December 30, 2022

BioBeat Technologies Ltd.
% John Smith
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K222010
Trade/Device Name: Biobeat Platform-2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DXN, DRG, BZQ, FLL, DXG
Dated: July 7, 2022
Received: July 7, 2022

Dear John Smith:

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,

Robert T. Kazmierski -S

for LCDR Stephen Browning
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)*

K222010

Device Name

Biobeat Platform-2

Indications for Use *(Describe)*

The Biobeat Platform-2 is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate (RRp), hemodynamic parameters (stroke volume, cardiac output), and body temperature.

The Biobeat Platform-2 tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor.

The Biobeat Platform-2 is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. The data from the Biobeat Platform-2 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.

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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"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."

K222010

510(k) SUMMARY

Biobeat Technologies Ltd.'s Biobeat Platform-2

Submitter:

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Contact Person: Johanan May

Date Prepared: December 29, 2022

Name of Device: Biobeat Platform-2

Common or Usual Name: Cardiopulmonary monitor

Classification Name/Product Code:

- 868.2375 Breathing frequency monitor, BZQ
- 870.1130 Noninvasive blood pressure measurement system, DXN
- 870.1435 Computer, Diagnostic, Pre-Programmed, Single-Function, DXG
- 870.2700 Oximeter, DQA
- 870.2910 Radiofrequency physiological signal transmitter and receiver, DRG
- 880.2910 Clinical electronic thermometer, FLL

Regulatory Class: Class II

Predicate Devices

Biobeat Platform, BB-613WP Patch (K212153) (Primary Predicate)
EV1000 Clinical Platform™ NI with the ClearSight™ Finger Cuffs or ClearSight™ System (K182245) (Additional Predicate)

System Description

The Biobeat Platform-2 includes a sensor device that is attached to the patient's chest to collect physiological data for later review by their healthcare provider. The device consists of a light source (LEDs), thermistors and sensor array on the backside of the device. The LEDs transmit light into the subject's skin and part of this light is reflected from the tissue and detected by a photo-diode. This allows measurement of arterial oxygenation, pulse rate, change in blood pressure, stroke volume, cardiac output, and respiration rate. Body temperature is measured by the thermistors. Data is transmitted to a gateway via Bluetooth and then uploaded to the cloud. From the cloud, data is transmitted and presented in a web application for review by a healthcare professional. The device does not contain any alarms.

Intended Use / Indications for Use

The Biobeat Platform-2 is a wireless non-invasive remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate (RRp), hemodynamic parameters (stroke volume, cardiac output), and body temperature.

The Biobeat Platform-2 tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor.

The Biobeat Platform-2 is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. The data from the Biobeat Platform-2 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.

Summary of Technological Characteristics

The subject and predicate devices are all intended to measure and display physiological signals. The subject device combines the parameters measured by the predicate devices into one device. Specifically, the subject device uses identical technology (i.e., the same sensor units and algorithms) for measuring SpO2, pulse rate, blood pressure, respiratory rate (RRp), and temperature compared to the primary predicate (Biobeat Platform; K212153), which is an earlier iteration of the subject device also manufactured by Biobeat. Both devices are adhesive unit-based devices intended to be attached to the chest to collect the data. In addition to the primary predicate device, a new algorithm, derived from the existing photoplethysmogram, was added for measuring stroke volume and cardiac output. This measurement capability is equivalent to the methodology used by the additional predicate, ClearSight™ System (K182245), to measure the same parameters.

There have been no physical modifications to the BB-613WP Patch itself or to the Biobeat Platform-2 as compared to the version cleared in K212153.

The subject device is supplied and used non-sterile, just like the predicate devices. The subject device uses software to control the device and analyze and display the results. The new software elements have been documented and validated per FDA guidance. The subject device contains electronics that present an electrical hazard and EMC risks. As the electronic components are identical to the primary predicate, repeated safety testing was not needed.

In sum, although there are minor differences in the technological characteristics, these differences do not raise different questions of safety or effectiveness, and the provided testing establishes equivalent performance as compared to the predicate devices.

Table 7.1: Comparison of Intended Use

Device (K number)	Subject Device Biobeat Platform-2 / BB-613WP Patch	Primary PredicateDevice Biobeat Platform / BB-613WP Patch (K212153)	Predicate Device ClearSight System (K182245)
Indications for use	The Biobeat Platform-2 is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate (RRp), hemodynamic parameters (stroke volume, cardiac output), and body temperature. The Biobeat Platform-2 tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor. The Biobeat Platform-2 is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. The data from the Biobeat Platform-2 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.	The Biobeat Platform / BB-613WP Patch is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate, and body temperature. The Biobeat Platform tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor. The Biobeat Platform is intended for spot- checking and tracking changes of adult patients in hospitals, clinics, long-term care, and home use. The data from the Biobeat 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.	The EV1000 Clinical Platform NI and the ClearSight™ Finger Cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status, and vascular resistance needs continuous or intermittent assessment. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. In addition, the non-invasive system is indicated or use in patients with co- morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform and the ClearSight™ Finger Cuffs noninvasively measures blood pressure and associated hemodynamic parameters.
Use Population	Adults	Adults	Adults
Use Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	Hospitals and other appropriate clinical environments.
Monitoring	Spot-checking	Spot-checking	Intermittent and continuous

Table 7.2: Comparison of Technological Characteristics:

