May 9, 2024

Biofourmis Singapore Pte. Ltd.
Seth Kuzdzal
VP of QA/RA
2 Venture Drive, Vision Exchange, #23-01
Singapore, SG 608526
Singapore

Re: K233418
Trade/Device Name: Biofourmis Everion+ (G2)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, BZQ, MWI, DRG, DQA, FLL
Dated: March 29, 2024
Received: October 20, 2023

Dear Seth Kuzdzal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kimberly N. Crowley -S

For: Jennifer Shih Kozen
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233418

Device Name

Biofourmis Everion+ (G2)

Indications for Use *(Describe)*

Biofourmis Everion+ (G2) provides continuous monitoring of the following vital signs in adults, 18 years of age or older, when at rest:

- Pulse rate
- Respiration rate
- Movement
- Skin temperature

Biofourmis Everion+ (G2) also provides Blood oxygen saturation (SpO2) as a vital for continuous data collection in adults, 18 years of age or older, when at rest.

Biofourmis Everion+ (G2) is intended for use in a hospital or home environment to support monitoring of wearers under the care of a trained healthcare professional. Biofourmis Everion+ (G2) is not intended for use in a critical care environment such as an ICU or operating room. The device information should not be the sole basis for clinical decisions.

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.

510(k) SUMMARY

Submitter Name:	Biofourmis Singapore Pte. Ltd. 2 Venture Drive Vision Exchange, #07-15 Singapore Singapore 608526 SG
Contact Person:	Seth Kuzdzal
Phone Number:	(508) 907 9005
Submission Correspondent:	Seth Kuzdzal
Phone Number:	(508) 907 9005
Date Prepared:	April 5, 2024
Device Trade Name:	Biofourmis Everion + G2 System
Device Common Name:	Multi Parameter Monitor
Classification regulation:	21 CFR 870.2300, Product Code MWI, MSX
Predicate Devices:	Biofourmis Everion + System, G1, K213863
Predicate Devices:	Current Health Ltd., Current Health Monitoring System Gen 2 (G2)., K210133
Classification Name:	Cardiovascular
Classification regulation:	Everion + System: 21 CFR 870.2300, Product Code MSX, MWI, DRG, BZQ Current Health: 21 CFR 870.2300, Product Code MSX, FLL, DQA, BZQ, DRG, BZG

Device Description:

The Biofourmis Everion+ (G2) is a wireless multi-parameter vital-signs monitoring system. The Everion+ was includes an Application Programming Interface (API), which is intended to allow development of user interface applications that enable clinicians and medically-qualified personnel to access recorded vital signs information for patient monitoring.

The system is comprised of the following components:

- Wearable device with multiple sensors
- Secure cloud environment with an API
- Charger with accessories
- Armband

The Everion+ G2 wearable is battery-operated with integrated sensors and wireless transceiver. The device is reusable and considered multi-patient use. After a healthcare professional (HCP) prescribes a device to a patient, they can clean the device according to the accompanying documentation for normal expected wear and buildup on the device. When the patient no longer needs the device for remote monitoring, the device can be returned to the HCP and undergo a low-level disinfection process, so it can be prescribed to a new patient.

The wearable is worn on the upper arm via the adjustable armband that snaps to it. The armband is made of a stretchy material and has an adjustable clip to enable fitting to most adults. The patient contacting components primarily involved in permanent contact are the bottom device housing and the armband. The wearable continuously gathers multi-parameter vital signs data from the person being monitored and securely transmits the data to the server component of the system, via cellular communication, when in range of a third-party receiver. When not in range, the collected data is stored on the Everion+ G2 wearable and transmitted when connection has been restored. Through APIs of the cloud environment, the data may be accessed from the cloud storage or integrated into a third-party application for monitoring.

Indications for Use:
Biofourmis Everion+ G2 provides continuous monitoring of the following vital signs in adults, 18 years of age or older, when at rest:

- Pulse rate
- Respiration rate
- Movement
- Skin temperature

Biofourmis Everion+ G2 also provides Blood oxygen saturation (SpO2) as a vital for continuous data collection in adults, 18 years of age or older, when at rest.

The Biofourmis Everion+ G2 device is intended to be used in a hospital or home environment in order to support monitoring of wearers under the care of a trained healthcare professional. Everion+ is not intended for use in a critical care environment such as an ICU or operating room. The device information should not be the sole basis for clinical decisions.

Rationale for Substantial Equivalence:

The table below is a comparison of the Indications for use of the Everion + against the predicate device.

