July 30, 2021

Zhuhai Linte Medical Instrument Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District,
Shenzhen, Guangdong 518067
China

Re: K210274
Trade/Device Name: Fingertip Pulse Oximeter, Model LT-F20 and LT-F21
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 29, 2021
Received: July 2, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210274

Device Name
Fingertip Pulse Oximeter, model: LT-F20 and LT-F21

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.

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: 2021/07/25

1. Submission sponsor

Name: Zhuhai Linte Medical Instrument Co., Ltd.
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2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
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Contact person: Kevin Wang
E-mail: kevin@chonconn.com
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3. Subject Device Information

Trade/Device Name	Fingertip Pulse Oximeter
Model	LT-F20 and LT-F21
Common Name	Fingertip Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Shenzhen Aeon Technology Co., Ltd.
Device name: Pulse Oximeter
510(K) Number: K190869

5. Device Description

The Fingertip Pulse Oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).

The Fingertip Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 905 nm, which is Infrared light. Skin, bone, tissue, and venous vessels normally absorb a

constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2. The Pulse Oximeter is powered by 2 AAA alkaline batteries.
The device mainly composed of PCB board, On/Off button, mode button, OLED or LED screen, battery compartment, and plastic shell.
The device is a spot-check pulse oximeter and does not include alarms. The device is not intended for life-supporting or life-sustaining.

6. Intended use & Indication for use

The Fingertip Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.

7. Comparison to the Predicate Device

Features	**Subject Device** Fingertip Pulse Oximeter	**Predicate Device K190869** **AEON Pulse Oximeter**	**Compariso n**
Applicant	Zhuhai Linte Medical Instrument Co., Ltd.	Shenzhen Aeon Technology Co., Ltd.	/
Classification Regulation	21CRF 870.2700	21CRF 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Common name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter	Same
Intended use	The Fingertip Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.	The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.	Same
Patient populations	Adults	Adults	Same
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse	Same

Features		Subject Device Fingertip Pulse Oximeter	Predicate Device K190869 AEON Pulse Oximeter	Comparison
		rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	
Light Emitting		Red: 660 nm Infrared: 905 nm	Red: 660 nm Infrared: 905nm	Same
Power source		2 AAA alkaline batteries	2 AAA alkaline batteries	Same
Display data		SpO2%, PR	SpO2%, PR	Same
SpO2 Measuring Range		35%-100%	35%-100%	Same
SpO2 Resolution		1%	1%	Same
SpO2 Accuracy		70% ~ 100%, Arms ± 3%. <70%, unspecified.	70 ~ 100%, ±3%. <70%, unspecified;	Same
PR Range		30 bmp – 250 bmp	30 bmp – 250 bmp	Same
PR Resolution		1 bpm	1 bpm	Same
PR Accuracy		±1% or ±3bpm, whichever is greater	± 2	Different (1)
Sterile		No	No	Same
Application site		Finger	Finger	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 accuracy of PR is different. The PR measurement has been verified according to declared range and accuracy. Thus, this difference does not raise different questions of safety and effectiveness.

8. Performance Data

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 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 devices are considered surface contacting for a duration of not exceed 24 hours.

Non-clinical data

The Fingertip Pulse Oximeter 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
- 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.
- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- FDA Guidance for Pulse Oximeters - Premarket Notification Submissions [510(k)s]

The test was selected to show substantial equivalence between the subject device and the predicate.

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

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.