January 25, 2021

Shenzhen Creative Industry Co., Ltd.
% Charles Mack
Principal Engineer
International Regulatory Consultants (IRC)
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K201468
Trade/Device Name: Pulse Oximeter, AP-10
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 11, 2020
Received: December 28, 2020

Dear Charles Mack:

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 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)*

K201468

Device Name
Pulse Oximeter,AP-10

Indications for Use *(Describe)*

This Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check and continuous recording of SpO2, PR of adult or pediatric patients in hospitals, clinics, or home. This device is not intended for continuous monitoring.

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 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: December 11, 2020

1. Company and Correspondent submitting:

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Contact – Mrs. Jia Wang
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US Agent and Correspondent
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Principal Engineer
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Email: charliemack@irc-us.com

2. Device:

Trade/proprietary name: Pulse Oximeter, AP-10
Common Name : Pulse Oximeter
Classification Name : Oximeter
Product Code : DQA
Regulation Number: 21CFR870.2700
Device Class : 2

3. Predicate Devices:

Manufacturer	Device	510(k) Number
Shenzhen Creative Industry Co., Ltd	Handheld Pulse Oximeter, SP-20	K172792

4. Reason for submission: New device

5. Device Description:

This AP-10 Pulse Oximeter is wrist-worn. It measures the SPO_2 physiological parameter, and the measurement results are displayed and stored. The data can be transferred to a phone or PC via a USB connection or via Bluetooth. The AP-10 Pulse Oximeter measures SPO2 and Pulse Rate simultaneously. The device can store up to 500 hours of SPO_2 and Pulse rate data.

The following page exhibits a brief tabular display of the device functions and operation as compared to the predicate device.

Indication for use:

This Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check and continuous recording of SpO2, PR of adult or pediatric patients in hospitals, clinics, or home. This device is not intended for continuous monitoring.

Comparison with the predicate device:

Shenzhen Creative Industry Co., Ltd. believes that the Pulse Oximeter, AP-10 is substantially equivalent to the Shenzhen Creative Industry Co., Ltd; Handheld Pulse Oximeter, Model SP-20 (K172972).

Comparison to Predicate Devices

Characteristics	Submitted Device	Predicate Device	Differences Discussion
Manufacturer	Shenzhen Creative Industry Co., LTD.	Shenzhen Creative Industry Co., LTD.	N/A
Name and model	Pulse Oximeter, AP-10	Handheld Pulse Oximeter, SP-20	N/A
510(K) Number	Pending	K172792	N/A
Product Code	DQA	DQA	Same
Indication for Use	This Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check and continuous recording of SpO2, PR of adult or pediatric patients in hospitals, clinics, or home. This device is not intended for continuous monitoring.	This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO2), and temperature (optional). It is intended for spot check and recording of SpO2, pulse rate, and temperature of adult and pediatric patients in clinical institutions and homes. The Handheld Pulse Oximeter is not intended for active continuous monitoring.	Similar.
Type of SpO2 Sensor	Transmittance Optical Sensor	Transmittance Optical Sensor	The difference of SpO2 Sensor does not raise any new questions of safety and effectiveness and still complies with the ISO80601-2-61
SpO2 Module	KM-SPO-04 SpO2 Module with KS-AR01 Probe	KM-SPO-01 SpO2 Module with KS-C01, KS-YW02 probe	
Application Site	Finger	Finger	
Output Wavelength and Radiant Power of SpO2 Sensor	Red (660 nm) @ 2 mW maximum	Red (660 nm) @ 2 mW maximum	
	Infrared (905 nm) @ 2 mW maximum	Infrared (905 nm) @ 2 mW maximum	
Display	1.44'' color TFT LCD	3.5'' color TFT LCD	The display size difference does not raise any new questions of safety and effectiveness.
Measuring Mode	Spot-check and Continuous recording	Spot-check and Continuous recording	Spot-check and Continuous recording
Display Range	SpO2: 0-100 % Pulse Rate: 30-250 bpm	SpO2: 0-100 % Pulse Rate: 30-240 bpm	The Pulse Rate display range of AP-10 is wider than SP-20, but still complies with ISO80601-2-61

