May 4, 2023

Shenzhen Changkun Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting., Ltd
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518000
China

Re: K221798
Trade/Device Name: Finger Pulse Oximeter, Model: X1906P
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 4, 2023
Received: May 4, 2023

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 and Part 809); 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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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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)*
K221798

Device Name
Finger Pulse Oximeter, Model: X1906P

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 7mm and 25.4mm in diameter (0.28 inches to 1.0inches). And it is not intended to be used under motion or low perfusion scenarios.

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

The assigned 510(k) number is: K221798

1.0 Information of Submitter and Correspondent

Submitter's information:

Company Name: Shenzhen Changkun Technology Co. Ltd.

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Contact Person: Wang Qingpeng

Contact Title: General Manager

Contact Email: 757168025@qq.com

Submission correspondent's information:

Company Name: Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1407, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen, Guangdong Province, China

Contact person: Reanny Wang

E-Mail: Reanny@reanny.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Fingertip Pulse Oximeter
Model:	X1906P
Classification name:	Oximeter
Review Panel:	Anesthesiology
Product Code:	DQA
Device Class:	Class II
Regulation Number:	870.2700

3.0 Predicate Device Information

Sponsor: Beijing Choice Electronic Technology Co., Ltd.

Device: Fingertip Pulse Oximeter

510(K) Number: K160268

4.0 Intended Use

The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 7mm and 25.4mm in diameter (0.28 inches to 1.0inches). And it is not intended to be used under motion or low perfusion scenarios.

5.0 Product introduction

The Fingertip Pulse Oximeter X1609P is a fingertip device, which can measure the arterial SpO2 and pulse rate value and can display the results to the user.

Moreover, the X1609P also has the function of low battery voltage indicate and automatically power off. The power source is 2×AAA batteries. Fingertip Pulse Oximeter X1609P is small in volume, light in weight and convenient in carrying. It is composed of light signal driving circuit, preamplification circuit, low pass filtering circuit, DC bias circuit, gain control circuit, display control circuit, and main control circuit.

The device is for prescription. It is neither for life-supporting nor for implanting. It does not contain any drug or biological product and it does not need to be sterile.

The intended use, design principle, operation principle, functions, material and the applicable standards of X1609P Fingertip Pulse Oximeter are the same as the predicated device MD300CG51 Fingertip Pulse Oximeter (K160268) manufactured by Beijing Choice Electronic Technology Co., Ltd.

6.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Indications for use	Same
Design principle	Same
Appearance	Similar
Patients contact materials	Same
Performance	Similar
Biocompatibility	Same
Mechanical and 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 Fingertip 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 testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety, Home Healthcare environment and electromagnetic compatibility (EMC)

Electrical safety, Home Healthcare environment 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)+A1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance, IEC 60601-1-11: 2015 Medical

electrical equipment –Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment and the 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.

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 Fingertip 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.

The above tests were selected to show substantial equivalence between the subject device and the predicate device.

Clinical test:

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.

There were 13 adult volunteers to validated the accuracy of finger pulse oximeter (Model: X1906P). 5 males and 8 females (including 3 subjects with Fitzpatrick VI, 3 subjects with Fitzpatrick II and 7 with Fitzpatrick IV). The measure result between the SpO2 measured by subject device and the SaO2 measured by the blood gas analyzer, the measure result between the PR measured by subject device and the HR measured by the patient monitor

were conformed with the requirements of this clinical trial and related standards. The pulse oximeter had not been found any safety issues, adverse effects and complications during the clinical trial.

8.0 Comparison to predicate device

The subject device X1906P Fingertip Pulse Oximeter is substantially equivalent to MD300CG51 Fingertip Pulse Oximeter whose 510(k) number is K160268.

Elements of Comparison	Subject Device	Predicate Device	Judgment
Company	Shenzhen Changkun Technology Co. Ltd.	Beijing Choice Electronic Technology Co., Ltd.	--
Device Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter	---
Model	X1906P	MD300CG51	--
510(k) Number	Pending	K160268	--
Product code	DQA	DQA	Same
Intended patient population	Adult and Children	Adult, adolescent, child and infant patient	Same, within the range of predicate device
Intended application site	Finger	Finger	Same
Intended use	The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 7mm and 25.4mm	The Fingertip Pulse Oximeter MD300CG11/ D300CG51 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, child and infant patient with the fingers between 0.9 - 2.2 m (0.4 - 0.9 inch) thick in hospital.	Same, the description is difference and the finger thick range have been evaluated in clinical trial according

Elements of Comparison	Subject Device	Predicate Device	Judgment
	in diameter (0.28 inches to 1.0inches). And it is not intended to be used under motion or low perfusion scenarios.		to ISO 80601-2-61.
Presentation or OTC	Presentation	Presentation	Same
Measurement range of SPO2	0~99%	0~99%	Same
Accuracy of SPO2	70% to 99% range ± 2%; less than 70% are unspecified	70%-99%, ±2%; Less than 70% no definition	Same
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: 940nm	Red light: 660nm, Infrared light: 940nm	Same
Measurement range of pulse rate	30-250bpm	30-235bpm	Similar
Accuracy of pulse rate	±3bpm	30-99bpm, ±2bpm; 100-235bpm, ±2%	Similar
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		Same

Elements of Comparison	Subject Device	Predicate Device	Judgment
	Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lightscan 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.		
Power source	Internal powered equipment DC3V, 2 × AAA batteries	Internal powered equipment 1 AAA-size alkaline battery	Same
Dimensions	60mm×35mm×37mm	Unknown	/
Weight	About 56g (including 2 AAA alkaline batteries)	Unknown	/
Classification	Internally powered equipment, type BF applied part	Internally powered equipment, type BF applied part	Same
Grade of waterproof	IP22	IPX2	Same
Material of pulse oximeter	ABS and silicone rubber	ABS and Silicone gel	Same
Performance	Compliance with ISO 80601-2-61	Compliance with ISO 80601-2-61	Same
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	Compliance with IEC 60601-1-11	Compliance with IEC 60601-1-11	Same

Elements of Comparison	Subject Device	Predicate Device	Judgment
environment			
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

The Fingertip Pulse Oximeter is monitoring the patient's SpO2 and pulse rate in non-invasive, timely and convenient. Non-clinical testing and clinical testing were conducted on the subject device and all testing passed pre-specified criteria. The risks of Finger Pulse Oximeter also have been evaluated according to ISO 14971, the overall residual risk and side effect are acceptable, the benefit is greater than risk and hazard. Which demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed device predicate. The subject device is substantially equivalent to the predicate device.

10. Summary prepared date

May 4, 2023