February 23, 2023

Biofourmis Singapore Pte. Ltd
% Nandini Murthy
Regulatory Consultant to Biofourmis
Biofourmis
33 Arch Street, Floor# 17
Boston, Massachusetts 02110

Re: K213863
Trade/Device Name: Everion+ System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, MSX, BZQ, DRG
Dated: January 20, 2023
Received: January 23, 2023

Dear Nandini Murthy:

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 Shruti N. Mistry -S

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.

510(k) Number *(if known)*
K213863

Device Name
Everion+ System

Indications for Use *(Describe)*
Everion+ 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 Everion+ 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.

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) SUMMARY

Submitter Name:	Biofourmis Singapore Pte. Ltd. 2 Venture Drive Vision Exchange, #23-01 Singapore Singapore 608526 SG
Contact Person:	Milan Shah
Phone Number:	(617) 947-8255
Submission Correspondent:	Nandini Murthy
Phone Number:	(781) 710-5378
Date Prepared:	February 22, 2023
Device Trade Name:	Everion + System
Device Common Name:	Multi Parameter Monitor
Classification regulation:	**Primary Product Code:** 21 CFR 870.2300, Product Code MWI, MSX Device: Class 2, Classification Panel: Cardiovascular **Secondary Product Code:** 21 CFR 868.2375, Product Code BZQ Device: Class 2, Classification Panel: Anesthesiology 21CFR 870.2910, Product Code DRG Device: Class 2, Classification Panel: Cardiovascular
Predicate Devices:	Current Health Ltd., K191272 Vitls Inc., K191620
Classification Name:	Cardiovascular
Classification regulation:	Current Health: 21 CFR 870.2300, Product Code MSX, DQA, BZG 21 CFR 868.2375, Product Code BZG 21CFR 870.2910, Product Code DRG, FLL 21 CFR 858.1840, Product Code BZQ Vitls Inc: 21CFR 870.2910, Product Code DRG, FLL

Device Description:

The Everion+ 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 active 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+ wearable is battery-operated with integrated sensors and wireless transceiver. 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 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.

Indications for Use:

Everion+ is intended to provide continuous monitoring of the following vital signs in adults, 18 years of age or older, when at rest:

• Pulse rate

• Respiration rate

• Movement

The Everion+ 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 Everion +	Primary Predicate K191272	Predicate 2 K191620	Comments
Indications for use	Everion+ 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 Everion+ 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.	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring	The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in in healthcare and home settings. This includes heart rate (HR) and body temperature. The data from the Tego VSS Sensor is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care. The device is intended for use as a general	The intended use and indications for use of the proposed device and the primary predicate are the same for continuous measurement of • Pulse rate • Movement The Everion + device also provides continuous measurement of Respiration Rate but does not provide for alarms and does not include temperature, heart rate, and oxygen saturation like the Current (primary predicate) Wearable device. The secondary predicate, Vitls Platform, does not include alarms, and is cleared under similar

Characteristics	Subject device Everion +	Primary Predicate K191272	Predicate 2 K191620	Comments
		where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults: • Pulse rate • Oxygen saturation • Temperature • Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of: • Respiration rate • Non-invasive blood pressure • Lung function & spirometry • Weight The Current Wearable Health Monitoring System is not intended	patient monitor, to provide physiological information, on patients who are 2 years of age or older.	product codes of DRG, FLL as the Current Wearable system. Therefore, the differences between the subject Everion + and the primary predicate Current Health wearable system and secondary Vitls Platform are not significant, does not raise new questions of safety and effectiveness.