Characteristics	Submitted Device	Predicate Device	Differences Discussion
Display Resolution	SpO2: 1% Pulse Rate: 1 bpm	SpO2: 1% Pulse Rate: 1 bpm	SpO2: 1% Pulse Rate: 1 bpm
SpO2 Measurement Accuracy	SpO2: Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)	SpO2: Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)	SpO2: Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)
Pulse Rate Accuracy	Pulse Rate: ±2bpm or ±2% (whichever is greater)	Pulse Rate: ±2bpm or ±2% (whichever is greater)	Pulse Rate: ±2bpm or ±2% (whichever is greater)
Data Memory	Up to 24 hours data storage (500 pieces of record at most)	Up to 500 hours of data storage for SpO2 and PR and can be recalled	The little difference does not raise any new questions of safety and effectiveness.
Power Supply	Rechargeable Lithium-Ion Polymer Battery (3.7V,500mAh)	Rechargeable Lithium-Ion Polymer Battery (3.7V d.c.,1000mAh)	Both devices are powered by a lithium battery, which matches the design requirement and complies with the applicable standards, including IEC60601-1, IEC60601-1-2, and IEC62133, etc.
AC Power for Battery Charger	100-240VAC, 50-60Hz,15VA max	100-240VAC, 50-60Hz,0.5A	Both devices are powered by a lithium battery that full match the design requirement and comply with the applicable standards, including IEC60601-1 and IEC60601-1-2.
Type of Protection	Internal Powered	Internal Powered	Internal Powered
Degree of Protection – sensor	Type BF – applied part	Type BF – applied part	Type BF – applied part
Enclosure Degree of Ingress Protection	IP22	IP22	The enclosure Degree of Ingress Protection complies with the applicable standards, including IEC60601-1 and ISO80601-2-61.

Characteristics	Submitted Device	Predicate Device	Differences Discussion
Dimension (LxWxH)	Watch Case: D 56mm× W 44mm×H 16mm	158 mm (L) × 73 mm (W) × 25 mm (H)	The physical dimension difference does not raise any new questions of safety and effectiveness.
Weight	Net Weight: about 45g	230g (including battery)	The weight difference does not raise any new questions of safety and effectiveness.
Patient Contact Materials	Complies with ISO10993-1	Complies with ISO10993-1	Complies with ISO10993-1
Data update	USB, Bluetooth	N/A	The AP-10 can upload data to the PC through USB or to a smartphone through Bluetooth. It complies with the applicable standard FCC part 15B.
Operating	Operating temperature: 5~40℃ Operating humidity: 15%~93% (non-condensing) Atmospheric pressure: 70kPa~106kPa	Operating Temperature: 5°C ~40°C Operating Humidity: 15%~93%, non-condensing Atmospheric pressure: 70kPa~106kPa	Operating Temperature: 5°C ~40°C Operating Humidity: 15%~93%, non-condensing Atmospheric pressure: 70kPa~106kPa
Storage	Ambient temperature: -20ºC ~60ºC, Relative humidity 10%~95%, Atmospheric pressure: 50kPa~107.4kPa.	Ambient temperature: -20ºC ~60ºC Relative humidity: 10%~95% Atmospheric pressure: 50kPa~107.4kPa	Ambient temperature: -20ºC ~60ºC Relative humidity: 10%~95% Atmospheric pressure: 50kPa~107.4kPa

Testing Summary:

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

Non-Clinical:

Safety and EMC

To verify the basic safety and essential performance of the AP-10, we performed the tests as noted below:

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-11 Edition 2.0 2015-01Medical 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

The test results demonstrate the subject device complies with the standard's requirements.

Biocompatibility

Patient contact classification is surface contact <24 hours. The biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1, and the testing included the following test results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Performance

For the subject device, AP-10, it meets the performance standards:

ISO 80601-2-61 First edition 2011-04-01 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Software Verification and Validation

Software documentation, including verification & validation, was provided following FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

Cleaning Validation

The AP-10 was cleaned following the procedure defined in the User's Manual. The device was checked for performance following the cleaning and met all performance requirements following the cleaning.

Shelf Life:

The Pulse Oximeter, AP-10, is not subject to the shelf life, as the device doesn't contain any sterile or degradable components.

Clinical:

Clinical testing was conducted per Annex EE Guideline for evaluating and documenting SpO2 accuracy in human subjects of ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Shenzhen Creative Industry Co., Ltd. concludes that the Pulse Oximeter, AP-10 is substantially equivalent to predicate device as described herein. The subject device has the same intended use as the predicate device and the technological differences do not raise different questions of safety and effectiveness

END