Shenzhen Creative Industry Co., Ltd.
% Charlie Mack
Principal Engineer
IRC USA
2095 East Lindrick Drive
Chandler, Arizona 85249

Re: K172792
Trade/Device Name: Handheld Pulse Oximeter, SP-20
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, FLL
Dated: September 20, 2018
Received: October 12, 2018

Dear Charlie 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D.
Courtney -S

for

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172792

Device Name
Handheld Pulse Oximeter, SP-20

Indications for Use *(Describe)*
The Handheld Pulse Oximeter is intended for measuring and displaying the pulse rate, functional oxygen saturation (SpO2) and temperature (optional). It is intended for spot checking 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.

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.***

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# 510(k) Summary

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

Date: September 23, 2018

1. Company and Correspondent submitting:

Name – Shenzhen Creative Industry Co., Ltd.
Address – 2/F, Block 3, Nanyou Tian'an Industry Town Shenzhen, China 518054
Tel: +86-755-26431671
Fax: +86-755-26435433
Contact – Mrs. Jia Wang
General Manager

US Agent and Correspondent
Mr. Charles Mack
Principal Engineer
IRC USA
2950 E Lindrick Drive, Chandler, Arizona 85249 USA
Tel: 931-6254938
Email: charliemack@irc-us.com

2. Device:

Trade/proprietary name: Handheld Pulse Oximeter, SP-20
Common Name: Pulse Oximeter
Classification Name: Oximeter

3. Predicate Devices:

| Manufacturer | Device | 510(k) Number |
|---|---|---|
| Shenzhen Creative Industry Co., Ltd | PATIENT MONITOR, UP-7000 | K123711 |
| Shenzhen Mindray Bio-Medical Electronics Co., Ltd | PM-50 PULSE OXIMETER | K052693 |

4. Classifications Names & Citations:

DQA, SpO2; FLL, Temperature;

5. Description:

Device Description:

This SP-20 Handheld Pulse Oximeter is an integrated product with a modular design. It simultaneously measures physiological parameters by integrated modules and corresponding accessories. The measurement results are displayed, stored and transferred by the central processing unit.

The SP-20 Handheld Pulse links with the compatible 510(k) cleared IR Ear thermometer Device (option). Since the SP-20 receives data from the 510(k) cleared IR Ear thermometer and no data is transmitted to the thermometer, it does not affect the operations or accuracy of the linked IR Ear thermometer Device.

Below is a brief tabular display of the monitor functions and operations.

| | Function | Product Code | Module 510K Status |
|---|---|---|---|
| Built-in Function: | | | |
| Built-in | SpO2<br>Pulse Rate | DQA | Creative $SpO_2$ sensor only (K063641) |
| External Linked Function (Optional): | | | |
| Built-in | TEMP | FLL | Valeo VT-601E IR Ear thermometer (K111463) |

6. Indication for use:

The Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO2) and temperature (optional). It is intended for spot checking 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.

7. Comparison with the predicate device:

Shenzhen Creative Industry Co., Ltd. believes that the Handheld Pulse Oximeter, SP-20 is substantially equivalent to the Shenzhen Creative Industry Co., Ltd; Patient Monitor, UP-7000 (K123711) and the Shenzhen Mindray Bio-Medical Electronics Co., Ltd; Pm-50 Pulse Oximeter (K052693)

Performance Testing:

| Serial Number/Version | Standard and Description | Scope |
|---|---|---|
| IEC 60601-1: 1990+A1+A2+A13 | Medical devices Part1: General requirements for safety and Amendment 1, Amendment 2 and Amendment 13 | General requirements: Electrical Safety |
| IEC 60601-1-2: 2014 | Medical electrical equipment-part 1-2: General requirements for basic safety and essential performance – Collateral standards: Electromagnetic compatibility –Requirements and tests | General requirements: EMC |
| IEC 60601-1-11: Ed. 2.0, 2015 | Medical electrical equipment-part 1-11: general requirements for basic safety and essential performance -collateral standard: Requirement for medical electrical equipment and medical electrical systems used in home healthcare environment | General requirements: Electrical Safety |
| ISO80601-2-61_SpO2 | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment | General requirements: Alarm system |
| IEC/TR60878: 2003 | Graphical symbols for electrical equipment in medical practice | General requirements: Graphical symbols |
| ISO 10993-1:2009 | Biological evaluation of medical devices--Part 1: Evaluation and testing | Biological evaluation |
| ISO 10993-5:2009 | Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity. | General requirements: Biological Estimation |
| ISO 10993-10:2010 | Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity | General requirements: Biological Estimation |

All of the test results noted in the table above complied with the standard's requirements.

