August 29, 2023

BodiMetrics, LLC
℅ Michael Nilo
President & Prinicipal Consultant
Nilo Medical Consulting Group, LLC
3491 Denny Street
Pittsburgh, Pennsylvania 15201

Re: K221361
Trade/Device Name: circul™ pro Ring
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 11, 2023
Received: August 14, 2023

Dear Michael Nilo:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K221361

Device Name
circul™ pro Ring

Indications for Use *(Describe)*

The circul™ pro Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot-check and/or continuous data collection of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) through the index finger in adult patients. It can be used in hospitals and home environments for up to twelve hours in non-motion and well perfused conditions. It is not intended for single-use and out-of-hospital transport use and does not have alarms.

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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This 510(k) Summary was prepared in accordance with 21 CFR 807.92

1. Date Prepared

December 2022

2. Submitter

Applicant:	BodiMetrics, LLC 1601 N. Sepulveda Blvd, Suite 839 Manhattan Beach, CA 90266
Official Contact:	Mark Goettling CEO, CFO, and Co-Founder Phone: (818) 268-6828 Email: mgoettling@bodimetrics.com
Application Correspondent:	Michael Nilo President and Principal Consultant, Nilo Medical Consulting Group Phone: (717) 421-4396 Email: michael.nilo@nilomedicalconsulting.com

3. Proposed Device Information

Trade Name:	circul™ pro Ring
Common Name:	Oximeter
Device Classification:	Name: Oximeter Regulation No.: 21 CFR 870.2700 Product Code: DQA Class: II

4. Predicate Device Information

Trade Name:	Belun Ring BLR-100X
510(k) Number:	K211407
Common Name:	Oximeter
Device Classification:	Name: Oximeter Regulation No.: 21 CFR 870.2700 Product Code: DQA Class: II

5. Reference Device Information

Trade Name:	Oxiband (Checkme) O2 Pulse Oximeter
510(k) Number:	K191088
Common Name:	Oximeter
Device Classification:	Name: Oximeter Regulation No.: 21 CFR 870.2700 Product Code: DQA Class: II

6. Device Description

The circul™ pro Ring is a small, wearable, non-invasive, wireless device that the user wears on one finger. The ring features an adjustable fit (by means of multiple ring sizes (S, L, XL) and a spring fit) for comfort and can be worn on any finger on either hand. The circul pro Ring relies on an optical sensor to detect oxygen saturation (SpO2) and pulse rate (PR). The sensor uses two wavelengths of LEDs:

- Red: with a wavelength of 660 nm ± 10 nm
- Infrared: with a wavelength of 940 nm ± 20 nm

The wavelength beyond this range has a certain impact on the accuracy of the measurement results. The blood oxygen percentage is calculated based on measuring the passage of the two wavelengths of light (with different absorption rates) through the body, also known as Reflective Oximetry. The integrated sensor technology works to determine the blood oxygen content by determining the light absorption when the skin is illuminated. The circul pro Ring features a spring mechanism, and the elastic structure of the embedded sensor and inner arch of the ring are ergonomically shaped to offer a snug fit, preventing it from slipping off the finger, stabilizing the sensor on the 'belly' of the finger, and minimizing twisting of the ring on the wearer's finger. This also helps to reduce the likelihood of poor SpO_2 readings in patients with darker skin pigments.

7. Indications for Use

The circul™ pro Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot-check and/or continuous data collection of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) through the index finger in adult patients. It can be used in hospitals and home environments for up to twelve hours in non-motion and well perfused conditions. It is not intended for single-use and out-of-hospital transport use and does not have alarms.

8. Comparison of Technical Characteristics with the Predicate Device

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
Basic Elements				
Product Name	Pulse Oximeter	Pulse Oximeter	Pulse Oximeter	Identical
Manufacturer	Hangzhou Megasens Technology Company, Ltd.	Belun Technology Company Ltd.	Shenzen Viatom Technology Co., Ltd.	N/A
FDA 510(k) Document Number	K221361	K211407	K191088	N/A
Regulation Number	870.2700	870.2700	870.2700	Identical
Classification	II	II	II	Identical
Classification Name	Oximeter	Oximeter	Oximeter	Identical
Product Code	DQA	DQA	DQA	Identical

