October 10, 2019

Belun Technology Company Limited
Lydia Leung
CEO
Unit 531B, Floor 5, Core Building 2
1 Science Park West Avenue, Hong Kong Science Park
Sha Tin
HONG KONG

Re: K191417
Trade/Device Name: Belun Ring BLR-100C
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 2, 2019
Received: September 4, 2019

Dear 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 (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,

*for* Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191417

Device Name
Belun Ring BLR-100C

Indications for Use *(Describe)*
Belun Ring BLR-100C is a non-invasive and stand-alone pulse oximeter, intended to be used for spot-checking and/or 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. It is not intended for single-use and out-of-hospital transport 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

# 510(k) Summary

# K191417

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.
There is no prior submission for the device.

## I. SUBMITTER

Belun Technology Company Limited
Unit 531B, 5 Floor, Core Building 2, 1 Science Park West Avenue,
Hong Kong Science Park, Shatin, Hong Kong
Contact Person: Lydia Leung
Phone: +852 3706 5640

## II. PROPOSED DEVICE

Device Common Name: Pulse Oximeter
Device Proprietary Name: Belun Ring BLR-100C
Model: BLR-100C
Classification Name and Reference: Oximeter (21 CFR 870.2700)
Regulatory Class: II
Product Code: DQA
510(k) Number: K191417

## III. PREDICATE DEVICE

The identified predicates:
Belun Ring BLR-100 (manufactured by Belun Technology Company Limited and the subject of FDA 510(k) document no. K180174)
The reference device:
Nonin 3150 WristOx2 (K102350, Nonin Medical, Inc.)

## IV. DEVICE DESCRIPTION

The proposed device Belun Ring BLR-100C is a non-invasive and stand-alone pulse oximeter, which can detect, display and transfer the measured oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate in hospital and home environment.
The proposed device consists of two parts: A Ring and a Cradle.
The Ring, which is of a smooth and a light design and is easy to be worn and taken off, is intended to be worn on the base of the index finger. It provides comfortable and accurate measurements with the Cradle in the spot-checking mode or without the Cradle in the recording mode. The Cradle collects data from the Ring and translates the data into text and graph which can be easily understood by the user. It also exports the collected data via USB port to a host such as computer or mobile equipment for recording data transfer and review. They usually outside of patient environment, which is remote from the patient. There is no wireless function in this device.

Using spectrophotometric methodology, the proposed device measures oxygen saturation by illuminating the skin and measuring changes in the light absorption of oxygenated (oxyhemoglobin) and deoxygenated blood (reduced hemoglobin) using light of two wavelengths: red and infrared. The ratio of absorbance at these wavelengths is calculated and calibrated against direct measurements of arterial oxygen saturation (SaO2) to establish the pulse oximeter's measurement of functional oxygen saturation of arterial hemoglobin (SpO2). The sensor of the Ring should be placed on the palmar side of the proximal phalanx of the index finger and along the radial artery.

The system is using a customized dual CPU design to realize the functions. It consists of two main platforms: The Ring is responsible for signal pre-conditioning, data post-processing (SPO2/PR algorithm), parameters calculation and sensor interfacing, while the Cradle takes care of the user interface including a display for output and a button for input.

The system includes two embedded software, namely the Ring firmware and the Cradle firmware. It is modularized and provides high stability. The software systems work in conjunction with the Ring and the Cradle. The two platforms (Ring and Cradle) are connected via "Connectivity software module". The communication protocol is proprietary which provides a reliable and fast communication.

## V. INDICATIONS FOR USE

Belun Ring BLR-100C is a non-invasive and stand-alone pulse oximeter, intended to be used for spot-checking and/or 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. It is not intended for single-use and out-of-hospital transport use.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND THE REFERENCE DEVICE

| Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100C) and Predicate Device (BLR-100) and Reference Device (Model 3150 WristOx2) | | | |
|---|---|---|---|
| **Comparison Elements** | **Proposed Device (BLR-100C)** | **Predicate Device (BLR-100)** | **Reference Device (Model 3150 WristOx2)** |
| Product Name | Pulse Oximeter | Pulse Oximeter | Pulse Oximeter |
| Model | BLR-100C | BLR-100 | Model 3150 WristOx2 |
| FDA 510(k) Document No. | - | K180174 | K102350 |
| Regulation No. | 21 CFR 870.2700 | 21 CFR 870.2700 | 21 CFR 870.2700 |
| Classification | II | II | II |
| Classification Name | Oximeter | Oximeter | Oximeter |
| Product Code | DQA | DQA | DQA |
| Intended Use | Belun Ring BLR-100C is a non-invasive and stand-alone pulse oximeter, intended to be used for spot-checking and/or 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. It is not intended for single-use and out-of-hospital transport use. | Belun Ring BLR-100 is a non-invasive and stand-alone pulse oximeter, intending for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients through index finger in hospital and home environment. It is not intended for single-use and out-of-hospital transport use. | Nonin's Model 3150 WristOx2 Pulse Oximeter is a small wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and / or data collection and recording of patients who are well or poorly perfused. The intended use environments are sleep and pulmonary rehab labs, surgical recovery, critical care, emergency room, longterm care, home use and mobile units. |

| Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100C) and Predicate Device (BLR-100) and Reference Device (Model 3150 WristOx2) | | | | |
|---|---|---|---|---|
| **Comparison Elements** | | **Proposed Device (BLR-100C)** | **Predicate Device (BLR-100)** | **Reference Device (Model 3150 WristOx2)** |
| **Comparison Statement** | | The proposed device and the predicate device have the similar intended use and classification. The proposed device includes data collection and recording that are similar to the reference device. The additional risk of safety and effectiveness of the proposed device is evaluated. | | |
| Components | | Pulse Oximeter Ring, CPU, display screen, signal processing unit, power unit, built-in battery | Pulse Oximeter Ring, CPU, display screen, signal processing unit, power unit, built-in battery | Sensor block, analog block, controller, LCD display and battery |
| Measurement Wavelength | Red | 658 nm ± 2 nm | 658 nm ± 2 nm | 660 nm |
| | Infrared | 886 nm ± 6 nm | 886 nm ± 6 nm | 910 nm |
| Technology Type | | reflective light | reflective light | transmissive light |
| **Comparison Statement** | | The proposed device has same components, measurement wavelength and technology as the predicate device. | | |
| **Performance specification** | Display Type | OLED | OLED | LCD |
| | Battery | 3.7V lithium battery | 3.7V lithium battery | Two 1.5-volt AAA alkaline batteries |
| | Power Supply Requirement | 3.1 V~ 4.2V DC | 3.1 V~ 4.2V DC | 3.0V DC |
| | Rated Current | 500mA | 1A | N/A |
| | Spo2 Measurement Range | 70% ~ 100% | 70% ~ 100% | 70% ~ 100% |
| | Spo2 Accuracy | ± 2% | ±2% | ± 2 digits (8000J/Q/R series, no motion) |
| | PR Measurement Range | 30 bpm ~ 250 bpm | 30 bpm ~ 250 bpm | 18 bpm ~ 300 bpm |

| Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100C) and Predicate Device (BLR-100) and Reference Device (Model 3150 WristOx2) | | | | |
|---|---|---|---|---|
| **Comparison Elements** | | **Proposed Device (BLR-100C)** | **Predicate Device (BLR-100)** | **Reference Device (Model 3150 WristOx2)** |
| | PR Accuracy | ±2 bpm or ± 2%, which is larger | ±2 bpm or ± 2%, which is larger | ± 3 digits |
| | Data Average | Spot checking mode: 8s<br>Recording mode: 1s | Spot checking mode: 8s | 8-beat SpO2/pulse rate extended average;<br>4-beat SpO2/pulse rate average |
| | Data Update Period | Spot checking mode: ≤20s<br>Recording mode: 1s | Spot checking mode: ≤20s | Recording mode: 1/3 second<br>Spot check mode: 1.5 second |
| | Waveform Display | No | No | No |
| | Pulse Intensity Indication | Yes | Yes | Yes |
| | Low-Voltage Indication | Yes | Yes | Yes |
| | Data Storage | Yes | No | Yes |
| | Can Be Connected with An External Oximeter Probe | Can only be connected to the special designed oximeter ring | Can only be connected to the special designed oximeter ring | Yes |
| | Data Export | USB | No | USB and Bluetooth |
| | Atmosphere Pressure | 700hPa~1060hPa | 700hPa~1060hPa | Up to 4 atmospheres |

| Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100C) and Predicate Device (BLR-100) and Reference Device (Model 3150 WristOx2) | | | | |
|---|---|---|---|---|
| **Comparison Elements** | | **Proposed Device (BLR-100C)** | **Predicate Device (BLR-100)** | **Reference Device (Model 3150 WristOx2)** |
| | Operating Temperature | 10 ~ 40°C | 10 ~ 40°C | -5 ~ 40 °C |
| | Relative Humidity | ≤75% | ≤75% | 10 % to 95 % relative humidity, non-condensing |
| | Storage Environment | a) Temperature: -10 ~ +60 °C<br>b) Relative humidity: 10~95%<br>c) Atmospheric pressure: 500hPa~1060hPa | a) Temperature: -10 ~ +60 °C<br>b) Relative humidity: 10~95%<br>c) Atmospheric pressure: 500hPa~1060hPa | a) Temperature: -40 ~ +70 °C<br>b) Relative humidity: 10 % to 95 % relative humidity, non-condensing |
| | Dimensions | Ring: 45 x 60 x 20mm<br>Cradle: 60 x 140 x 60mm | Ring: 45 x 60 x 20mm<br>Cradle: 60 x 140 x 60mm | 51 x 73 x 19 mm (without sensor or wristband) |
| | Weight | About 200g (with the lithium battery) | About 200g (with the lithium battery) | 70g (with batteries and wristband) |
| | IP Classification | IP22 | IP22 | IP33 |
| | Normal Service Life | 3 years | 3 years | 5 years |
| **Comparison Statement** | | Comparing with the predicate device, the additional specifications of the proposed device are Rated Current, Data Average, Data Update Period, Data Storage and Data Export. Those differences of the performance specification are like the reference device. | | |
| Contacting Material | | TPU, PC | TPU, PC | Not indicated |
| **Comparison Statement** | | The proposed device uses the same contacting material as the predicate device. | | |

## VII. PERFORMANCE DATA

**Non-clinical Test**

The proposed device Belun Ring BLR-100C is tested in accordance with both mandatory and voluntary standards, including:

- *IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *IEC 60601-1-11:2015 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 60601-1:2005 + a1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- *ISO 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

BLR-100C is using the same PCB assembly (PCBA), materials for mechanical parts and bill-of-material as predicate device BLR-100 (K180174) except that the firmware, a resistor value on a PCB and an adhesive tape model have been changed such that “data collection and recording” function can be added in BLR-100C. Hence, the proposed device Belun Ring BLR-100C is verified in bench studies to meet the specifications fulfilled by the cleared predicate Belun Ring BLR-100 (K180174).

The Software Validation is in compliance with *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* from FDA.

There is no change in batteries of the proposed device Belun Ring BLR-100C and the cleared predicate Belun Ring BLR-100 (K180174). Therefore, the tests performed and submitted for K180174 with respect to the IEC 62133 and UN38.3 are applicable to the proposed device.

BLR-100C in its final finished form is identical to predicate BLR-100 (K180174) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Therefore, the tests performed and submitted with K180174 with respect to ISO 10993-1, ISO 10993-5 and ISO 10993-10 support the biocompatibility equivalence of the proposed device BLR-100C.

**Clinical Study**

BLR-100C is using the same PCB assembly (PCBA), materials for mechanical parts and bill-of-material as predicate device BLR-100 (K180174) except that the firmware, a resistor value on a PCB and an adhesive tape model have been changed such that “data collection and recording” function can be added in BLR-100C. Hence, the clinical study of predicate BLR-100 remains valid for BLR-100C.

## VIII. CONCLUSIONS

In conclusion, the proposed device of Belun Ring BLR-100C has the same classification information, same intended use, similar design principle, similar product design and specification as the predicated device. The differences in technological characteristics do not raise different questions of safety and

effectiveness. According to the results of non-clinical test, the proposed device is Substantially Equivalent (SE) to the predicate device.