Characteristics	Subject device Everion +	Primary Predicate K191272	Predicate 2 K191620	Comments
		for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.		
Regulation	21 CFR 870.2300 21 CFR 870.2910 21 CFR 868.2375	21 CFR 870.2300 21 CFR 870.2910 21 CFR 868.2375 21 CFR 858.1840	21 CFR 870.2910	Equivalent to primary predicate

Characteristics	Subject device Everion +	Primary Predicate K191272	Predicate 2 K191620	Comments
Product code	MWI, MSX, BZQ	MSX, FLL, DQA, BZQ, DRG, BZG	DRG, FLL	Equivalent to primary predicate for claimed measurement parameters
Device design	The Everion+ wearable is battery-operated with integrated sensors and wireless transceiver. The wearable is worn on the upper arm via the adjustable armband that snaps to it.	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)	Comprised of a wearable device with multiple sensors (the Tego VSS Sensor – an Adhesive Patch with integrated Sensors)	Equivalent to the primary device predicate system performance with the exception of not containing an alarming system.
Principle of Operation	An optical sensor allows reflective photoplethysmography (PPG) measurements to be performed on the skin and underlying tissue	Optical based system	Photoplethysmography (PPG) measurements performed using sensors integrated into an adhesive patch	Everion+ is equivalent to the secondary predicate device and similar to the primary predicate.
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	Current Health includes a user interface to allow presentation of vital signs data both on mobile devices and a central station	The encrypted wireless data recorded by the Sensor is sent, by the third-party connectivity relay, to the Secure Server. The data may be downloaded from the Secure Server Library or integrated into a Third-Party Application via the APIs of the Secure Server Library. In addition, the wireless data may be transferred to an optional Secure	Everion + is equivalent to the secondary predicate. The display of data is via use of APIs, a technological option as opposed to a custom display with the system. This difference between Everion + and the primary predicate is not significant.

Characteristics	Subject device Everion +	Primary Predicate K191272	Predicate 2 K191620	Comments
	the cloud storage or integrated into a third-party application for monitoring.		Server Library where they may be stored for future analysis.	
Use Environment	Healthcare facilities or Home environment in subjects ≥18y	Healthcare facilities & Home in subjects ≥18y	Healthcare facilities & Home in subjects ≥2y	Equivalent to primary predicate
Parameters monitored	• Pulse rate • Respiration rate • Movement	• Pulse rate • Respiration Rate • Oxygen saturation • Temperature • Movement	• Heart rate • Temperature	Similar to primary predicate and does not raise concerns on safety and efficacy.

Performance Data:
Preclinical software/algorithm testing, biocompatibility, shipping/packaging and clinical study results validate Everion + System towards its proposed intended use, and supports substantial equivalence to the predicate.

The following are the referenced standards during design and development of Everion + system:
Table 2

Standard	Name	Result
Labeling	The Everion+ System was tested and confirmed to meet all the applicable requirements for medical device symbols and labeling per ISO 15223-1, and EN 50419	Passed
Cleaning Method	The Everion+ System was tested and confirmed to meet all the applicable requirements for cleaning reusable medical devices	Passed
Biocompatibility	The Everion+ System was tested and confirmed to meet all the applicable requirements for Biocompatibility per ISO 10993-1, 10993-5, 10993-10, and 10993-12	Passed
Software Life Cycle	The Everion+ System was tested and confirmed to meet all the applicable requirements for software life cycle per IEC 62304	Passed
Risk Management	The Everion+ System was tested and confirmed to meet all the applicable requirements for Application of risk management to medical Device per ISO 14971	Passed
Product Safety and Environment	The Everion+ System was tested and confirmed to meet all the applicable requirements for product safety per IEC 60601-1 and IEC 60529, IEC 62133-2, and UL1642	Passed
Product Performance	The Everion+ System was tested and confirmed to meet all the applicable requirements for pulse rate and respiration rate per ISO 80601-2-61	Passed
EMI/EMC	The Everion+ System was tested and confirmed to meet all the applicable requirements for product emissions and immunity, wireless coexistence per IEC 60601-1-2, ANSI IEEE C63.27, CISPR11, IEC 61000-3, AAMI TIR69	Passed
Usability	The Everion+ System was tested and confirmed to meet all the applicable requirements for usability per IEC 60601-1-6 and IEC 62366-1	Passed
Home use	The Everion+ System was tested and confirmed to meet all the applicable requirements for electrical systems used in home healthcare environment per IEC 60601-1-11.	Passed
Shipping	The Everion+ System was tested and confirmed to meet all the applicable requirements for Packaged-Products	Passed

