December 22, 2021

Dongguan Lingxin Technologies Co., LTD
% Reanny Wang
Manager
Shenzhen Reanny Medical Devices Mangement Consulting., Ltd
Room 1813 of Gebu Commercial Building, Hongxing,
Songgang Street, Baoan District
Shenzhen, Guangdong 518000
China

Re: K210305
Trade/Device Name: Pulse Oximeter, Model: OX201
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 22, 2021
Received: November 22, 2021

Dear Reanny 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210305

Device Name
Pulse Oximeter, Model: OX201

Indications for Use *(Describe)*
The OX201 Pulse Oximeter is a non-invasive device intended for prescription use spot-check of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients (weight ≥ 40kg) in home, hospital and clinic environments. The device is not intended for continuous monitoring, use during motion or use with low perfusion.

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

This 510(K) summary is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

The assigned 510(k) number is: K210305

1.0 Information of Submitter and Correspondent

Submitter's information:

Company Name: Dongguan Lingxin Technologies Co., LTD
Street Address: Room 301, No.3 Liantang Road, Aoshitang, Dongcheng Street,
City: Dongguan
State/ Province: Guangdong
Country: China
Telephone: +86(769)-89605029
Fax: +86(769)-89605029
Contact Person: Wayne
Contact Title: General Manager
Contact Email: Wayne@ijoyen.com

Summary prepared: December 22, 2021

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
Address: Room 1407#, Jingting Building, Dongzhou Community, Guangming Street, Guangmeing District, Shenzhen 518000, China
Contact Person: Reanny Wang; E-mail: reanny@reanny.com

2.0 Device Information

Type of 510(k) submission: Traditional
Trade Name: Pulse Oximeter
Model: OX201
Classification name: Oximeter
Review Panel: Anesthesiology

Product Code:	DQA
Device Class:	Class II
Regulation Number:	870.2700

3.0 Predicate Device Information

Sponsor:	Contec Medical Systems Co., Ltd.
Device:	CMS-50D Finger Pulse Oximeter
510(K) Number:	K082641

4.0 Device Description

The OX201 pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rage (PR) of single adult and pediatric patient in home and hospital.

The fingertip pulse oximeter features small size, low power consumption, convenient operation and portability. Power consumption of the product is low and two AAA batteries can be operated continuously for 24 hours. It is only necessary for a patient to put one of his/her fingers into the fingertip clips for measurement, use it very easy.

Principle of the fingertip pulse oximeter as follows:

A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones.

Operation principle of the instrument:

Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. Relevant dada is shown on the Oximeter's display through electronic circuits and a microprocessor.

5.0 Intended Use

The OX201 Pulse Oximeter is a non-invasive device intended for prescription use spot-check of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients (weight ≥ 40kg) in home, hospital and clinic environments. The device is not intended for continuous monitoring, use during motion or use with low perfusion.

6.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Same
Appearance	Similar
Patients contact materials	Same
Performance	Similar
Biocompatibility	Same
Mechanical safety	Same
Energy source	Same
Electrical safety	Same
Standards met	Same
EMC	Same
Function	Similar

7.0 Performance Summary

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Testing:

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

Biocompatibility testing

The biocompatibility evaluation for the Pulse Oximeter was 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 worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the 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 and the IEC 60601-1-2: 2007 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests standard for EMC.

Bench Testing

Bench testing was conducted, and the results show that the subject device complies with the ISO 80601-2-61: 2017 Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment standard. And Pulse Rate Accuracy meets the requirements defined in ISO 80601-2-61, Clause 201.12.1.104.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

Cleaning Validation

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17,2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the manual.

Clinical data:

Clinical testing is conducted per Annex EE Guideline for evaluating and documenting SpO 2 ACCURACY in human subjects of ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

8.0 Comparison to predicate device

The subject device OX201 Pulse Oximeter is substantially equivalent to CMS-50D Fingertip Pulse Oximeter whose 510(k) number is K082641.

