March 25, 2022

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

Re: K212153
Trade/Device Name: Biobeat Platform, BB-613WP Patch
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, DRG, BZQ, DXG, FLL
Dated: July 9, 2021
Received: July 9, 2021

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,

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)*

K212153

Device Name

Biobeat Platform, BB-613WP Patch

Indications for Use *(Describe)*

The Biobeat Platform 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), 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 at home. 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.

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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K212153

510(k) SUMMARY

Biobeat Technologies Ltd.'s BB-613 WP Patch

Submitter:

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Contact Person: Johanan May

Date Prepared: February 14, 2022

Name of Device: Biobeat Platform, BB-613WP Patch

Common or Usual Name: Breathing frequency monitor

Classification Name/Product Code:

- 868.2375 Breathing frequency monitor, BZQ
- 870.1130 Noninvasive blood pressure measurement system, DXN
- 870.1435 Single-function, preprogrammed diagnostic computer, 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's BB-613 WP (K190792) (Primary Predicate)
Masimo Corporation's MightySat Rx Fingertip Pulse Oximeter (K181956) (SecondaryPredicate)
VitalConnect, Inc,'s VitalConnect Platform (K183078) (Secondary Predicate)

System Description

The Biobeat Platform and the BB-613WP Patch sensor include a device that is attached to thepatient'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 thetissue and detected by a photo-diode. This allows measurement of arterial oxygenation, pulserate, change in blood pressure, 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 is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot-checking 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), 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 at home. The data from the Biobeat Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The deviceis 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 three predicates into one device. Specifically, the subject device uses identical technology (i.e., the same sensor unit and algorithms) for measuring SpO2, pulse rate, and blood pressure compared to the primary predicate (BB-613 WP; K190792), 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. As compared to the primary predicate, a new algorithm, derived from the existing photoplethysmogram, was added for measuring respiration rate (RRp). RRp relies upon cyclic variations in the photoplethysmogram due to respiration. This measurement capability is nearly identical to the methodology used by the MightySat Rx predicate (K181956) to measure the same parameter.

In addition, a sensor array (two thermistors) that was inactive in the prior version (K190792) has been activated as part of this submission to allow for the measurement of body temperature. The measurement methodology is nearly identical to another previously-cleareddevice (VitalConnect; K183078), which serves as the third predicate device for this submission.

There have been no physical modifications to the BB-613WP itself as compared to the versioncleared in K190792. A gateway device has been added to the system for transmission of datato the cloud and software to access the data on the cloud has been added.

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 testingestablishes equivalent performance as compared to the predicate devices.

Comparison of Intended Use

Device (K number)	Subject Device BB-613WP Patch	Primary Predicate Device BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
Indications foruse	The Biobeat Platform isa wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot-checking collection ofphysiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate (RRp), and body temperature. The Biobeat Platform tracks changes in blood pressure based on Pulse Wave TransitTime (PWTT) which is obtained utilizing pulsemeasurements 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 at home . The data from the Biobeat	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave TransitTime (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care,and home use.	The Masimo MightySat Rx Fingertip Pulse Oximeter is intendedfor hospitals, hospital-type facilities, home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicatedfor the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are wellor poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicatedfor the noninvasive spot checking of respiration rate (RRp) for adult patients.	The VitalConnect Platform is a wireless remote monitoring system intended for use byhealthcare professionals for continuous collection of physiological data in home and healthcare settings.This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Biosensor for storage and analysis. The VitalConnect Platform can include the ability tonotify healthcare professionals when physiological data fall outside selected parameters. The device is intended for use on

Device (K number)	Subject Device BB-613WP Patch	Primary Predicate Device BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
	Platform are intended for use by healthcare professionals as an aidto diagnosis and treatment. The device is not intended for use on critical care patients.			general care patients who are 18years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect 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.
Use Population	Adults	Adults	Adults and pediatrics	Adults
Use Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	Hospitals, hospital-type facilities, home environments, and transport.	Home and healthcare settings
Monitoring	Spot-checking	Spot-checking	Spot-checking	Spot-checking

Table 7.2: Comparison of Technological Characteristics:

Device (K number)	Subject Device BB-613WP Patch	Primary PredicateDevice BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
Principle of Operation	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is doneby pulse wave transit time (PWTT) which is obtained utilizing pulse	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is doneby pulse wave transit time (PWTT) which is obtained utilizing pulse	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)	Electrocardiography and accelerometer

