October 21, 2021

Belun Technology Company Limited
Leung Lap Wai Lydia
CEO
Unit 218, 2/F, Core Building 2, No. 1 Science Park
West Avenue, Hong Kong Science Park
Sha Tin, Hong Kong
China

Re: K211407
Trade/Device Name: Belun Ring BLR-100X
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 17, 2021
Received: September 20, 2021

Dear Leung Lap Wai Lydia:

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,

Todd Courtney
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

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)*
K211407

Device Name
Belun Ring BLR-100X

Indications for Use *(Describe)*
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 (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.

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Vol 5 – 510(k) Summary

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 218, 2 Floor, Core Building 2, 1 Science Park West Avenue,
Hong Kong Science Park, Shatin, Hong Kong
Contact Person: Leung Lap Wai Lydia
Phone: +852 3706 5640

II. PROPOSED DEVICE

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

III. PREDICATE DEVICE

The identified predicates:
Belun Ring BLR-100C (manufactured by Belun Technology Company Limited and the subject of FDA 510(k) document no. K191417)
The reference device:
WatchPAT™ONE (WP1) (K183559, Itamar Medical, Inc.)

IV. DEVICE DESCRIPTION

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 (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.
The proposed device consists of three parts: A Ring, a Cradle and a Host program.
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 without the Cradle in the recording mode. 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 Cradle collects data from the Ring and charges up the Ring. It transfers the collected data to host via an attached USB cable or Bluetooth low power technology.
The host program translates the data into text and graph which can be easily understood by the user.
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 consists of three main platforms. Ring is responsible for signal acquisition, data processing, parameters calculation (SpO2/PR algorithm), sensor interfacing and user interface. Cradle takes care of the data storage, data transfer and user interface. Host program is for data display, data export and user interface.

The system includes two embedded software and one host program, namely the Ring firmware, the Cradle firmware and the Belun Ring Management. It is modularized and provides high stability. It is a highly robust and secure system with proper measure on the data integrity and security. The communication protocol is proprietary which provides a reliable and fast communication.

V. INDICATIONS FOR USE

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 (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.

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

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)			
Comparison Elements	**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
Product Name	Belun Ring BLR-100X	Belun Ring BLR-100C	WatchPAT™ONE (WP1)
FDA 510(k) Document No.	K211407	K191417	K183559
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	21 CFR 868.2375
Classification	II	II	II
Classification Name	Oximeter	Oximeter	Ventilatory Effort Recorder
Product Code	DQA	DQA	MNR
Intended Use	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 (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.	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.	The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and snoring level and body position

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)				
Comparison Elements		**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
				discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP1's PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.
Comparison Statement		The proposed device and the predicate device have the similar intended use and classification. The proposed device includes user Interface Display/Indicators that are similar to the reference device. The additional risk of safety and effectiveness of the proposed device is evaluated.		
Components		Pulse Oximeter Ring, sensor unit, CPU, accelerometer, LED indicator light, signal processing unit, power unit, built-in battery	Pulse Oximeter Ring, sensor unit, CPU, accelerometer, display screen, signal processing unit, power unit, built-in battery	uPAT finger probe, actigraph, controller, microphone, accelerometer, ZzzPAT software, chest sensor
	Red	658 nm ± 2 nm	658 nm ± 2 nm	-

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)				
Comparison Elements		**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
Measurement Wavelength	Infrared	886 nm ± 6 nm	886 nm ± 6 nm	-
Technology Type		reflective light	reflective light	transmissive light
Comparison Statement		The proposed device has same measurement wavelength and technology as the predicate device. The proposed device had passed the clinical validation on the accuracy of the spo2 and pulse rate. Thus, it is proven to be effective.		
Performance specifications	User Interface Display/ Indicators	Via host program interface Via Cradle (LED) Via Ring (LED)	Via Cradle display interface (OLED)	Via Smartphone User Interface Via Main device (LED)
	Battery	3.7V lithium battery	3.7V lithium battery	One OTS 1.5V Alkaline AAA battery
	Power Supply Requirement	3.1 V~ 4.2V DC	3.1 V~ 4.2V DC	3.3V DC
	Rated Current	500mA	500mA	N/A
	Spo2 Measurement Range	70% ~ 100%	70% ~ 100%	-
	Spo2 Accuracy	± 2.7%	±2%	-
	PR Measurement Range	30 bpm ~ 250 bpm	30 bpm ~ 250 bpm	-
	PR Accuracy	±2.5 bpm or ± 2%, which is larger	±2 bpm or ± 2%, which is larger	-
	Data Average	Recording mode: 8s	Spot checking mode: 8s	-
	Data Update Period	Recording mode: 8s	Spot checking mode: ≤20s	-

