes in relationship among vital sign parameters, with a lower bound of the 95% confidence interval of the positive percent agreement (PPA) greater than 0.7.

Software

Biofourmis followed IEC 62304:2015 and the FDA Guidance Document, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January, 2002) with respect to software development and validation. The Biofourmis software is classified as a "moderate level of concern" per the FDA guidance document.

Verification and validation testing were completed in compliance with the following standards and guidance documents:

- AAMI ANSI IEC 62304:2015, Medical device software – Software life cycle processes
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January 2002)
- IEC 62366-1 Edition 1.0 2015-02 - Medical devices - Application of usability engineering to medical devices

Conclusion

Based upon the intended use, product technical information, clinical and non-clinical testing and standards compliance provided in this premarket notification, Biovitals Analytics Engine has been shown to be substantially equivalent to the legally-marketed predicate.