October 11, 2019

Shenzhen Changke Connect Electronics Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical devices Industrial Park
Nanshan District
Shenzhen, 518067 Cn

Re: K191420
Trade/Device Name: Reusable SpO2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 9, 2019
Received: September 9, 2019

Dear Kevin Wang:

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,

for 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)*
K191420

Device Name
Reusable SpO2 Sensor

Indications for Use *(Describe)*
The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) and pediatric (10-50 kg) patients.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2019/10/10

1. Submission sponsor

Name: Shenzhen Changke Connect Electronics Co., Ltd.
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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Reusable SpO2 Sensor
Common Name	Oximeter (Accessory-sensor)
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

By submission of the Traditional 510(k), Shenzhen Changke Connect Electronics Co., Ltd. is requesting clearance for Reusable SpO2 Sensor. It is comparable to the following legally marketed system:

1. UNIMED MEDICAL SUPPLIES INC. Unimed Reusable SpO2Sensors under K142832.

5. Device Description

The proposed device, Reusable SpO2 Sensors are accessories to patient monitors, which are intended for continuous non-invasive monitoring of functional arterial oxygen saturation and pulse rate. The compatible patient monitor is EDAN iM50 with Nellcor SpO2 module (K113623).

The sensor shall be connected with its corresponding monitor. Oxygenation of blood is measured by

detecting the infrared and red-light absorption characteristics of deoxygenated hemoglobin and oxygenated hemoglobin, which consists of a probe attached to the patient's finger. The sensor is connected to a data acquisition system which is used to calculate and display oxygen saturation levels and pulse rate conditions.

Each sensor has two LEDs, emitting both red and infrared light, and a photodiode. The light is emitted through human finger and received by a photodiode. Then the received signal is forwarded to the corresponding oximeter that amplifies the signal and an algorithm that calculates the ratio. The saturation value is determined by the percentage ratio of the oxygenated hemoglobin (HbO2) to the total amount of hemoglobin (Hb).

6. Intended use & Indication for use

The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) and pediatric (10-50 kg) patients.

7. Comparison to the Predicate Device

Features	**Subject Device Reusable SpO2 Sensors**	**Predicate Device K142832 Unimed Reusable SpO2 Sensors**	**Comparison**
Applicant	Shenzhen Changke Connect Electronics Co., Ltd.	Unimed Medical Supplies Inc.	/
Classification Regulation	21CRF 870.2700	21CRF 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Common name	Oximeter (Accessory-sensor)	Oximeter (Accessory-sensor)	Same
Intended use	The Reusable SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult (> 40 kg) and pediatric (10-50 kg) patients.	Unimed Disposable and Reusable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than40kg, pediatric patients weighing 10 -50 kg, and neonatal patients weighing no less than 3 Kg.	Different (1)
Principle of operation	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light	Red: 660-666nm	Red: 660-666nm	Same

Features	Subject Device Reusable SpO2 Sensors	Predicate Device K142832 Unimed Reusable SpO2 Sensors	Comparison
Emitting	Infrared: 880-950nm	Infrared: 880-950nm	
Signal Detection Method	Photodetector	Photodetector	Same
SpO2 Range	70%-100%	70%-100%	Same
SpO2 Accuracy	±3%	±3%	Same
PR Range	30 bmp - 250 bmp	30 bmp - 250 bmp	Same
PR Accuracy	±3	±3	Same
Sterile	No	No	Same
Usage	Reusable	Disposable, reusable	Same
Supplication site	Finger	Finger or toes	Different (2)
Patient contacting Materials	Silica gel	Silica gel, Foam, 3M Textile	Different (3)
Cable length	3000 mm	Finger clip: 1100 ± 100 mm	Different (4)
Patient end design	finger clip,	finger clip, soft tip, Textile Adhesive, and Non-Adhesive	Different (5)
Connector design	6 pin LEMO Connector	DB9M Connector Masimo 6p Connector Hypertronic 7pin Connector	Different (6)
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same
Performance	Complied with ISO 80601-2-61	Complied with ISO 80601-2-61	Same
Biocompatibility			
Cytotoxicity	Complied with ISO 10993-5	Complied with ISO 10993-5	Same
Skin Irritation	Complied with ISO 10993-10	Complied with ISO 10993-10	Same
Sensitization	Complied with ISO 10993-10	Complied with ISO 10993-10	Same

Justifications for differences between proposed device and the predicate device are shown as below:

Different (1): The intended population of proposed devices is within the range of predicate devices. This specification has been verified and validated according to ISO 80601-2-61: 2017 clause 201.12.1.101 clinical accuracy of pulse oximeter equipment. Thus, this difference does not raise different questions of safety and effectiveness.

Different (2): The proposed devices are intended used on finger. This clinical use has been verified and validated according to ISO 80601-2-61: 2017 clause 201.12.1.101 clinical accuracy of pulse oximeter equipment. Thus, this difference does not raise different questions of safety and effectiveness.

Different (3): The predicate devices have 3 type of patient contacting materials and the proposed devices

have 1 type. The proposed devices can meet the requirement of ISO 10993-5/-10, so this difference does not raise different questions of safety and effectiveness.

Different (4): The cable length is different. However, the proposed devices can meet the requirement of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-61, so this difference does not raise different questions of safety and effectiveness.

Different (5): The predicate devices have 4 type of patient end design (finger clip, soft tip, Textile Adhesive, and Non-Adhesive). The proposed devices have 1 type of patient end which is finger clip. The proposed devices can meet the requirement of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-61, so this difference does not raise different questions of safety and effectiveness.

Different (6): The connector design depends on the socket of the compatible patient monitor. The proposed devices can meet the requirement of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-61 with the compatible patient monitor, so this difference does not raise different questions of safety and effectiveness.

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the Changke Reusable SpO2 Sensors was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject devices are considered surface contacting for a prolonged duration exceeding 24 hours but not 30 days.

Non-clinical data

The Changke Reusable SpO2 Sensors have been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests
- ISO 80601-2-61: 2011 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

The tests accordance with IEC 60601-1, IEC 60601-1-2, ISO 80601-2-61 and ISO 10993 series are selected to show substantial equivalence between the subject device and the predicate.

Clinical data

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Changke Reusable SpO2 Sensors versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed devices are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.