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
Intended Use	The circul™ pro Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot-check and/or continuous data collection of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) through the index in adult patients. It can be used in hospitals and home environments for up to twelve hours in non-motion and well perfused conditions. It is not intended for single-use and out-of-hospital transport use and does not have alarms.	Belun Ring BLR-100X is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for continuous data collection and recording of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult patients through index finger in hospital and home environment for up to ten hours, during no motion and motion conditions, and for patients who are well or poorly perfused. It is not intended for single-use and out-of-hospital transport use and does not have alarms.	The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.	Substantially Equivalent Both the subject and predicate device share the indication for collection of oxygen saturation or arterial hemoglobin (SpO2) and pulse rate (PR) through the index finger and are therefore considered substantially equivalent. The subject device's indication statement reflects its functionality, in that the subject device is not intended for motion conditions. Use of the subject device for up to twelve hours is supported by testing which demonstrated safe and effective performance under these conditions. Also, the performance of the subject device was not evaluated in poorly perfused subjects and the indication reflects this. The subject device is used for spot-check or continuous data collection, and not continuous monitoring whereas the predicate device is indicated for continuous data collection. The subject device shares the same indication as the legally marketed reference device for use conditions and is therefore considered substantially equivalent. Although the subject device proposes a longer performance window and does not seek indication for motion or poorly perfused conditions relative to the predicate device, the differences in the proposed indication does not raise different questions of safety or effectiveness as the performance of the subject device is adequately supported by test data.
Technology				
Technology Type	Reflective Light	Reflective Light	Reflective Light	Identical
Intended Application Site	Finger	Finger	Finger	Identical

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
Measurement Wavelength				
Red	660 nm ± 10 nm	658 nm ± 2 nm	Not Reported	Substantially Equivalent Although the measurement wavelengths of the subject and predicate device differ slightly, the ability of the subject device to perform accurate measurements was confirmed by meeting the requirements ISO 80601-2-61 as well as a clinical validation which included darkly pigmented subjects. Therefore, the minor differences between the measurement wavelength of the subject and predicate devices do not raise different questions of safety or effectiveness.
Infrared	940 nm ± 20 nm	886 nm ± 6 nm	Not Reported	
Performance				
Interface	Bluetooth (BLE 4.1)	• USB • Bluetooth	Bluetooth	Substantially Equivalent
User Interface	Via mobile application	Via host program interface	Not reported	Substantially Equivalent The user interface of the subject and predicate device are similar, and the ability of the subject device to perform and report accurate measurements was confirmed by meeting the requirements ISO 80601-2-61 as well as a clinical validation. Therefore, the minor differences between the subject and predicate device interfaces do not raise different questions of safety or effectiveness.
Battery	3.7 V Lithium Battery	3.7 V Lithium Battery	Lithium Rechargeable Battery	Substantially Equivalent
Power Supply Requirement	5 V DC (minimum)	3.1 V – 4.2 V DC	Not reported	Substantially Equivalent The differences in power supply requirements do not raise different questions of safety or effectiveness.

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
SpO2 Measurement Range	70% - 100%	70% - 100%	Not reported	Substantially Equivalent The SpO2 measurement range of the subject device is similar to the SpO2 measurement range of the predicate and reference devices. The SpO2 measurement of the subject device meets the requirements of the ISO 80601-2-61.
SpO2 Accuracy	± 3.5% (SpO_2 within 70% - 100% range)	± 2.7%	70% - 100%: ±2% (Arms:1.88) 70%-80%: ± 3% 80%-90%: ± 2% 90%-100%: ± 2% 0%-69%: not defined	Substantially Equivalent The SpO2 measurement accuracy of the subject device is similar to the SpO2 measurement accuracy of the predicate and reference devices. The SpO2 measurement of the subject device meets the requirements of the ISO 80601-2-61, so the difference does not affect the safety and effectiveness of the subject device.
PR Measurement Range	30 bpm – 240 bpm	30 bpm – 250 bpm	30 bpm – 250 bpm	Substantially Equivalent The PR measurement range of the subject device is similar to the PR measurement range of the predicate and reference devices. The PR measurement of the subject device meets the requirements of the ISO 80601-2-61, so the difference does not affect the safety and effectiveness of the subject device.
PR Accuracy	± 2% or ± 2 bpm, whichever is greater	± 2.5bpm or ± 2%, which is larger	± 2bpm or ± 2%, whichever is greater	Substantially Equivalent The PR measurement accuracy of the subject device is within the range of the predicate and reference devices. The PR measurement accuracy of the subject device meets the requirements of ISO 80601-2-61, so any minor differences do not raise new questions of safety or effectiveness.
Atmospheric Pressure	70 kPa – 106 kPa	70 kPa – 106 kPa	70 kPa – 106 kPa	Identical

