January 14, 2025

BioBeat Technologies Ltd.
℅ John Smith
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20003

Re: K241066
Trade/Device Name: BB-613-BPM
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 18, 2024
Received: April 18, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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)*
K241066

Device Name
BB-613-BPM

Indications for Use *(Describe)*
The Biobeat BB-613-BPM is a noninvasive blood pressure monitor which provides a notification to the user every 15 minutes over a 24 hour period for user- initiated measurements. It includes a device and a platform (BPM) for use in adults by healthcare professionals, for collection of pulse rate and tracking changes in blood pressure based on Pulse Wave Transit Time (PWTT) in hospitals, clinics, long-term care and at home. The BB-613-BPM tracks changes in blood pressure and requires calibration using an FDA-cleared oscillometric blood pressure monitor. The data from the Biobeat BB-613-BPM can be accessed through the Biobeat platform for review by a healthcare professional or can be downloaded as a report. The device is not intended to be used 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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."

K241066

510(k) SUMMARY

Biobeat Technologies Ltd.'s Biobeat BB-613-BPM

Submitter:

Biobeat Technologies Ltd.
22 Efal Street Petah Tikva
Israel 4951122

Phone: +972 3 933 3022
Facsimile: +972 77 460 1636

Contact Person: Johanan May

Date Prepared: January 14, 2025

Name of Device: Biobeat BB-613-BPM

Common or Usual Name: Noninvasive Blood Pressure Measurement System

Classification Name/Product Code:

- 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

Regulatory Class: Class II

Predicate Devices

BB-613 WP (K190792)
Biobeat Platform-2 (K222010)

System Description

The Biobeat BB-613-BPM 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 is designed to measure systolic and diastolic blood pressure and pulse rate, in adults, using a noninvasive technique using a light source (LEDs), and sensor array on the backside of the device. Identical to the method cleared in K190792 and in K222010, 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 pulse rate, and noninvasive blood pressure. The device is a pre-programmed 24-hour blood pressure monitor (BPM), prompting the use to take measurements at fixed intervals every 15 minutes.

In addition, the data is transmitted to a mobile application via Bluetooth and then uploaded to the cloud, accessed through the Biobeat platform for review by a healthcare professional. In addition, the data could be downloaded as a report. The device does not contain any alarms. The device is intended to be used by healthcare professionals and patients in clinical and patient's environments.

Indications for Use

The Biobeat BB-613-BPM is a noninvasive blood pressure monitor which provides a notification to the user every 15 minutes over a 24 hour period for user- initiated measurements. It includes a device and a platform (BPM) for use in adults by healthcare professionals, for collection of pulse rate and tracking changes in blood pressure based on Pulse Wave Transit Time (PWTT) in hospitals, clinics, long-term care and at home. The BB-613-BPM tracks changes in blood pressure and requires calibration using an FDA-cleared oscillometric blood pressure monitor. The data from the Biobeat BB-613-BPM can be accessed through the Biobeat platform for review by a healthcare professional or can be downloaded as a report. The device is not intended to be used on critical care patients.

Summary of Technological Characteristics

The subject and predicate devices are all intended to measure and display blood pressure. The subject device uses identical technology (i.e., the same sensor units and algorithms) for measuring pulse rate and blood pressure compared to the predicate devices cleared in K190792 (BB-613 WP – wrist and patch devices) and K222010 (Biobeat Platform-2), also manufactured by Biobeat. Both these predicates and the subject devices are skin attached devices intended to collect the data. In addition to the predicate devices, an updated software was added for the 24-hour measuring of blood pressure.

There have been no physical modifications to the BB-613-BPM Patch itself as compared to the versions cleared in K190792 and K222010.

