September 23, 2020

Shenzhen Aeon Technology Co., Ltd.
℅ Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical devices Industrial Park
Nanshan District
Shenzhen, 518067 Cn

Re: K200414
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 25, 2020
Received: September 1, 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)*

K200414

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.

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510(K) Summary

K200414

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/09/17

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Pulse Oximeter
Model	A310B, A330B
Common Name	Fingertip Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

By submission of the Traditional 510(k), Shenzhen Aeon Technology Co., Ltd. is requesting clearance for Pulse Oximeter. It is comparable to the following legally marketed system:

1. Shenzhen Aeon Technology Co., Ltd. Fingertip Pulse Oximeter under K190869.

The subject device has same intended use, same target patient population, same performance effectiveness, performance safety as the predicate devices and no question is raised regarding to effectiveness and safety. So, the conclusion is that the subject device is substantial equivalent to the predicate.

5. Device Description

The Pulse Oximeter is a battery powered device 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 device mainly composed of PCB board, On/Off button, mode button, OLED&LED screen, battery compartment, Bluetooth® module and plastic shell. The device has wireless connection function via Bluetooth®.

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 A310B and A330B**	**Predicate Device K190869 Model: A310 and A330**	**Remark**
Applicant	Shenzhen Aeon Technology Co., Ltd.	Shenzhen Aeon Technology Co., Ltd.	Same
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 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	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	Same

Features	**Subject Device** **A310B and A330B**	**Predicate Device K190869** **Model: A310 and A330**	**Remark**
	institution and home environments.	institution and home environments.	
Patient Populations	Adults	Adults	Same
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) 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.	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) 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.	Same
LED wavelength	Red=660 nm; Infrared=905 nm;	Red=660 nm; Infrared=905 nm;	Same
Power source	2 AAA alkaline batteries	2 AAA alkaline batteries	Same
Display data	SpO2%, PR	SpO2%, PR	Same
SpO2 Measuring Range	0%-100%	0%-100%	Same
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	70~100%, ±3%; 0-69%, unspecified;	70~100%, ±3%; 0-69%, unspecified;	Same
PR Measuring Range	30-250 bpm	30-250 bpm	Same
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	± 2 bpm	± 2 bpm	Same
Wireless connection	Bluetooth	None	Different [1)]
Standard	IEC 60601-1	IEC 60601-1	Same
	IEC 60601-1-2	IEC 60601-1-2	
	IEC 60601-1-11	IEC 60601-1-11	
	ISO 80601-2-61	ISO 80601-2-61	
	ISO 10993-5	ISO 10993-5	
	ISO 10993-10	ISO 10993-10	

Justification of difference:

Different 1): The subject device is identical to predicate device except the wireless connection function. The subject device can transmit the measurement of SpO2, PR and Plethysmogram to the mobile application on the cell phone. The mobile application A-OXIMETER is only to display, store and review the measurement from pulse oximeter models A310B and A330B. The software is validated according to FDA's Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. The wireless testing is conducted according to FDA's Guidance Radio Frequency Wireless Technology in Medical Devices. So, the different 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Pulse Oximeter is considered surface contacting for a duration of exceed 24 hours but not 30 days.

Non-clinical data

The Pulse Oximeter has been tested according to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: 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: Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- IEC 60601-1-11: 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
- 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]
- FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Wireless testing:

- Bluetooth test according to FCC CFR Title 47 Part 15 Subpart C.
- ANSI C63.27L: 2017: American National Stand for Evaluation of Wireless Coexistence.
- AAMI TIR69: 2017 Risk management of radio-frequency wireless coexistence for medical devices and systems.
- Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)

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

Clinical data

The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61. The clinical testing was completed on a total of 12 healthy adult volunteers (4 men and 8 women) with light to dark skin pigmentations in the range of 70% to 100% against a laboratory CO-Oximeter. The subjects include 3 people with medium skin, 6 with light skin, and 3 with dark skin pigmentation. Total 1440 data points were sampled for analysis.

The measured arterial hemoglobin saturation value (SpO2) of the proposed device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter. The accuracy of the device is in comparison with the CO-oximeter samples measured over the SpO2 range 70%-100%.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, the result showed that the error is far less than the scope specified in the standard; and the Agreement between Methods of Measurement with Multiple Observations per each subject was analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement.

The SpO2 accuracy result showed that the root-mean-square (Arms) value of the Fingertip Pulse Oximeter is ±3% with the saturations from 70% to 100%.

9. Conclusion

According to the 510(k) submission, the subject device and the predicate device has the same intended use, and the difference in technological features of the proposed devices and the predicate devices do not raise different questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed device models are substantially equivalent to the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.