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
Operating Temperature	5°C – 40°C	10°C – 38°C	5°C – 40°C	Substantially Equivalent The operating temperature of the subject device is identical to the reference device, which is a wider range than the predicate device. The subject device met the requirements of IEC 60601-1, IEC 60601-1-11, and ISO 80601-2-61. The difference in operating temperature between the subject and predicate device does not raise new questions of safety or effectiveness.
Relative Humidity	30% - 80% (non-condensing)	≤ 75%	10% - 95%	Substantially Equivalent The relative humidity of the subject device falls within the range of the reference device. The subject device met the requirements of IEC 60601-1, IEC 60601-1-11, and ISO 80601-2-61. The difference in relative humidity between the subject and predicate device does not raise new questions of safety or effectiveness.
Storage Environment	-10°C – 50°C Temperature 15% - 95% Relative Humidity (non-condensing) 70 kPa - 106 kPa Atmospheric Pressure	-10°C - 60°C Temperature 10% - 95% Relative Humidity 50 kPa - 106 kPa Atmospheric Pressure	-25°C – 70°C	Substantially Equivalent The storage environment conditions of the subject device fall within the range of the subject and reference devices and are expressed in the device labeling. The subject device met the requirements of IEC 60601-1, IEC 60601-1-11, and ISO 80601-2-61. The difference in storage conditions between the subject and predicate device does not raise new questions of safety or effectiveness.
IP Classification	IP65	IP22	Not Reported	Substantially Equivalent The subject device met the requirements of ISO 80601-2-61. The difference in ingress protection between the subject and predicate device does not raise new questions of safety or effectiveness.
Normal Service Life	3 Years	3 Years	Not Reported	Identical

Comparison Element	Subject Device circul pro Ring	Predicate Device Belun Ring BLR 100X	Reference Device Oxiband (Checkme) O2 Pulse Oximeter	Comments
Contacting Materials	Stainless Steel, PC	TPE, PC	Not Reported	Substantially Equivalent The subject device met the requirements of ISO 10993 testing for skin-contacting materials. Therefore, the difference in contacting materials does not raise new questions of safety or effectiveness.

9. Performance Data

Non-Clinical Testing

The proposed device was tested in accordance with both mandatory and voluntary standards, including:

- ISO 80601-2-61:2017 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- EN 60601-1:2006+A1:2013 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2+A1: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The results of bench testing for pulse oximetry accuracy showed an acceptable accuracy of ± 3.5% SpO2 within a range of 70% - 100%. No claims are made for SpO_2 accuracy under conditions of motion or low perfusion. The results of bench testing for pulse rate accuracy showed an acceptable accuracy of ± 2% or ± 2 bpm (30 bpm – 240 bpm). No claims are made for Pulse Rate accuracy under conditions of motion or low perfusion.

Software validation was performed per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The management of cybersecurity is in compliance with the FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Biocompatibility testing successfully met the requirements for the skin-contacting components of the circul pro Ring per applicable standards:

- ISO 10993-5:2009: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 1099-3-10:2010: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Clinical Testing

A clinical study was performed per clause 201.12.1 of ISO 80601-2-61:2017, *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.* The study enrolled a total of twelve subjects, four of which had dark pigmentation (33.3%). In the study, the subjects' blood oxygen saturation was measured using the circul pro Ring and the values were then compared with arterial saturation values recorded by a Blood Gas, Blood Oxygen, Electrolyte, and Metabolite Analyzer.

The primary endpoint of the study was the accuracy of the circul pro pulse blood oxygen saturation measurements as compared to the SaO_2 measurements of the control device. The measurement error of the circul pro Ring in the range of 70% - 100% should be ≤ 3.5%. The secondary endpoints of the study were:

- The accuracy of the pulse rate recorded by the circul pro Ring as compared to the heart rate measured by a control patient monitor (IntelliVue Patient Monitor MX500/MX550)
- The overall device safety, operational stability, device defects, and incidence of adverse events (complications)
    - Overall device safety
        - Breaking of the connecting parts of the overall device system
        - Parts loose and falling off during use, resulting in abnormal operation
        - Unable to return to normal when rebooting
        - Other (with a description provided)
    - Operational stability
        - Unable to match the machine
        - Poor contact during use
        - Abnormal interruption occurring for reasons attributable to the machine during use
        - Other (with a description provided)
    - Device defects
        - Device failures or defects (including the overall safety of the tested device, operational stability, and whether any failure of the tested device caused any injury to the subject) during the trial
    - Incidence of adverse events
        - Where a medical oximeter is placed, the probe overheated and the skin showed an allergic reaction
        - Other (with a description provided)

The Accuracy Root Mean Square (ARMS) of the blood oxygen saturation measured by the circul pro Ring was 1.85%, within the range of ≤ 3%. The mean bias between the measured pulse rate and the heart rate measured by the control device was -0.33 bpm, and

its 95% confidence interval was [-0.59, -0.07] bpm, all within the allowable error range of ± 2 bpm. None of the results exceeded the evaluation range to be satisfied, and no adverse reactions occurred during the trial. The results of the clinical study demonstrated that the measurement accuracy of the circul pro Ring for blood oxygen saturation and pulse rate met the protocol requirements, and that it is accurate and safe during use.

10. Conclusion

The proposed circul pro Ring has the same classification information, similar intended use, and similar technologies as the predicate device. According to non-clinical and clinical test results, the proposed device is substantially equivalent to the predicate and reference devices.