January 24, 2020

Shenzhen SINO-K Medical Technology 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: K192608
Trade/Device Name: Disposable SpO2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 26, 2019
Received: December 26, 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,

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)*

K192608

Device Name
Disposable SpO2 Sensor

Indications for Use *(Describe)*

The Disposable SPO2 Sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40 kg at hospital facilities.

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

Prepared Date: 2019/09/17

1. Submission sponsor

Name: Shenzhen SINO-K Medical Technology Co., Ltd.
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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Disposable 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

Manufacturer: Orantech Inc.
510 (k) #: K181270
Product Name: Disposable SpO2 Sensors

5. Device Description

The proposed device, Disposable SpO2 Sensor is accessory to the oximeter, which is intended for continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with U.S. legally marketed oximeter. It is only intended for adult.

The sensor shall be connected with the corresponding monitor (Nellcor N-600). 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 heart rate conditions.

Each sensor has two LEDs, emitting both red and infrared light, and a photodiode. Red and infrared light lit alternately according to certain sequence, when the fingertips of capillary repeatedly with the heart pumps blood congestion, light emitting diode after blood vessels and tissues and projected onto a photodiode, photodiode can be induced to change with pulse light intensity, the electrical signals in the form of change. Then the received signal is forwarded to the corresponding oximeter that amplifies the signal and an algorithm that calculates the ratio. By measuring the wave crest of the pulse wave and the absorbance of the trough, SpO2 is calculated to obtain the correct oxygen saturation value. 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 Disposable SPO2 Sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40 kg at hospital facilities.

7. Comparison to the Predicate Device

Features	**Subject Device Disposable SpO2 Sensors**	**Predicate Device K181270 Disposable SpO2 Sensors**	**Comparison**
Applicant	Shenzhen SINO-K Medical Technology Co., Ltd.	Orantech Inc.	/
Classification Regulation	21CFR 870.2700	21CFR 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 Disposable SPO2 Sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40 kg at hospital facilities.	The 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 than 40 kg at hospital facilities.	Same
Principle of operation	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same

Features	Subject Device Disposable SpO2 Sensors	Predicate Device K181270 Disposable SpO2 Sensors	Comparison
Light Emitting	Red: 660-666nm Infrared: 880-950nm	Red: 660, 661 and 663nm Infrared: 890, 904 and 940nm	Different [1)]
Signal Detection Method	Photodetector	Photodetector	Same
SpO2 Range	70%-100%	70%-100%	Same
SpO2 Accuracy	±3%	±3%	Same
PR Range	30 bpm - 250 bpm	35 bpm - 240 bpm	Different [2)]
PR Accuracy	±3 bpm	±2 bpm	
Sterile	No	No	Same
Usage	Disposable	Disposable	Same
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 light emitting between proposed device and predicate device is slightly different. The light emitting affects the SpO2 measurement. The SpO2 and PR measurement has been verified and validated according to ISO 80601-2-61: 2017 clause 201.12.1.101 SpO2 accuracy of pulse oximeter equipment. This difference does not raise any different questions of safety or effectiveness.

Different (2): The PR measurement between proposed device and predicate device is different. This specification has been verified and validated according to ISO 80601-2-61: 2017. This difference does not raise any different questions of safety or effectiveness.

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the subject device 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 device is considered surface contacting for a duration of not exceed 24 hours.

Non-clinical data

The disposable SpO2 Sensor has 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: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

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 disposable SpO2 Sensor versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

9. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.