Elements of Comparison	Subject Device	Predicate Device (K082641)	Judgment
Company	Dongguan Lingxin Technologies Co., LTD	Contec Medical Systems Co., Ltd.	--
Device Name	Pulse Oximeter	Fingertip Pulse Oximeter	Same
Model	OX201	CMS-50D	--
510(k) Number	Pending	K082641	--
Intended patient population	Adult and Children	Adult and Children	Same
Intended application site	Fingertip	Fingertip	Same
Intended use	The OX201 Pulse Oximeter is a non-invasive device intended for prescription use spot-check of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients (weight ≥ 40kg) in home, hospital and clinic environments. The device is not intended for continuous monitoring, use during motion or use with low perfusion	The Fingertip Pulse Oximeter is a non-invasive device intended for spot-check of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc). The device is not intended for continuous monitoring.	Same
Prescription or OTC	Prescription	Prescription	Same
Contact material	Silica rubber	Silica rubber	Same
Display type	Color OLED display, 4 display directions	Color OLED display, 4 display directions	Same
Measurement range of SPO2	70-100%	0-100%	Similar
Accuracy of SPO2	70%-100%, ±2%; Less than 70% no definition	70%-100%, ±2%; Less than 70% no definition	Same

Elements of Comparison	Subject Device	Predicate Device (K082641)	Judgment
Resolution of SPO2	1%	1%	Same
Transducer of SPO2	Dual-wavelength LED sensor	Dual-wavelength LED sensor	Same
Measurement wavelength of SPO2	Red light:660nm, Infrared light: 905nm	Red light: 660nm, Infrared light: 880nm	Similar Note 1
Measurement range of pulse rate	25-250bpm	20-250bpm	Similar Note 2
Accuracy of pulse rate	±2bpm or ±2% (whichever is greater)	±2bpm or ±2% (whichever is greater)	Same
Resolution of pulse rate	1 bpm	1 bpm	Same
Pulse intensity of pulse rate	Bar graph indicator	Bar graph indicator	Same
Design principle	A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of light scan be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor shown on the Oximeter's display through electronic circuits and a microprocessor.		Same
Power source	DC3V, 2 × AAA batteries	DC3V, 2 × AAA batteries	Same
Other function	Low battery voltage indicate; Automatically power off; General setup and sounds setup and Bluetooth	Low battery voltage indicate; Automatically power off; General setup and sounds setup,	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device (K082641)	Judgment
Dimensions	62 × 34 × 34mm (L×W×H)	57 × 31 × 32mm (L ×W×H)	Similar
Weight	50g (including two AAA batteries)	50g (including batteries)	Same
Operation condition	10-40℃, 15-95%RH, 70kPa-106kPa	5-40℃, ≤90%RH, 70kPa-106kPa	Similar
Storage condition	-20-60℃, 15-95%RH, 70kPa-106kPa	-40-60℃, ≤95%RH, 50kPa-106kPa	Similar
Classification	Internally powered equipment, type BF applied part	Internally powered equipment, type BF applied part	Same
Grade of waterproof	IPX2	IPX1	Similar
Material of applied part	Silicon rubber	Silicon rubber	Same
Material of housing	ABS	ABS	Same
Performance	Compliance with ISO 80601-2-61	Compliance with ISO 9919	Similar Note 4
Biocompatibility	All the patient contacting materials are compliance with ISO 10993-1/-5/-10	All the patient contacting materials are compliance with ISO 10993-1/-5/-10	Same
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
Safety of home healthcare environment	Compliance with IEC 60601-1-11	--	Similar
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same

As seen in the comparison tables, the subject and predicate devices have same design principle, similar design features and performance specifications. The different technological characteristics between the subject and predicate devices will not raise different questions of safety or effectiveness

9. Conclusion

Verification and validation testing was conducted on the subject device Pulse Oximeter and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device. The subject device and the predicate device has the same intended use, and technological differences does not raise different questions of safety and effectiveness.