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 predicate devices cleared in K190792 and K222010, repeated EMC or 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 BB-613-BPM Patch	Predicate Device Biobeat Platform-2 (K222010)	Predicate Device BB-613 WP (K190792)	
Indications for use	The Biobeat BB-613-BPM is a noninvasive 24-hour blood pressure monitor which provides a notification to the user every 15 minutes over a 24 hour period for user-initiated measurements. It includes a device and a platform (BPM) for use in adults by healthcare professionals, for collection of pulse rate and tracking changes in blood pressure based on Pulse Wave Transit Time (PWTT) in hospitals, clinics, long-term care and at home. The BB-613-BPM tracks changes in blood pressure and requires calibration using an FDA-cleared oscillometric blood pressure monitor. The data from the Biobeat BB-613-BPM can be accessed through the Biobeat platform for review by a healthcare professional or can be downloaded as a report. The device is not intended to be used on critical care patients.	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 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 Transit Time (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.	
Use Population	Adults	Adults	Adults	

Device (K number)	Subject Device Biobeat BB-613-BPM Patch	Predicate Device Biobeat Platform-2 (K222010)	Predicate Device BB-613 WP (K190792)	
Use Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	
Monitoring	Spot-checking	Spot-checking	Spot-checking	

Table 7.2: Comparison of Technological Characteristics:

Device (K number)	Subject Device Biobeat BB-613-BPM Patch	Predicate Device Biobeat Platform-2 (K222010)	Predicate Device BB-613 WP (K190792)	
Principle of Operation	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attached SpO_2 sensor.	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse 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.	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attached SpO_2 sensor.	
Outputs	Pulse Rate (PR) Blood Pressure (BP)	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 (SpO_2) Pulse Rate (PR) Blood Pressure (BP)	
Measurement site	Chest-patch attached to the skin	Chest-patch attached to the skin	Wrist watch or Chest-patch attached to the skin	
Body attachment method	Adhesive patch	Adhesive patch	Wrist watch or Adhesive patch	
Measurement type	Spot	Spot	Spot	
Emitted light peak wavelength	880nm (IR), 650nm (Red)	880nm (IR), 650nm (Red)	880nm (IR), 650nm (Red)	

Device (K number)	Subject Device Biobeat BB-613-BPM Patch	Predicate Device Biobeat Platform-2 (K222010)	Predicate Device BB-613 WP (K190792)	
Measurement Range, PR/HR	40 to 250 bpm	40 to 250 bpm	40 to 250 bpm	
A_{rms}, PR	±3%	±3%	±3%	
Measurement Range, BP	60 - 220 for SBP, 40 - 110 for DBP	0 – 299 mmHg	0 – 299 mmHg	
Accuracy blood pressure	±5 mmHg	±5 mmHg	±5 mmHg	
Single use	Yes	Yes	Skin patch – Yes Wrist watch - No	
Wireless BLE	Yes	Yes	Yes	
Operation time	24 hours	120 hours	120 hours	
Contact material	Polycarbonate, photodiode window, silicone, adhesive unit	Polycarbonate, photodiode window, silicone, adhesive unit	Polycarbonate, photodiode window, silicone, adhesive unit for the skin patch	
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	The device is attached to the chest skin using a biocompatible adhesive unit or to the wrist using a silicone band	
Sterility	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile	
Data display	Handheld display unit (e.g., tablet) running the Biobeat software	Handheld display unit (e.g., tablet) running the Biobeat software	Handheld display unit (e.g., tablet) running the Biobeat software	
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, but can transmit the data to a handheld device for storage and analysis	

Performance Data

The Biobeat BB-613-BPM uses the same hardware as the cleared Biobeat Platform-2 and the BB-613WP Patch but features some software changes. The device contains the same sensor unit and uses the same algorithm to compute pulse rate and blood pressure. Therefore, these signals' evaluation testing, which was submitted in K222010 and K190792, remains applicable to the subject device. Additional testing was conducted on the updated product features, including:

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

Conclusions

The Biobeat BB-613-BPM is as safe and effective as its predicate devices. The minor technological differences between the Biobeat BB-613-BPM and its predicate devices cleared in K190792 and K222010, namely adding notifications to the user to allow for 24-hour, patient initiated measurements, raise no new issues of safety or effectiveness. Performance data demonstrate that the Biobeat BB-613-BPM is as safe and effective as the predicates. Thus, the Biobeat BB-613-BPM is substantially equivalent.