Orantech Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K181270
Trade/Device Name: Disposable SpO2 Sensors, Reusable SpO2 Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 23, 2018
Received: August 10, 2018

Dear Diana Hong:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181270

Device Name
Disposable SpO2 Sensors, Reusable SpO2 Sensors

Indications for Use *(Describe)*
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.

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 being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K181270

1. Date of Preparation: 8/21/2018

2. Sponsor Identification

Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, Shenzhen, 518132, Guangdong, China.

Establishment Registration Number: Not yet registered

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Disposable SpO_2 Sensors, Reusable SpO_2 Sensors
Model: SSD-001-W09AN, SS-010-AF10 and SS-018-AF10
Classification Name: Oximeter (Accessory-sensor)
Classification: II
Product Code: DQA
Regulation Number: 21 CFR 870.2700
Review Panel: Anesthesiology

Indications for Use:
The 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 than 40 kg at hospital facilities.

Device Description
The proposed device, Disposable and Reusable SpO_2 Sensors are accessories to the oximeters, which are intended for spot checking or continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with U.S. legally marketed oximeters or patient monitors. The SSD-001-W09AN sensors is disposable while the SS-010-AF10 and SS-018-AF10 sensors are reusable. They are only intended for adult.

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 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, SpO_2 is calculated to obtain the correct oxygen saturation value. The saturation value is determined by the percentage ratio of the oxygenated hemoglobin (HbO_2) to the total amount of hemoglobin (Hb).

5. Identification of Predicate Device

Predicate Device
510(k) Number: K153184
Product Name: Caremed Reusable & Disposable SpO2 Sensors

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with 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.
- 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 skin sensitization

The proposed device have also been demonstrated to comply with the requirements of US electrical safety differences according to US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010.

The accuracy test on proposed device demonstrated that the accuracy of pulse and SpO2 meets the specified requirements.

The accuracy test on proposed device under low perfusion conditions demonstrated that the accuracy of pulse and SpO2 under low perfusion conditions meets the specified requirements.

The proposed device belongs to skin contact, and the contact duration is less than 24h. Biocompatibility tests have been conducted on proposed device, including cytotoxicity, sensitization, and skin irritation. The test results show that the proposed device has no cytotoxicity, sensitization, or skin irritation.

7. Clinical Test Conclusion

Clinical studies were conducted to verify the accuracy of proposed device. All of three models were included in the studies. The clinical studies were conducted per following standards:

- ➢ ISO 80601-2-61: 2011 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

The clinical studies are conducted with proposed device and compatible oximeter, the device included in the clinical studies are listed as follow:

Table 1 Device in Clinical Studies

Proposed Sensor Model	Compatible Oximeter	K Number of Oximeter
SSD-001-W09AN	Nellcor NPB-40	K963707
SS-010-AF10	GE TuffSat	K001688
SS-018-AF10	GE TruSat	K040831

There are two clinical studies for proposed device, one is conducted on SS-010-AF10 and SSD-001-W09AN, and the other is conducted on SS-018-AF10.

Clinical studies were performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in 12 human adult volunteers for each study, to validate the accuracy of proposed device versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

8. Substantially Equivalent (SE) Comparison

Table 2 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device K153184
Product Code	DQA	DQA
Regulation Number	21 CFR 870.2700	21 CFR 870.2700
Class	II	II
Indications for Use	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.	Caremed Reusable & 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 40 kg and pediatric patients weighing 10 -50 kg at hospital facilities
Principle of	2-wavelength Relative Optical	2-wavelength Relative Optical Absorption

Operation	Absorption	
Light Emitting	Red:660, 661 and 663nm Infrared:890, 904 and 940nm	Red:660-666nm Infrared:880-950nm
Signal Detection Method	Photodetector	Photodetector
SpO_2 Range	70%-100%	70-100%
SpO2 Accuracy	f3%	f3% @ 70-100%
PR Range	35-240bpm	30-250 bpm
PR Accuracy	f2 bpm	f3 bpm
Sterile	No	No
Usage	Reusable & Disposable	Reusable & Disposable
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2
Performance	Complied with ISO 80601-2-61	Complied with ISO 80601-2-61
Biocompatibility		
Cytotoxicity	Complied with ISO 10993-5	Complied with ISO 10993-5
Skin Irritation	Complied with ISO 10993-10	Complied with ISO 10993-10
Sensitization	Complied with ISO 10993-10	Complied with ISO 10993-10

9. Substantially Equivalent (SE) Conclusion

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