In addition to tests to the above referenced standards, the following tests were conducted:

Everion+ Hardware Test
Everion+ Product Requirement Verification
Everion+ Label Verification
Everion+ Software Verification Report – Firmware
Everion+ Software Verification Report – Cloud
Validation of Pulse Rate, Respiratory Rate, And Movement with clinical supporting data

Clinical Study Validation Summary:

The Everion + device accuracy was assessed in 50 collective subjects (M/F) of ages (46±17, 21-80 years) and wide ranges of BMI (18.6–49.3), skin tones (range: 1-6 on Fitzpatrick scale) and disease conditions from two clinical studies. The study participants wore two Everion+ devices on both left and right upper arms along with ECG monitor (for PR reference), and end-tidal CO2 capnograph monitor (for RR reference).

The device accuracy was assessed by the root-mean-square (RMSE) and mean absolute error (MAE), using the differences between the Everion+ device outputs and the respective ECG monitor's PR or manual RR reference values.

Overall. the device met the performance objectives for PR, with an RMSE of ≤ 3 bpm, and for RR, with an RMSE of ≤ 3 brpm.=

Movement detection is intended to aid in analysis of raw data, towards display of PR and RR. The multi-class confusion matrix considering all Rest, Low, Moderate and High movement level categories are given in Table 3 with the corresponding epoch count ratio and percentages in parentheses.

Table 3. Confusion Matrix with the epoch count ratio and percentages.

		Actual			
		Rest_a	Low_a	Mod_a	High_a
Device	Rest_d	1026/1535 (66.8%)	33/1529 (2.2%)	3/1600 (0.2%)	5/1411 (0.4%)
	Low_d	463/1535 (30.2%)	909/1529 (59.5%)	114/1600 (7.1%)	70/1411 (5.0%)
	Mod_d	46/1535 (3.0%)	586/1529 (38.3%)	1482/1600 (92.6%)	344/1411 (24.4%)
	High_d	0/1535 (0%)	1/1529 (0.1%)	1/1600 (0.1%)	992/1411 (70.3%)

The multi-class confusion matrix essentially captures positive percent agreement (i.e., sensitivity) on the diagonal elements for all four movement classes. Besides the sensitivity

metric, the specificity and accuracy performance metrics were also considered to understand the device performance, particularly for movement algorithm's primary purpose of differentiating rest from any movements.

Confusion matrices from one-versus-all binary classifiers and with sensitivity alongside the accuracy and specificity is in Table 4 below.

Table 4

Positive Class	Accuracy (%)	Sensitivity (%)	Specificity (%)
Level 1 – REST	88.9	66.8	98.8
Level 2 – LOW	77.7	59.5	84.4
Level 3 – MODERATE	80.1	92.6	75.0
Level 4 – HIGH	91.3	70.3	99.9
Levels 2, 3 & 4 – NONREST	88.9	98.8	66.8

Accordingly, the Everion+ device is shown to differentiate the Rest condition from other movement of any type (low, moderate, and high) with an accuracy of 88.9%

A detailed listing of all applicable V&V testing is captured in the 510(k) submission.

The Everion+ system meets the same applicable performance standards and nonclinical testing as the primary predicate device. Therefore, the Everion+ subject device is substantially equivalent to the primary predicate device.

Conclusion:

Based on the information contained within the 510(k) premarket notification, evaluation of device performance in preclinical and clinical testing where no adverse indications or results were observed, and comparison to the legally marketed predicate devices, the Everion+ is considered substantially equivalent. Therefore, we conclude that the Everion+ is substantially equivalent to the predicate devices.