Substantial Equivalence Comparison:

Table 1 Substantial Equivalence Comparison

Characteristics	Subject Device Biofourmis Everion+ G2	Primary Predicate Biofourmis Everion+ G1 (K213863)	Secondary Predicate Current Health (K210133)	Comments
Indications for use	Biofourmis Everion+ G2 provides continuous monitoring of the following vital signs in adults, 18 years of age or older, when at rest: • Pulse rate • Respiration rate • Movement • Skin temperature Biofourmis Everion+ G2 also provides Blood oxygen saturation (SpO2) as a vital for continuous data Biofourmis Everion+ G2 is intended for use in a hospital or home environment to support monitoring of wearers (adults ≥ 18 years) under the care of a trained healthcare professional. Biofourmis Everion+ G2 is not intended for use in a critical care environment such as an ICU	Biofourmis Everion+ G1 provides continuous monitoring of the following vital signs in adults, 18 years of age or older, when at rest: • Pulse rate • Respiration rate • Movement The data from Biofourmis Everion+ G1 is intended to be used in a hospital or home environment in order to support monitoring of wearers (adults ≥ 18 years) under the care of a trained healthcare professional. Biofourmis Everion+ G1 is not intended for use in a critical care environment such as an ICU or operating room. The device information should not be the sole basis for clinical decisions.	The Current Health Gen 2 Wearable is intended for continuous monitoring of the following parameters in adults: • Pulse rate • Movement • Oxygen saturation • Temperature The Current Health Gen 2 Wearable is intended for intermittent or spot-check monitoring, in adults, of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight The Current Health Gen 2 Wearable is not intended for SpO2 monitoring in conditions of high motion or low perfusion. The Current Health Gen 2 Wearable is intended for	Subject is equivalent to primary predicate, with the addition of DQA and FLL for oximeter and thermometer functionality. Subject is equivalent to secondary predicate, except without BZG for spirometer functionality.

Characteristics	Subject Device Biofourmis Everion+ G2	Primary Predicate Biofourmis Everion+ G1 (K213863)	Secondary Predicate Current Health (K210133)	Comments
	or operating room. The device information should not be the sole basis for clinical decisions		temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Health Gen 2 Wearable is intended to provide visual and audible physiologic multi-parameter	
Regulation	21 CFR 870.2300	21 CFR 870.2300	21 CFR 870.2300	Subject is equivalent to predicates.
Product code	MWI, (21 CFR 870.2300), MSX (21 CFR 870.2300), DRG (21 CFR 870.2910), BZQ (21 CFR 868.2375), DQA (21 CFR 870.2700), FLL (21 CFR 880.2910)	MWI, (21 CFR 870.2300), MSX (21 CFR 870.2300), DRG (21 CFR 870.2910), BZQ (21 CFR 868.2375),	MSX, (21 CFR 870.2300), DRG (21 CFR 870.2910), BZQ (21 CFR 868.2375), DQA (21 CFR 870.2910), FLL (21 CFR 880.2910), BZG (21 CFR 886.1840)	Subject is equivalent to primary predicate, with the addition of DQA and FLL for oximeter and thermometer functionality. Subject is equivalent to secondary predicate, except without BZG for spirometer functionality.
Device design	The Everion+ wearable is battery-operated with integrated sensors and wireless transceiver. The wearable is worn on the upper	The Everion+ wearable is battery-operated with integrated sensors and wireless transceiver. The wearable is worn on the upper	Current Health System consists of a single battery-operated monitoring device worn on the upper arm, along with a software platform (containing an alarming system)	Subject is equivalent to primary predicate. Subject is equivalent to secondary

Characteristics	Subject Device Biofourmis Everion+ G2	Primary Predicate Biofourmis Everion+ G1 (K213863)	Secondary Predicate Current Health (K210133)	Comments
	arm via the adjustable armband that snaps to it.	arm via the adjustable armband that snaps to it.		predicate, except for an alarm system.
Principle of Operation	Optical sensors allow reflective photo-plethysmography (PPG) measurements on the skin and underlying tissue.	Optical sensors allow reflective photo-plethysmography (PPG) measurements on the skin and underlying tissue.	Optical based system	Subject is equivalent to predicates.
Data storage, transmission, display	The wearable continuously gathers multi-parameter vital signs data from the person being monitored and securely transmits the data to the server component of the system, via cellular communication, when in range of a third-party receiver. When not in range, the collected data is stored on the Everion+ wearable and transmitted when connection has been restored. Through APIs of the cloud environment, the data may be accessed from the cloud storage or integrated into a third-party application for monitoring.	The wearable continuously gathers multi-parameter vital signs data from the person being monitored and securely transmits the data to the server component of the system, via cellular communication, when in range of a third-party receiver. When not in range, the collected data is stored on the Everion+ wearable and transmitted when connection has been restored. Through APIs of the cloud environment, the data may be accessed from the cloud storage or integrated into a third-party application for monitoring.	Current Health includes a user interface to allow presentation of vital signs data both on mobile devices and a central station	Subject is equivalent to primary predicate.
Use Environment	Healthcare facilities or home environment in subjects ≥ 18 year.	Healthcare facilities or home environment in subjects ≥ 18 year.	Healthcare facilities or home environment in subjects ≥ 18 year.	Subject is equivalent to predicates.

