Bio-Beat Technologies Ltd.
% Yarmela Pavlovic
Partner
Hogan Lovells US LLP
3 Embarcadero Center
Suite 1500
San Francisco, California 94111

Re: K181006
Trade/Device Name: BB-613 Watch Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 30, 2018
Received: August 30, 2018

Dear Yarmela Pavlovic:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: June 30, 2020
See PRA Statement on last page

510(k) Number *(if known)*

K181006

Device Name

BB-613 Watch Oximeter

Indications for Use *(Describe)*

The BB-613 Watch Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

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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K181006

510(k) SUMMARY

Bio-Beat Technologies Ltd.'s BB-613 Watch Oximeter

Submitter

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Contact Person: Johanan May

Date Prepared: September 18, 2018

Name of Device: BB-613 Watch Oximeter

Common or Usual Name: Oximeter

Classification Name: 21 C.F.R. 870.2700 Oximeter

Regulatory Class: Class II

Product Code: DQA

Predicate Devices

K163382 Oxitone Medical's Oxitone 1000

Reference Devices

K040178 SPO's PulseOX 7500
K100428 Masimo's Rainbow SET Radical 7R

Device Description

The BB-613 device is a wrist-worn device consisting of a light source (LEDs) and sensor array on the backside of the device, with a user interface on the front side of the device. The LEDs transmit light into the subject's skin at their wrist, and part of this light is reflected from the tissue and detected by a photo-diode. The integrated display is used to display the blood saturation and pulse rate results. It also displays symbols that show if there was no signal or a weak signal. The device is powered by a rechargeable battery.

Intended Use / Indications for Use

The BB-613 Watch Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

Comparison of Technological Characteristics and Indications

BB-613 is substantially equivalent to other legally marketed oximeters**.** Specifically, the BB-613 is substantially equivalent to primary predicate Oxitone Medical's Oxitone 1000 (K163382) and the reference predicates, SPO's PulseOX 7500 (K040178) and Masimo's Radical 7 (K100428). All devices are indicated for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate, although the PulseOX 7500 can also store this information. All devices are used in hospitals, clinics, long-term care, and home use, although PulseOX 7500 can also be used in sleep study environments. All devices are indicated for spot-checking of adults except for Radical 7 which is indicated for continuous noninvasive monitoring. The BB-613 has identical indications to the Oxitone 1000 except that it does not have a limitation on compatible wrist size as this limitation is not applicable to the BB-613.

Both the BB-613 and the predicates measure SpO_2 by monitoring relative changes to signal intensity of light that has passed through the patient's skin. The devices are similar in regards to the wavelengths of the emitted light and the use of reflected light measurement to assess SpO_2. The devices differ with respect to the specific anatomic structures off of which the light is reflecting. The company has performed clinical validation to show equivalent device performance in regards to SpO_2 measurements, and the pulse rate algorithm has been validated per ISO 80601-2-61:2011.

All of the devices are wrist worn and raise similar concerns of biocompatibility of permanent contact device with intact skin. All devices are supplied and used non-sterile. All devices use software to control the device and analyze and display the results. The software has been documented and validated per FDA guidance. All devices contain electronics that present electrical hazard and EMC risks. These risks have been mitigated via IEC 60601 testing. In sum, although there are minor differences in technological characteristics, these differences do not raise different questions and the provided testing establishes equivalent performance as compared to the predicates.

Item	**Subject Device BB-613**	**Primary Predicate Oxitone 1000 (K163382)**	**Reference Device PulseOX 7500 (K040178)**	**Reference Device Masimo Radical 7 (K100428)**
Device	BB-613	Oxitone 1000	PulseOX 7500 Wrist Device	Rainbow SET Radical 7R
Principle of Operation	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light	Pulse reflectance technology One LED (red + IR)	Pulse reflectance technology, One LED (red + IR) and photo diode absorbs reflected light	Absorption of red and infrared light
Measurement site	Wrist	Wrist	Finger	Finger

Item	Subject Device BB-613	Primary Predicate Oxitone 1000 (K163382)	Reference Device PulseOX 7500 (K040178)	Reference Device Masimo Radical 7 (K100428)
Measurement type	Spot	Spot	Spot	Continuous
Emitted light peak wavelength	880nm (IR), 650nm (Red)	940nm (IR), 640nm (Red)	880nm (IR), 650nm (Red)	Not specified
Measurement Range SpO_2	70% to 100%	Not specified	40% to 99%	60% to 100%
A_{rms}, SpO_2	±3%	Not specified	±2%	No motion (adults, pediatrics, infants) 60% to 80%: ±3% 70% to 100%: ±2%
Measurement Range, HR	40 to 240 bpm	Not specified	40 to 250 bpm	25 to 240 bpm
A_{rms}, HR	±3%	Not specified	±3%	No motion ±3 bpm
Contact material	Polycarbonate, photodiode window, silicone	Polycarbonate, ABS	Silicone, photodiode window	Not specified
Application Method	User wears the device as a watch and powers it on	User wears the device as a watch and powers it on	User wears the device as a watch, places the finger measurement attachment, and powers it on	User wears the device on finger
Sterility	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile
Data display	LCD on device	LCD on device	LCD on device	LCD on device
Data storage	No	No	Yes	Not specified

Performance Data

The following tests were performed to demonstrate substantial equivalence:

- Clinical validation of the oximeter per FDA pulse oximeter guidance on 10 patients with varying Fitzpatrick skin types (I – V). Patient's age ranged from 18 – 40 and 6 were male and 4 were female. Testing showed equivalence to simultaneous measurements from the predicate oximeter. No adverse events were observed.
- Pulse rate validation per ISO 80601-2-61 using a custom built simulator for reflectance oximetery.
- Software validation per FDA guidance including cybersecurity
- Electrical safety and EMC testing per ANSI/AAMI/IEC 60601-1 and IEC 60601-1-2
- Home use validation per IEC 60601-1-11

- Cytotoxicity, sensitization and irritation per ISO 10993-5, and 10993-11 to evaluate permanent contact of silicone, polycarbonate, carbon black, and stainless steel with intact skin.

Conclusions

The BB-613 Watch Oximeter is as safe and as effective as the Oxitone 1000. The BB-613 Watch Oximeter has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device when used as labeled. In addition, the minor technological differences between the BB-613 Watch Oximeter and its predicate devices do not raise different questions of safety or effectiveness. Performance data demonstrate that the BB-613 Watch Oximeter is as safe and as effective as the predicates. Thus, the BB-613 Watch Oximeter is substantially equivalent.