Device (K number)	Subject Device BB-613WP Patch	Primary PredicateDevice BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
	measurements from the integrated skin attached SpO_2 sensor. RRp measured by analyzing cyclic variations in the photoplethysmogram due to respiration. Body temperature measured with thermistors.	measurements from the integrated skin attached SpO2 sensor.	in adults and pediatrics. RRp measured by analyzing cyclic variations in the photoplethysmogram due to respiration	Body temperature measured with thermistors.
Outputs	Oxygen Saturation (SpO2) Pulse Rate (PR) Blood Pressure (BP) Respiration Rate (RRp) Body Temperature	Oxygen Saturation (SpO2) Pulse Rate (PR) Blood Pressure (BP)	Oxygen Saturation (SpO2) Pulse Rate (PR) Perfusion Index (Pi) Pleth Variability Index (PVi) Respiration rate (RRp)	ECG Dynamic Range Heart Rate (HR) Respiration Rate (RRp) Fall Detection Step Count Heart Rate Variability Body Temperature
Measurement site	Chest-patch attached to the skin	Wrist area and attached to the skin	Fingertip	Chest-patch attached to the skin
Includes adhesive sheet	Yes	N/A	N/A	Yes
Measurement type	Spot	Spot	Spot	Spot
Emitted light peak wavelength	880nm (IR), 650nm (Red)	880nm (IR), 650nm (Red)	Similar	N/A
Measurement Range SpO_2	40% to 100%	40% to 100%	70% to 100%	N/A
A_{rms}, SpO_2	±2%	±2%	±2%	N/A
Measurement Range, PR/HR	40 to 250 bpm	40 to 250 bpm	25 to 240 bpm	30 to 200 bpm
A_{rms}, PR/HR	±3%	±3%	±3 bpm	<±5 or 10% bpm, whichever is greater

Device (K number)	Subject Device BB-613WP Patch	Primary PredicateDevice BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg	N/A	N/A
Accuracy blood pressure	±5 mmHg	±5 mmHg	N/A	N/A
Measurement Range, Respiration rate	4 to 40 RPM	N/A	4 to 70 RPM	10 to 30 RPM
Accuracy respiration rate	±3 RPM	N/A	±3 RPM	<±3 RPM
Measurement Range, Body Temperature	32 °C to 42 °C	N/A	N/A	32 °C to 42 °C
Body temperature iscalculated from skin temp' and ambient temp'	Yes	N/A	N/A	Yes
Accuracy Temperature	±0.3 °C	N/A	N/A	±1.0 °C
Single use	Yes	No	No	Yes
Wireless BLE	Yes	No	Yes	Yes
Operation time	120 hours	72 hours	Operation time of two AAA alkaline batteries	120 hours
Contact material	Polycarbonate, photodiode window, silicone, adhesive unit	Polycarbonate, photodiode window, silicone	Unknown	Hydrocolloid adhesive
Application Method	The device is attached tothe chest skin using a biocompatible adhesive unit	The device is attached to the skin using a wrist band or a biocompatibleadhesive unit	User attaches the device to the fingertip	The device is attached to the chest skin using a biocompatible adhesive unit
Sterility	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile
Data display	Handheld display unit (e.g. tablet)	LCD on device or handheld display unit	OLED color display screen on device and	Handheld display unit

Device (K number)	Subject Device BB-613WP Patch	Primary PredicateDevice BB-613 Watch Oximeter (K190792)	Predicate Device MightySat Rx (K181956)	Predicate Device VitalConnect (K183078)
			handheld display unit (e.g. mobile phone)	
Data storage	Limited, but can transmitthe data for storage and analysis	Yes	Yes, and can transmit the data tohandheld device	No, but can transmit the data for storage and analysis

Performance Data

The Biobeat Platform and the BB-613WP Patch uses the same hardware as the cleared BB- 613WP but features some software changes, including activation of two thermistors to measure body temperature and an option of an additional gateway device. The device contains the samesensor unit and uses the same algorithm to compute SpO2 and pulse rate and to compute andtrack changes in blood pressure. Therefore, these signals' evaluation testing, which was submitted in K190792, remains applicable to the subject device. Additional testing was conducted on the updated product features, including:

- Respiration rate validation
- Clinical validation of temperature per ISO 80601-2-56:2018
- Software validation per FDA guidance, *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (January 11, 2002)
- Cybersecurity assessment
- IEC 60601-1-2:2014 (4th Edition) EMC – Requirements and tests
- IEC 60601-1:2012 (3.1 Edition) General requirements for basic safety andessential performance
- ANSI C63.27-2017 Standard for Evaluation of Wireless Coexistence

Performance Data - Clinical Tests

Clinical validations of respiration rate and body temperature were performed to evaluate the efficacy of the new parameters. It was shown that the Biobeat Platform met the pre-specified efficacy requirements and performed in a manner that was substantially equivalent to the predicate devices.

Conclusions

The Biobeat Platform 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 and BB-613WP Patch and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Biobeat Platform and BB-613WP

Patch is as safe and effective as the predicates. Thus, the Biobeat Platform and BB-613WP Patch is substantially equivalent.