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)				
Comparison Elements		**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
	Waveform Display	No	No	No
	Pulse Intensity Indication	No	Yes	No
	Low-Voltage Indication	Yes	Yes	-
	Data Storage	Yes	Yes	-
	Can Be Connected with An External Oximeter Probe	Can only be connected to the special designed oximeter	Can only be connected to the special designed oximeter	Yes
	Data Collection	• Sensors connect direct to cradle • Study data is transferred from cradle to host through USB or wirelessly through Bluetooth	• Sensors connect direct to cradle • Study data is transferred from cradle to host through USB	• Sensors connect direct to main device • Study data is wirelessly transferred (Bluetooth) from main device to mobile phone and from the mobile phone to a storage on a web server, over the Internet
	Atmosphere Pressure	700hPa~1060hPa	700hPa~1060hPa	-
	Operating Temperature	10 ~ 38°C	10 ~ 40°C	-

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)				
Comparison Elements		**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
	Relative Humidity	≤75%	≤75%	-
	Storage Environment	a) Temperature: -10~ +60 °C b) Relative humidity: 10~95% c) Atmospheric pressure: 500hPa~1060hPa	a) Temperature: -10~ +60 °C b) Relative humidity: 10~95% c) Atmospheric pressure: 500hPa~1060hPa	-
	Dimensions	Ring: 44 x 60 x 18 mm Cradle: 32 x 100 x 59 mm	Ring: 45 x 60 x 20mm Cradle: 60 x 140 x 60mm	-
	Weight	About 110 g (with the lithium battery)	About 200g (with the lithium battery)	-
	IP Classification	IP22	IP22	-
	Normal Service Life	3 years	3 years	-
Comparison Statement		The technological characteristics and principles of operation of the subject device are similar to the predicate device. The subject BLR-100X, like its predicate, is a pulse oximeter that utilizes reflective red/IR wavelength for oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate measurement. Both Rings where are of a smooth and a light design and are easy to be worn and taken off, are intended to be worn on the base of the index finger. Both devices provide comfortable and accurate measurements without the Cradle in the recording mode. The Cradle collects data from the Ring and transfers to the host program for data display, which can be easily understood by the user. Comparing with the predicate device, the proposed device different from BLR-100C by exporting the collected data via Bluetooth or USB instead of USB only to a host such as computer equipment for recording data transfer and review. A computer program also replaced the predicate BLR-100C's user interface and communication similar to the reference device. In addition, the user interface of the computer program was designed to provide similar display and input as the BLR-100C. The differences in technological characteristics and principle of operation do not raise different questions of safety or effectiveness.		

Table 1 Performance Specification Comparison Table between the Proposed Device (BLR-100X) and Predicate Device (BLR-100C) and Reference Device (WatchPAT™One – WP1)			
Comparison Elements	**Proposed Device (BLR-100X)**	**Predicate Device (BLR-100C)**	**Reference Device (WatchPAT™One – WP1)**
Contacting Material	TPE, PC	TPU, PC	Not indicated
Comparison Statement	The difference of material used in proposed device is TPE in which passed the bio-compatibility test, so that the contacting material was proven to be safe to be used.		

VII. PERFORMANCE DATA

Non-clinical Test

The proposed device Belun Ring BLR-100X 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*
- *IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*
- *ISO 80601-2-61:2017 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*

The Belun Ring BLR-100X has been validated for low perfusion saturation accuracy in bench testing against functional tester with signal strength of greater than 0.1% for saturation values ranging from 70 to 100%. The results of the bench testing showed that the Belun Ring BLR-100X returned the same saturation values within ± 3 % when compared to the functional tester used.

The Belun Ring BLR-100X has been validated for SpO2 and pulse rate accuracy in bench testing against functional tester for SpO2 values ranging from 70% to 100% and pulse rate values ranging from 30 bpm to 250 bpm under no motion and motion conditions. The results of the bench testing showed that the Belun Ring BLR-100X returned the same SpO2 values within ± 2.7% and pulse rate values within ± 2.5 % or ± 2 bpm (which is larger) when compared to the functional tester used.

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.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are 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*
- *ISO 10993-10:2010 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity*

Clinical Study

The Clinical Test was conducted following the testing described in 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 purpose of this study was to evaluate the SpO2 accuracy performance of the Belun Ring BLR-100X placed on the index fingers during steady state / non-motion conditions over the range of 70-100% SaO2, arterial blood samples, assessed by CO-Oximetry.

The Accuracy Root Mean Square (ARMS) performance of the oximetry system met the required specification in non-motion conditions for the range of 70 – 100% SaO2. The results of the study provide supporting evidence that the Belun Ring BLR-100X is compliant to the accuracy specification claimed by the manufacturer.

VIII. CONCLUSIONS

In conclusion, the proposed device of Belun Ring BLR-100X has the same classification information, similar intended use, similar design principle, similar product design and specification as the predicated device. According to the results of non-clinical test and clinical study, the proposed device is Substantially Equivalent (SE) to the predicate device.