Comparison of technological characteristics:

| Characteristics | Submitted Device | Predicate Device | Discussion for the difference |
|---|---|---|---|
| Name and model | Handheld Pulse Oximeter SP-20 | Patient Monitor UP-7000 | - |
| Manufacturer | Shenzhen Creative Industry Co., LTD. | Shenzhen Creative Industry Co., LTD. | - |
| FDA Classification | $SpO_2$: CFR870.2700, DQA<br>TEMP: CFR880.2910, FLL<br>(Optional function-K111463) | $SpO_2$: CFR870.2700, DQA<br>TEMP: CFR880.2910, FLL<br>ECG: CFR870.2300, MWI<br>NIBP: CFR870.1130, DXN<br>$CO_2$: CFR868.1400, CCK | - |
| Physical dimension(mm) /weight(kg) | 158 mm (L) × 73 mm (W) × 25 mm (H)<br>/ 230g (including battery) | 300 (L) x150 (W) x290 (H)<br>/ 5.2kg (including battery) | The SP-20 is handheld device, and is smaller compared to the Predicate Device (UP-7000). The SP-20 device meets the mechanical test requirements defined in IEC60601-1, IEC60601-1-11 and ISO80601-2-61. |
| Display | 3.5" color TFT LCD | 12.1" Color TFT | N/A |
| Type, Degree of protection against electric shock | Class II with an internal electric power supply;<br>Type BF applied parts. | Class I with an internal electric power supply.<br>Where the integrity of the external protective earth(ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply(batteries)<br>$CO_2$: BF (defibrillation proof)<br>$SpO_2$/ NIBP/ TEMP/ ECG/ RESP: CF (defibrillation proof) | The SP-20 device is powered by an external adapter and battery, which is Class II with internal electric power supply device according to IEC60601-1, and applied parts of the SP-20 device are type BF according to IEC60601-1. |
| Power supply | Battery or AC | Battery or AC | Identical |
| Power source | Power adapter: input: 100-240VAC, 50/60Hz; output: 5VDC/1A<br>Internal power supply: 2000mAh lithium battery | (100-240) VAC 50/60Hz 100VA;<br>Rechargeable sealed lead-acid battery, 12V 2.3AH | According to product design request, the SP-20 device is powered by an external adapter and lithium battery, which meet IEC60601-1 and IEC60601-1-2 requirements. |
| Low battery indicator | Yes | Yes | Identical |

| Characteristics | Submitted Device | Predicate Device | Discussion for the difference |
|---|---|---|---|
| Storage data | Yes | Yes | Identical |
| Flammable anesthetics | No | No | Identical |
| Operating environment | Operating Temperature: 5°C~40°C<br>Operating Humidity: 15%~93%, non-condensing<br>Atmospheric pressure: 70kPa~106kPa | Operating Temperature: 5°C~40°C<br>Humidity: 30%~80%, non-condensing<br>Atmospheric pressure: 70kPa~106kPa | The environmental operating conditions of the SP-20 device meets IEC60601-1 and IEC60601-1-11 requirements. |
| Storage condition | Ambient temperature : -20ºC~60ºC<br>Relative humidity: 10%~95%, non-condensing<br>Atmospheric pressure: 50kPa~107.4kPa | Temperature: -20ºC~60ºC<br>Humidity: 10% ~95%, non-condensing<br>Atmosphere: 53k ~106kPa | The environmental storage conditions of the SP-20 device meets IEC60601-1 and IEC60601-1-11 requirements. |
| Optional printer | N/A | Available | N/A |
| Oximetry technique | Creative SpO2 module with the same principle as PC-60(K063641) Creative SpO2 sensor only<br>KM-SPO-01 SpO2 module with KS-C01<br>KM-SPO-01 SpO2 module with KS-YW02 | Creative SpO2 module with the same principle as PC-60(K063641) Creative SpO2 sensor only<br>KM-SPO-01 SpO2 module with KS-C01 | Identical |
| Measuring mode | Spot-check and Continuous recording. | Continuous monitoring | The SP-20 device is intended for spot checking and continuous recording of SpO2 measurement data, but is not intended for continuous monitoring, and meets ISO80601-2-61 requirements. |
| Applied part | Detachable SpO2 probe/ Dual-wavelength LED sensor | Detachable SpO2 probe/ Dual-wavelength LED sensor | Identical |