Characteristics	Subject Device Biofourmis Everion+ G2	Primary Predicate Biofourmis Everion+ G1 (K213863)	Secondary Predicate Current Health (K210133)	Comments
Parameters monitored	Continuous: • Pulse rate • Respiration rate • Movement • Skin temperature • Oxygen saturation (SpO2) as a vital for continuous data collection	Continuous: • Pulse rate • Respiration rate • Movement	Continuous: • Pulse rate • Movement • Oxygen saturation • Temperature Episodic: • Respiration rate • Blood pressure • Lung function & spirometry • Weight	Subject is equivalent to primary predicates for continuous vitals.
Sterile	No	No	No	Subject is equivalent to predicates.
Re-usable	Yes	No	Yes	Subject is equivalent to secondary predicate.
Materials	Plastic case, ISO 10993-1:2018 compliant	Plastic case, ISO 10993-1:2018 compliant	Plastic case, ISO 10993-1:2018 compliant	Subject is equivalent to predicates.

Technological Characteristics

Biofourmis Everion+ G2 has an identical intended use, operating principle, performance, and technical specification as the primary predicative device, Biofourmis Everion+ G1 with the addition of oxygen saturation and skin temperature that were added to the indications for use. The optical module in Biofourmis Everion+ G1 is unchanged in Biofourmis Everion+ G2, however the red and infrared LEDs are used to support oxygen saturation measurements. The hardware introduced an internal thermal tab, to support the indication for skin temperature measurements. Pulse rate, respiration rate, and movement are measured using the same technology as the primary predicate device.

Substantial equivalence is based on an assessment of non-clinical performance data and clinical performance data. No animal performance data is included.

Summary of Non-Clinical Tests (Performance Data)

The performance of the Biofourmis Everion+ G2 wearable is identical to Biofourmis Everion+ G1 for pule rate, respiration rate and movement. The following verification and validation activities establish the safety and effectiveness of Biofourmis Everion+ G2, which have all passed:

Electrical, Mechanical, and Thermal Safety: The Biofourmis Everion+ G2 system met the applicable standards for electrical safety per IEC 60601-1.

Electrical, Mechanical, and Thermal Safety: The Biofourmis Everion+ G2 system met the applicable standards for electrical, mechanical, and Thermal safety per IEC 60601-1.

Electromagnetic compatibility: The Biofourmis Everion+ G2 system met the applicable standards for electromagnetic compatibility per IEC 60601-1-2, Wireless Coexistence per ANSI IEEE C63.27 and electromagnetic immunity RFID readers per AIM 7351731

Packaging: The Biofourmis Everion+ G2 system met the applicable standards for packaged product handling and transportation in a parcel delivery system per ISTA 3A.

Oxygen Saturation Accuracy: The Everion+ G2 system validated oxygen saturation accuracy with supporting clinical data, per ISO 80601-2-61 and FDA Guidance, Pulse Oximeters – Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff, March 2013.

Skin Temperature Accuracy: The Biofourmis Everion+ G2 system validated skin temperature accuracy with supporting laboratory test data, per ISO 80601-2-56.

Biocompatibility: The plastic housing material remains unchanged from Biofourmis Everion+ G1, which is compliant to ISO 10993-1: Biological evaluation of medical devices – Guidance.

Cleaning & Disinfection: The Biofourmis Everion+ G2 system validated a low-level disinfection procedure per ISO 17664-2, allowing the product to be re-used between patients. The materials are unchanged, so the cleaning validation demonstrated with Biofourmis Everion+ G1 is still applicable for basic cleaning by a subject during daily use.

System and Subsystem Verification Performance: The Biofourmis Everion+ G2 system passed product level testing, after subsystems were verified. These subsystems include hardware, firmware, and cloud components.

Summary of Animal & Clinical Studies

A series of clinical trials were conducted to assess the Biofourmis Everion+ G2 accuracy for SpO_2. The trials spanned multiple subjects with ages ranging from 19-80 years old, a wide range of BMI (17-53.5), skin tones (1-6 on Fitzpatrick Scale), ethnicities, and physiologic conditions (including COPD, CHF, Asthma, Hypertension, Obesity, and Diabetes) within the five clinical studies. The study participants wore the Biofourmis Everion+ G2 device compared to corresponding FDA cleared reference devices, including ECG for heart rate, $etCO_2$ monitor for respiratory rate, and CO-Oximeter or pulse oximeter for blood oxygen saturation.

The device accuracy for SpO2 was assessed over a range of 70-100% SaO_2 as compared to arterial blood samples assessed by CO-Oximetry and was measured using the root-mean-square (RMSE) comparison that could be no greater than a 3.5% difference. The Everion+ G2 system was validated for oxygen saturation accuracy with supporting clinical data, per ISO 80601-2-61 and FDA Guidance, Pulse Oximeters – Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff, March 2013.

The performance results from the clinical validation tests demonstrates that the Everion+ G2 is substantial equivalent to the primary and secondary predicate devices captured in the Table 1: Substantial Equivalence Comparison – Subject device to FDA-cleared predicates of this document.

Conclusion
The Biofourmis Everion+ G2 system is substantially equivalent to the predicate devices.