October 11, 2024

Belun Technology Company Limited
Lap Wai Lydia Leung
Chief Executive Officer
Flat/Rm 225B, 2/F, Building 1W, Phase One
Hong Kong Science Park, Pak Shek Kok, N.T.
Hong Kong,
Hong Kong

Re: K234110
Trade/Device Name: Belun Ring BLR-200 (BLR-200)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 11, 2024
Received: March 11, 2024

Dear Lap Wai Lydia Leung:

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,

James J. Lee -S

for Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234110

Device Name

Belun Ring BLR-200 (BLR-200)

Indications for Use *(Describe)*

Belun Ring BLR-200 is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for spot-checking and/or continuous data collection and recording of oxygen saturation of arterial hemoglobin (SpO2) 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.

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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510(k) #: K234110

510(k) Summary

Prepared on: 2024-09-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Belun Technology Company Limited
Applicant Address	Flat/Rm 225B, 2/F, Building 1W, Phase One Hong Kong Science Park, Pak Shek Kok N.T. Hong Kong
Applicant Contact Telephone	+85237065640
Applicant Contact	Dr. Lap Wai Lydia Leung
Applicant Contact Email	belun_reg@beluntech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Belun Ring BLR-200 (BLR-200)
Common Name	Oximeter
Classification Name	Oximeter
Regulation Number	870.2700
Product Code	DQA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211407	Belun Ring BLR-100X	DQA
K221361	circul™ pro Ring	DQA

Device Description Summary

21 CFR 807.92(a)(4)

Belun Ring BLR-200 consists of two parts: a Ring, and a host program. The Ring, which has smooth and light design and is easy to wear and take off, is intended to be worn on the bottom of index finger providing comfortable and accurate measurements. To make the Optical module appropriately contact with the user's skin, the soft part of the Ring (hereinafter referred to as "the Ring arm") is designed to be changeable for fitting different sizes of fingers. The Ring transfers the collected data to host via Bluetooth low power technology. The host program translates the collected data into text and graph which can be easily interpreted by the user.
The system consists of two main platforms, namely Ring and host. It includes one embedded software and one host program, namely Ring firmware embedded in Ring and Belun Ring Management (BRM) executed in host respectively. The Ring is responsible for signal acquisition, data processing, parameters calculation (SpO2/PR algorithm), sensor interfacing data storage. The host is for data display, data export and user interface. The system is modularized, and the communication protocol is proprietary. The system is secured with cybersecurity measures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Belun Ring BLR-200 is a wireless, non-invasive and stand-alone pulse oximeter intended to be used for spot-checking and/or continuous data collection and recording of oxygen saturation of arterial hemoglobin (SpO2) 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The difference of intended use / indications for use of the proposed and predicate devices:
- The proposed device has an additional option of spot-checking display of measurement data from Ring on host program via Bluetooth communication, while the predicate device does not have, and the reference device has the real-time measurement data displaying on host device via Bluetooth communication.

Bench testing was performed to support the substantial equivalence.

Technological Comparison 21 CFR 807.92(a)(6)

The difference of intended use / indications for use of the proposed and predicate devices:
- The proposed device has an additional option of spot-checking display of measurement data from Ring on host program via Bluetooth communication, while the predicate device does not have, and the reference device has the spot-check measurement data displaying on mobile application via Bluetooth communication.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The proposed device Belun Ring BLR-200 is in compliance with both mandatory and voluntary standards and testings, including:

Electrical, EMC, Mechanical and Thermal Safety Testing:
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION - 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
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- BQB Bluetooth qualification
- FCC Part 15B & FCC Part 18 certification

Battery Safety Testing:
The battery of the proposed device is identical to that of predicate device which is in compliance with the standard- IEC 62133 Edition 2.0 2012-12

Biocompatibility Testing:
The patient intact skin contacting materials of the subject device are Identical as those of predicate device which is in compliance with the standards, including:
- ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Software and Cybersecurity Testing:
The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The Management of Cybersecurity is in compliance with FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Bench Testing:
The SpO2 and pulse rate accuracy of proposed device under low perfusion and motion conditions have been tested against functional tester. The SpO2 and pulse rate accuracy of proposed device have also been tested on healthy subjects and compared with the predicate device in hypoxia tests.

As the proposed devices use the same measurement technology as the previous clearance K211407, no additional clinical testing was required to support the substantial equivalence.

Based on the tests and information provided in this submission, the proposed device, Belun Ring BLR-200, is considered to be substantially equivalent to the predicate device.