Indications for Use differences:

Basic Function:

Both devices have the same functions, which includes Pulse Rate, SpO2, TEMP. Both devices also record data. The predicate has more functions, such as ECG, heart rate, $CO_2$ concentration, and respiration rate. Both the submitted device and predicate comply with the same performance testing standards for the common functions.

Both are Prescription Use.

TEMP:

- For the submitted TEMP is optional, but the predicate device's TEMP is a built-in function
- Both devices are for same target population (adult and pediatric)
- The subject device uses an IR thermometer cleared under K111463 (VT-60E IR thermometer), while the predicate Device uses the electronic thermometer cleared under K982140. Both use FDA cleared temperature measuring devices.
- The subject' device has a minor modification for the VT-60E IR thermometer(K111463). The modified VT-601E IR thermometer together with the SP-20 host device passed the applicable performance standards test including IEC60601-1, IEC60601-1-2 and performance test. The modification does not raise different questions of safety and/or effectiveness of VT-601E IR thermometer.

Where Used:

The predict device is applicable for use in hospitals and clinical institutions, while the subject device can also be used at home. Both devices comply with IEC60601-1-11, verifying device performance.

The above differences in the IFU don't result in a new intended use. The subject device complies with the same applicable standards requirement as the predicate device, and it is substantially equivalent to the predicate device.

8. Testing Summary:

**Safety and EMC**

To verify performance of the SP-20, the following tests were performed:

- IEC 60601-1: 2005+A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical devices part 1-2: General requirements for basic

safety and essential performance – Collateral standards: electromagnetic compatibility – Test and requirements

- IEC 60601-1-11 Edition 2.0 2015-01, 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.

The test results from these tests demonstrate the device complies with the requirements.

**Performance Data:**

For the subject device, SP-20, the following verification tests were performed:

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

The device uses 510(k) cleared $SpO_2$ modules with minor modifications and optional TEMP modules. Performance of the $SpO_2$ and TEMP in the performance test report includes normal operating states, appearance, structure, basic performance ($SpO_2$, PR, TEMP) and System Performance. The test results demonstrate compliance with the standards.

**Biocompatibility**

The subject devices, Handheld Pulse Oximeter, SP-20 is using the similar material as the previously cleared predicate device.

According to the ISO 10993-1: 2009 Annex 1 Biological evaluation tests, the subject device is classified: Surface Device – Contact Skin – Contact Duration≤24H

Tests were conducted for cytotoxicity, skin irritation and sensitization test according to the standards noted below:

- 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 Delayed-Type Hypersensitivity

The test results demonstrate compliance with the requirements of the standards.

**Shelf Life:**

The Handheld Pulse Oximeter, SP-20 is not subject to the shelf life, as the device doesn't contain any sterile or degradable components.

9. Clinical:

Clinical testing was performed to demonstrate substantial equivalence to the predicate device. The twelve (12) subjects in the testing were a group of volunteers consisting of 3 women and 9 men. All subjects had no known illnesses, and no subject was anemic. The group was a mixture of ethnic backgrounds, having skin color ranging from light to dark. The ages of the group were from 22 to 38. A total of 24 samples were obtained per subject. Data was recorded by Bickler-Ye Lab and provided for analysis.

Testing validated the submitted device was effective in determining $SPO_2$, and no adverse effects or complications were noted.

10. 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 Handheld Pulse Oximeter, SP-20 is substantially equivalent to predicate devices as described herein.