



November 27, 2020

Guangdong Long Yao Electronic Technology 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: K201294

Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 28, 2020
Received: October 30, 2020

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)

K201294

Device Name

Pulse Oximeter

Indications for Use (Describe)

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

K201294

Prepared Date: 2020/11/16

1. Submission sponsor

Name: Guangdong Long Yao Electronic Technology Co., Ltd.

Address: Unit A03, 2nd Floor, No. 19, Huali Road, Tianhe District, Guangzhou, Guangdong, P.R. China

Contact person: Lei Wang

Title: General Manager

E-mail: 965731439@qq.com

Tel: +86 135 80508450

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.

Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China 518067

Contact person: Kevin Wang

E-mail: kevin@chonconn.com

Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Pulse Oximeter
Model	LYOX01
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 Pulse Oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR).

The 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 smart phone and the measurement result will display on an Apple iPhone and Android phone.

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 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 Pulse Oximeter	Predicate Device K190869 AEON Pulse Oximeter	Comparison
Applicant	Guangdong Long Yao Electronic Technology Co., Ltd.	Shenzhen Aeon Technology Co., Ltd.	/
Classification Regulation	21CFR 870.2700	21CFR 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 Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO ₂) 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 (SpO ₂) 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	The device displays numerical values for functional oxygen saturation of arterial	Same

Features		Subject Device Pulse Oximeter	Predicate Device K190869 AEON Pulse Oximeter	Comparison
		hemoglobin (SpO ₂) and pulse 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.	hemoglobin (SpO ₂) and pulse 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 Infrared: 905nm	Red: 660 Infrared: 905nm	Same
Power source		Cell phone	2 AAA alkaline batteries	Different ⁽¹⁾
Display data		SpO ₂ %, PR	SpO ₂ %, PR	Same
SpO ₂ Measuring Range		50%-100%	35%-100%	Different ⁽²⁾
SpO ₂ Resolution		1%	1%	Same
SpO ₂ Accuracy		70~100%, ±3%; 0-69%, unspecified;	70~100%, ±3%; 0-69%, unspecified;	Same
PR Range		30 bmp – 240 bmp	30 bmp – 250 bmp	Different ⁽³⁾
PR Resolution		1 bpm	1 bpm	Same
PR Accuracy		±1	± 2	Different ⁽⁴⁾
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 power source is different. The subject device is powered by cell phone through connector cable. The predicate device is powered by internal battery. The electricity safety testing was conducted according to IEC 60601-1: 2012. Thus, this difference does not raise different questions of safety and effectiveness.

Different (2): The SpO₂ measuring range is different. The SpO₂ measurement of the subject device was validated according to ISO 80601-2-61. Thus, this difference does not raise different questions of safety and effectiveness.

Different (3) & (4): The pulse rate measuring range and accuracy is different. The PR measurement of the subject device was validated 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 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 testing included the following:

- Cytotoxicity
- Sensitization
- Irritation

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

Non-clinical data

The 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
- 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 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. The subject device has the same intended use as the predicate device, and the technological differences do not raise different questions of safety and effectiveness.