August 19, 2020

Xinkang Medical Instrument Co. Ltd.
% James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K201360
Trade/Device Name: Reusable and Disposable SpO2 Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 18, 2020
Received: May 21, 2020

Dear James Tsai:

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)*
K201360

Device Name
Reusable and Disposable SPO2 Sensors

Indications for Use *(Describe)*
The Reusable and Disposable 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 than 40kg. The sensors are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.

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.

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510(k) Summary

K201360

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Date of Summary prepared	July 13, 2020
Manufacturer information	Company: Xinkang Medical Instrument Co., Ltd. Company address: 2 Floor, Puhua Science and Technology Park, Tongsheng Community Dalang Street, Longhua District, 518109 Shenzhen, People's Republic of China Contact person: Xu Changsheng Phone: +86-755-23776681 Fax: +86-755-23776861 E-mail: 751857289@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com
Establishment registration number	

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Reusable and Disposable SpO_2 Sensors
Classification name:	Oximeter
Review Panel:	Cardiovascular devices
Product Code:	DQA
Device Class:	II

Regulation Number:	870.2700

3 Predicate Device Information

Sponsor:	Unimed Medical Supplies, Inc.
Device:	Unimed Reusable and Disposable SpO_2 Sensors
510(K) Number:	K142832
Review Panel:	Cardiovascular devices
Product Code:	DQA
Device Class:	II
Regulation Number:	870.2700

4 Device Descriptions

The proposed device, Reusable and Disposable SpO_2 sensors are the accessory of the patient monitors, which are intended for continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive way with legally marketed devices.

The sensor shall be connected to its corresponding monitor (Nellcor, N-600x cleared in K060576), and it is used to attach the patient's finger and measure oxygenation of blood from detecting the infrared-light and red-light absorption characteristics of deoxygenated hemoglobin and oxygenated hemoglobin. The sensor is connected to a data acquisition system which is used to calculate and display oxygen saturation values and heart rate conditions.

The Reusable and Disposable SpO_2 sensors consist of compatible connectors, cable, and patient sensor terminal. And the optical components of sensor are designed to a light emitting diode and a light detector. Red and Infrared lights are shone through the terminal tissues. Then parts of the emitting lights are absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. The light detector detects the light volume transmitted through the tissues on the basis of blood pulse, then the microprocessor calculates a value for the oxygen saturation by measuring the absorbance of the wave peak and the wave trough. The saturation values are determined by the percentage ratio of the oxygenated hemoglobin (HbO_2) to the total amount of hemoglobin (Hb).

5 Intended Use/ Indications for Use

The Reusable and Disposable SpO_2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensors are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.

6 Comparison to predicate device

Comparison item	Proposed Device	Predicate Device (K142832)
Product name	Reusable and disposable SpO_2 sensor	Unimed Reusable and Disposable SpO_2 Sensors
Model	Adult/reusable: XSAE3 Adult/disposable: XDAN	Adult/reusable: U403S-01 Adult/disposable: U503-01
Product Code	DQA	DQA
Regulation Number	870.2700	870.2700
Classification	II	II
Intended use & Indications for Use	The Reusable and Disposable SpO_2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensors are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.	Unimed Disposable and Reusable SpO_2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) 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.
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption
Light Emitting	Red: 660nm±3nm Infrared: 880-950nm	Red:660-666nm Ired:880-950nm
Signal Detection Method	Photodetector	Photodetector
SPO2 Accuracy	±3% (70-100%)	±3% (70-100%)
Pulse Rate Accuracy	±3(30-250bpm)	±3 (30-250bpm)
Applied population	Adult (≥40Kg)	Adult (≥40Kg)
Measurement part	Fingers	Fingers
Distal connector design	Soft tip, non-woven	Soft tip, textile adhesive
Compatible monitor	Nellcor	Nellcor
Sterile	No	No
Material	Silicone, Non-woven	Silicone, 3M
Biocompatibility	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization
Electrical Performance and Safety	IEC60601-1,IEC60601-1-2, ISO80601-2-61,ISO10993-5/10	IEC60601-1,IEC60601-1-2, ISO80601-2-61,ISO10993-5/10

The proposed device and the predicate device have the same intended use and similar technological characteristics; they both measure SpO_2 values for the patients.

7 Performance data

The following performance data of Reusable and Disposable SpO_2 Sensors were provided in support of the substantial equivalence determination:

Biocompatibility testing

The biocompatibility evaluation for the Reusable and Disposable SpO_2 Sensors were 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 terminal sensor and cable are considered to be contacted with patient's intact skin for duration of less than 24 hours. The biocompatibility testing includes the following:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the proposed device complies with the following standards:

- 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
- 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
- ISO 80601-2-61: 2017 + COR1:2018 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment standard for performance effectiveness

Clinical study

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 Reusable and Disposable SpO_2 Sensors versus arterial oxygen saturation (SaO_2) as determined by CO-oximeter. Clinical test results support device accuracy claims for the specified saturation range. The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, the volunteer population in the studies composed of healthy men and women from age 21 to 50, with variations of skin pigmentations and per FDA's guidance for Pulse Oximeters, three darkly pigmented subjects are included in the clinical study.

Summary

Based on the non-clinical performance and clinical data as documented in the device development, the proposed device has a safety and effectiveness profile that is similar to the predicate device.

8 Conclusions

Based on device comparison information and performance data, the proposed device has the same intended use as the predicate device, and the differences in technological characteristics does not raise different questions of safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.