February 23, 2023

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: K222579
Trade/Device Name: Belun Sleep System BLS-100
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: January 10, 2023
Received: January 13, 2023

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Opthalmic, 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)*
K222579

Device Name
Belun Sleep System BLS-100

Indications for Use *(Describe)*
The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in clinical and home settings under the direction of a Healthcare Professional (HCP).

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) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92 on 23-Feb-2023.

I. SUBMITTER

Belun Technology Company Limited
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Hong Kong Science Park, Shatin, Hong Kong
Contact Person: Leung Lap Wai Lydia
Phone: +852 706 5640

II. PROPOSED DEVICE

Trade/Device Name: Belun Sleep System BLS-100
Model: BLS-100
Classification Name: Ventilatory Effort Recorder
Regulation Number: 21 CFR 868.2375
Regulatory Class: II
Product Code: MNR

III. PREDICATE DEVICE

Device Name: NightOwl (K220028)
Classification Name: Ventilatory Effect Recorder
Regulation Number: 21 CFR 868.2375
Regulatory Class: II
Product Code: MNR

IV. DEVICE DESCRIPTION

The Belun Sleep System BLS-100 is prescribed by a Health Care Professional (HCP) for the patient to use in the home as a 'home sleep apnea test' (HSAT).

The Belun Sleep System BLS-100 comprises a sensor that is worn on the proximal phalanx of index finger (Belun Ring) over-night whilst the subject is sleeping and a stand-alone analysis software (Belun Sleep AI).

The Belun Ring has a small biocompatible enclosure. The sensor has 2 LEDs, one in the red spectrum and the other in the infrared spectrum, and an accelerometer. The sensor is placed on the proximal phalanx of the index finger, with the sensor window applied against the palmar side of the proximal phalanx of the index finger.

The sensor measures the reflected red/infrared signals to record the photoplethysmograph (PPG) signal. The accelerometer is used to detect movement.

The data recorded by the Belun Ring is stored in device on-board memory. The data is exported when the Belun Ring is returned to the prescribing HCP via USB or Bluetooth and passed to the Belun Sleep AI Software, which is standalone PC software. The Belun Sleep AI loads and processes the signal from the exported data and generates the apnea-hypopnea index (bAHI) and sleep staging identification (bSTAGES).

Signals from the Belun Ring device include the following:

- Oxygen saturation
- Beat-to-beat pulse period
- Photoplethysmography
- Actigraphy

V. INDICATIONS FOR USE

The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in clinical and home settings under the direction of a Healthcare Professional (HCP).

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

Table 1 Performance Specification Comparison Table between the Belun Sleep System BLS-100 and Predicate Device			
Characteristic	**Proposed Device** **Belun Sleep System BLS-100**	**Predicate Device** **NightOwl (K220028)**	**Comparison**
Regulation No.	21 C.F.R. 868.2375	21 C.F.R. 868.2375	**Identical to predicate device**
Classification	II	II	**Identical to predicate device**
Classification Name	Breathing frequency monitor	Breathing frequency monitor	**Identical to predicate device**
Product Code	MNR	MNR	**Identical to predicate device**
Intended Use	The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in clinical and home settings under the direction of a Healthcare Professional (HCP).	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).	**Substantially equivalent to predicate** The proposed system and the predicate have the similar intended use.

Table 1 Performance Specification Comparison Table between the Belun Sleep System BLS-100 and Predicate Device			
Characteristic	**Proposed Device** **Belun Sleep System BLS-100**	**Predicate Device** **NightOwl (K220028)**	**Comparison**
Use Environment	Recording in the home environment with the report interpretation performed in the clinical setting.	Recording in the home environment with the report interpretation performed in the clinical setting.	**Identical to predicate device**
Target population	22 years old and older	22 years old and older	**Identical to predicate device**
Sensor software	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.	**Identical to predicate device**
Analysis software location	Analysis performed off the recording device, exclusively stand-alone by the Belun software	Analysis performed off the recording device, exclusively cloud-based by the NightOwl software	**Substantially equivalent to predicate** The software is verified and validated. The difference of the analysis software location does not raise different questions of safety and effectiveness.