K number)	Subject Device Biobeat Platform-2 / BB-613WP Patch	Primary PredicateDevice Biobeat Platform / BB-613WP Patch (K212153)	Predicate Device ClearSight System (K182245)
Principle of Operation	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflectedlight. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attachedSpO_2 sensor. RRp measured by analyzing cyclic variations in the photoplethysmogramdue to respiration. Body temperaturemeasured with thermistors.	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflectedlight. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attachedSpO_2 sensor. RRp measured by analyzing cyclic variations in the photoplethysmogramdue to respiration. Body temperaturemeasured with thermistors.	Finger SpO2 sensor measurement of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), calculation of Perfusion Index (Pi) and optional Pleth Variability Index (PVi) in adults and pediatrics. RRp measured by analyzing cyclic variations in the photoplethysmogramdue to respiration
Outputs	Oxygen Saturation(SpO2) Pulse Rate (PR) Blood Pressure (BP), Respiration Rate (RRp), Body Temperature Hemodynamic parameters including: Cardiac Output (CO), Stroke Volume (SV)	Oxygen Saturation(SpO2) Pulse Rate (PR) Blood Pressure (BP), Respiration Rate (RRp), Body Temperature	Pulse Rate (PR) Blood Pressure (Systolic, Diastolic, and Mean Arterial Pressure) Hemodynamic parameters including: Cardiac Output (CO), Stroke Volume (SV) Cardiac Index (CI) Stroke Volume Index, Systemic Vascular Resistance (SVR), Systemic Vascular Resistance Index, Stroke Volume Variation.
Measurement site	Chest-patch attached to the skin	Chest-patch attached to the skin	Finger
Body attachment method	Adhesive patch	Adhesive patch	Clamp pressure from finger cuff
Measurement type	Spot	Spot	Continuous or intermittent

K number)	Subject Device Biobeat Platform-2 / BB-613WP Patch	Primary PredicateDevice Biobeat Platform / BB-613WP Patch (K212153)	Predicate Device ClearSight System (K182245)
Emitted light peak wavelength	880nm (IR), 650nm (Red)	880nm (IR), 650nm (Red)	N/A
Measurement Range SpO_2	40% to 100%	40% to 100%	N/A
A_{rms}, SpO_2	±2%	±2%	N/A
Measurement Range, PR/HR	40 to 250 bpm	40 to 250 bpm	0 to 220 bpm
A_{rms}, PR/HR	±3%	±3%	Not specified
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg	0 mmHg – 300 mmHg
Accuracy blood pressure	±5 mmHg	±5 mmHg	1% of full scale (max 3 mmHg)
Measurement Range, CO	1.5-13 L/min	N/A	1.0 to 20.0 L/min
Accuracy, CO	±30%	N/A	Bias ≤ ± 0.6 L/min or ≤ 10% (Whichever is greater). Precision (1σ) ≤ ± 20% over the range of Cardiac Output from 2 to 20 L/min
Single use	Yes	Yes	No
Wireless BLE	Yes	Yes	Yes
Operation time	120 hours	120 hours	N/A
Contact material	Polycarbonate, photodiode window, silicone, adhesive unit	Polycarbonate, photodiode window, silicone, adhesive unit	Unknown
Application Method	The device is attached to the chest skin using a biocompatible adhesive unit	The device is attached to the chest skin using a biocompatible adhesive unit	User attaches the device to the finger
Sterility	Supplied and used non- sterile	Supplied and used non- sterile	Supplied and used non-sterile
Data display	Handheld display unit(e.g. tablet)	Handheld display unit(e.g. tablet)	Display unit

K number)	Subject Device Biobeat Platform-2 / BB-613WP Patch	Primary PredicateDevice Biobeat Platform / BB-613WP Patch (K212153)	Predicate Device ClearSight System (K182245)
Data storage	Yes, but can transmit the data to a handheld device for storage and analysis	Yes, but can transmit the data to a handheld device for storage and analysis	Yes

Performance Data

The Biobeat Platform-2 uses the same hardware as the cleared BB-613WP Patch but features some software changes, including measurements of stroke volume and cardiac output. The device contains the same sensor unit and uses the same algorithm to compute SpO2 and pulse rate and to compute and track changes in blood pressure. Therefore, these signals' evaluation testing, which was submitted in K212153, remains applicable to the subject device. Additional testing was conducted on the updated product features, including:

- Clinical validation of stroke volume and cardiac output
- Software validation per FDA guidance, *General Principles of SoftwareValidation; Final Guidance for Industry and FDA Staff* (January 11, 2002)

Clinical Validation Data

Ambulatory congestive heart failure patients arriving for right heart catheterization as part of their clinical assessment were recruited. The non-invasive Biobeat devices were simultaneously attached to their chests and frequent monitoring started in parallel to a SGC inserted through the Internal Jugular vein. Comparison was performed retrospectively, after completion of the measurement phase.

Results

90 patients (19-89yo, 53 males) were recruited, 80 were included in the final analysis comparing the PPG device and Fick, 77 were included in the final analysis comparing TD with Fick, and 82 were included in the final analysis comparing PPG with TD. The mean values of the CO measured using the indirect Fick method, the PPG device, and using the thermodilution (TD) were compared. Bland-Altman analysis showed that the PPG had LOA to the Fick method and TD within 30%.

Conclusions

The Biobeat Platform-2 is as safe and effective as its predicate devices. Specifically, the subject device has the same intended use as the predicate devices and combines the indications for use and technological characteristics of the predicates into one device. The minor technological differences between the Biobeat Platform-2 and its predicate devices, namely adding algorithms to the cloud to provide stroke volume and cardiac output measurements, raise no new issues of safety or effectiveness. Performance data demonstrate that the Biobeat Platform-2 is as safe and effective as the predicates. Thus, the Biobeat Platform-2 is substantially equivalent.