July 17, 2023

Shenzhen brav electronic technologies co., Ltd
Yolanda Lan
Consultant
R4-5/F, Block 11, Tongfuyu Industrial District, Lezhujiao,
Huangmabu, Baoan
Shenzhen, GuangDong 518060
China

Re: K211143
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 13, 2023
Received: June 13, 2023

Dear Yolanda Lan:

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,

James J. Lee -S

James J. Lee, Ph.D.
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)*

K211143

Device Name

Pulse Oximeter(OP-101,OP-102)

Indications for Use *(Describe)*

The pulse oximeter is a non-invasive device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios. The device is reusable.

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.

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Submitter: Shenzhen Brav electronic technologies co., Ltd
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Contact Person: Yolanda Lan
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Prepare date: 2021-09-04

Device name and classification

Device Name: Pulse Oximeter

Models: OP-101, OP -102

Classification Name: 21 CFR 870.2700 Oximeter

Product code: DQA

Regulatory Class: Class II

Reason for Submission New Application. No prior submission associated with the current submission.

Predicate Device(s) Shenzhen IMDK Medical Technology Co., Ltd., C101H1 Pulse Oximeter/ K173123

Device Description

The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation (SpO_2).

The subjected device is a reusable device, and need to reprocess as suggested in the user manual after each use. And the device is intended to be used on the finger, and powered by 2*1.5V AAA battery.OP-101 display the measuring results on 1.5' LED screen, and the backlight of the three models are red, white and green respectively. And the screen of OP-102 and OP-103 are 0.96' OLED and 1.3' OLED. Additionally, battery indicator and pulse waveform can be displayed on OP-102 and OP-103.

Indications for Use

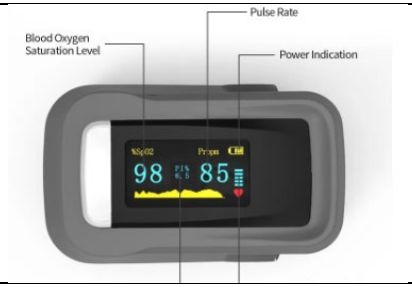
The subjected device is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult patients in hospitals and clinics.
The pulse oximeter is a non-invasive device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios. The device is reusable.

Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness, and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Table 1 Comparison between main predicate C101H1 and the subject device

ITEM	Proposed Device Brav series Pulse Oximeter	Proposed Device Brav series Pulse Oximeter	Predicate Device K173123
Manufacturer	Shenzhen Brav electronic technologies co., Ltd	Shenzhen Brav electronic technologies co., Ltd	Shenzhen IMDK Medical Technology Co., Ltd
Device Name	Pulse Oximeter	Pulse Oximeter	Pulse Oximeter
Models	OP-101	OP-102	C101H1
Appearance			

Indications for Use	The pulse oximeter is a non-invasive device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios. The device reusable.	The pulse oximeter is a non-invasive device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios. The device reusable.	Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.
Intended patient population	Adults in healthcare environments	Adults in healthcare environments	Adults in a clinic environment
Intended application site	Finger	Finger	Finger
use under motion and low perfusion conditions	No	No	No
Signal Detection Method	Photodetector	Photodetector	Photodetector
Display screen	LED	OLED	OLED

Display content	SpO2%, PR battery indication Pulse bar graph	SpO2%, PR battery indication Pulse bar graph pulse waveform	SpO2%, PR battery indication Pulse bar graph Perfusion Index
Contacting material	Shell: ABS Clip Pad: Silicon Button: PMMA	Shell: ABS Clip Pad: Silicon Button: PMMA	Shell: ABS Clip pad: Silicon Button: PC
SpO_2 Range	0~100%	0~100%	0~100%
SpO_2 Resolution	1%	1%	1%
SpO_2 Accuracy	70~100%: ±2% 0% to 69%: unspecified	70~100%: ±2% 0% to 69%: unspecified	70~100%: ±3% 0% to 69%: unspecified
Pulse Rate Range	40 bpm ~ 250 bpm	40 bpm ~ 250 bpm	30 bpm ~ 240 bpm
Pulse Rate Accuracy	±3 bpm or ±1%, whichever is greater	±3 bpm or ±1%, whichever is greater	±1 bpm or ±1%, whichever is greater
Pulse Rate Resolution	1 bpm	1 bpm	1 bpm
Shipped Sterile	No	No	No
Power source	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery
Storage and Transport Environment	Temperature: -20℃to 60℃ Atmospheric Pressure: 50 kPa to l07.4 kPa Relative Humidity: 10%-95% (no condensation)	Temperature: -20℃to 60℃ Atmospheric Pressure: 50 kPa to l07.4 kPa Relative Humidity: 10%-95% (no condensation)	Temperature: -10℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 10%-80% (no condensation)

Operating Environment	Temperature: 15℃to40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-95% (no condensation)	Temperature: 15℃to40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-95% (no condensation)	Temperature: 5℃to40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-80% (no condensation)
Bio-compatibility	ISO 10993-1 ISO 109903-5 ISO 10993-10	ISO 10993-1 ISO 109903-5 ISO 10993-10	ISO 10993-1 ISO 109903-5 ISO 10993-10
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Performance	ISO 80601-2-61	ISO 80601-2-61	ISO 80601-2-61
Dimension (Width*Height*Depth)	57mm×30mm×30 mm	57mm×30mm×30 mm	60mm×36mm×35 mm
Weight	<28 g (without the batteries)	<28 g (without the batteries)	51g

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

Performance Summary

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Testing:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Pulse Oximeter was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of permanent (>30 days).

And the testing included the following tests, results of which demonstrate the biological safety of the subject device:

- ✧ Cytotoxicity
- ✧ Skin Sensitization
- ✧ Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the IEC 60601-1: 2005+CORR. 1 (2006)+CORR. 2 (2007)+AM1 (2012) *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the 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* standard for EMC. So the Pulse Oximeter would be safe and effective during the intended application scenarios.

Bench Testing

Bench testing was conducted and the results show that the subject device complies with the ISO 80601-2-61: 2017 *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment* standard for performance effectiveness, 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, which can future demonstrate the safety and effectiveness of the subject device.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the* Content *of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern. And data shows the software work as expected to make sure the performance stable when operated as suggested by the manufacturer.

The above tests were selected to show substantial equivalence between the subject device and the predicate device.

Clinical data:

Randomized Clinical Study is conducted outside of United States per Annex EE Guideline for evaluating and documenting SpO2 ACCURACY in human subjects of ISO 80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment and Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff.

There were 12 adult volunteers to validated the accuracy of finger pulse oximeter (Model: OP-101). 5 males and 7 females (including 4 subjects with Fitzpatrick V, VI, 8 subjects with Fitzpatrick I ~ Fitzpatrick IV). The measure result between the SpO2 measured by subject device and the SaO2 measured by the blood gas analyzer, was conformed with the requirements of this clinical trial and related standards. The pulse oximeter had not been found any safety issues, adverse effects and complications during the clinical trial.

Summary

Based on the non-clinical performance and clinical data as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is equal to the predicate device.

Conclusion

The Pulse Oximeter is monitoring the patient's SpO2 and pulse rate in non-invasive and convenient. Non-clinical testing and clinical testing were conducted on the subject device and all testing passed pre-specified criteria. The risks of Pulse Oximeter also have been evaluated according to ISO 14971, the overall residual risk and side effect are acceptable, the benefit is greater than risk and hazard. Which demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed device predicate. The subject device is substantially equivalent to the predicate device.