Table 1 Performance Specification Comparison Table between the Belun Sleep System BLS-100 and Predicate Device			
Characteristic	**Proposed Device** **Belun Sleep System BLS-100**	**Predicate Device** **NightOwl (K220028)**	**Comparison**
Analysis software algorithm – AHI	bAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	pAHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea AND pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	**Substantially equivalent to predicate** The clinical evaluation has confirmed that the Belun Sleep System deep-learning algorithms calculating the Belun Apnea Hypopnea Index (bAHI) and Belun Sleep Stage (bSTAGES) generate comparable output to human manual scoring of an Apnea Hypopnea Index (AHI) from Polysomnography (PSG) studies, using American Academy of Sleep Medicine (AASM) scoring guidelines for adult patients, with accuracy, sensitivity and specificity similar to the predicate and reference devices.
Analysis software algorithm – Sleep stages	bSTAGES: WAKE, NREM and REM bTST calculation (time summation of REM and NREM stages)	Total Sleep Time (TST) calculation Total REM Time calculation	
Sensors	Optical plethysmography sensor, accelerometer	Optical plethysmography sensor, accelerometer	**Identical to predicate device**
Battery	3.7V Lithium Battery	Battery powered by coin cell	**Substantially equivalent to predicate** The battery safety is verified and validated. The difference in battery type does not raise different questions of safety and effectiveness.

Table 1 Performance Specification Comparison Table between the Belun Sleep System BLS-100 and Predicate Device			
Characteristic	**Proposed Device** **Belun Sleep System BLS-100**	**Predicate Device** **NightOwl (K220028)**	**Comparison**
Channels	Photoplethysmography (PPG), Pulse rate, Oximetry, Actigraphy	PAT, Pulse rate, Oximetry, Actigraphy	**Substantially equivalent to predicate** The proposed system and the predicate use the similar sensors: optical plethysmography sensor and accelerometer. The differences between predicate are that the proposed device feeds PPG whose envelop is similar to the information provided by PAT to its AI algorithms. Also, the PPG sensor and accelerometer components are worn on the proximal phalanx of index finger instead of fingertip. The clinical evaluation has confirmed that the Belun Sleep System deep-learning algorithms calculating the Belun Apnea Hypopnea Index (bAHI) and Belun Sleep Stage (bSTAGES) generate comparable output to human manual scoring of an Apnea Hypopnea Index (AHI) from Polysomnography (PSG) studies. As such, the proposed system does not introduce any change to the safety and effectiveness of the predicate device. Similar to Somnapatch (K183625) which uses PPG instead of PAT to aid in evaluating OSA.
Wearable sensor location	The photoplethysmography (PPG) sensor and accelerometer components are worn on the proximal phalanx of index finger.	The photoplethysmography (PPG) sensor and accelerometer components are worn on the fingertip.	

VII. PERFORMANCE DATA

Non-clinical Test

The proposed device Belun Ring is tested in accordance with the following standards and FDA guidance documents (leveraged from K211407), 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*
- *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*
- *IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices*
- *BQB Bluetooth qualification*
- *FCC Part 15B & FCC Part 18 certification*
- *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
- *FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*
- *FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices: 2016*

The Belun Ring BLR-100X has been validated for low perfusion saturation and pulse rate in K211407. There are no changes in those features or algorithms for clearance of this device to be used as a home sleep apnea test (HSAT).

Clinical Study

The Clinical Test consists of 2 parts:

(1) SpO2 accuracy: This testing was performed in K211407 and leveraged for this submission.

(2) Comparison to PSG sleep lab results: The purpose of this study is to evaluate the accuracy, sensitivity and specificity of the Apnea-Hypopnea Index (AHI) and sleep staging (wake, Rapid Eye Movement (REM) and Non-Rapid Eye Movement (NREM)) of the Belun Sleep System BLS-100 compared with overnight polysomnography (PSG) study according to the American Academy of Sleep Medicine (AASM) guidelines in a sleep laboratory with 106 patients suspected of obstructive sleep apnea (OSA). All sleep studies were manually scored based on the AASM scoring manual (version 2.4) by a senior sleep tech scorer and reviewed by a board-certified sleep physician. All investigators, sleep lab team, and scorers were blinded to the results until statistical analysis was performed. The accuracy, sensitivity and specificity at AHI cutoff 15 and 30 are summarized in the table below.

Cutoff	Accuracy	Sensitivity	Specificity
15	0.877	0.898	0.860
30	0.925	0.840	0.951

The accuracy, sensitivity, and specificity of 3-categorization sleep stages [wake, Rapid Eye Movement (REM) and Non-Rapid Eye Movement (NREM)] are summarized in the table below.

Class	Number of Epochs	Accuracy	Sensitivity	Specificity
Wake	85471	0.885	0.604	0.961
REM		0.908	0.712	0.944
NREM		0.827	0.904	0.695

The total sleep time (bTST) of the Belun Sleep System BLS-100 is the time summation of REM and NREM stages. The mean difference between bTST and PSG-TST was 21.8 minutes with a standard deviation of 41.6 minutes. The mean absolute difference between bTST and PSG-TST was 30.8 minutes.

VIII. CONCLUSIONS

In conclusion, the proposed device of Belun Sleep System BLS-100 has the same classification information, similar intended use, 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.