July 1, 2024

Shenzhen AOJ Medical Technology Co., Ltd
Jack Wang
Deputy Chief
Rm 301&4F, Block A, Bldg A,ingfa Intelligent Manufacturing
Park,Xiaweiyuan,Gushu Community,Xixiang St, Bao'an District
Shenzhen, Guangdong 518126
China

Re: K232989
Trade/Device Name: Pulse Oximeter (AOJ-70A); Pulse Oximeter (AOJ-70B); Pulse Oximeter (AOJ-70C); Pulse Oximeter (AOJ-70D); Pulse Oximeter (AOJ-70E)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: October 11, 2023
Received: October 11, 2023

Dear Jack 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
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.

Submission Number *(if known)*

K232989

Device Name

Pulse Oximeter (AOJ-70A);
Pulse Oximeter (AOJ-70B);
Pulse Oximeter (AOJ-70C);
Pulse Oximeter (AOJ-70D);
Pulse Oximeter (AOJ-70E)

Indications for Use *(Describe)*

The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in home and healthcare environments. 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.

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510(k) #: K232989

510(k) Summary

Prepared on: 2024-05-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen AOJ Medical Technology Co., Ltd
Applicant Address	Room 301&4F, Block A, Building A,ingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, Shenzhen Guangdong 518126 China
Applicant Contact Telephone	86 755-27786026
Applicant Contact	Mr. Jack Wang
Applicant Contact Email	regulation@aojmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Pulse Oximeter (AOJ-70A); Pulse Oximeter (AOJ-70B); Pulse Oximeter (AOJ-70C); Pulse Oximeter (AOJ-70D); Pulse Oximeter (AOJ-70E)
Common Name	Oximeter
Classification Name	Oximeter
Regulation Number	870.2700
Product Code	DQA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202173	AOJ-70A, AOJ-70B, AOJ-70C, AOJ-70D and AOJ-70E Pulse Ox	DQA
K200414	Pulse Oximeter, A310B, A330B	DQA

Device Description Summary

21 CFR 807.92(a)(4)

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. There are five models AOJ-70A, AOJ-70B, AOJ-70C, AOJ-70D, and AOJ-70E. Only AOJ-70B and AOJ-70D have 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.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in home and healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indication for use of the subject device is extended for home environment and is the same as the secondary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is a modification device to the device cleared by K221039.The modifications are add Bluetooth communication to a non-device APP and enclosure and display screen changes.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were referenced in support of the substantial equivalence determination.
Biocompatibility testing
The biocompatibility testing is referenced to K221039.
Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the oximeters. The device complies with the IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety, 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, and the IEC 60601-1-2 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 on the oximeters which complies with the ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" The software for this device was considered as a "Basic" Documentation level.

The clinical data is referenced to K221039.The Clinical Study was conducted at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine. The study was conducted in accordance to ISO 14155-1,ISO 80601-2-61:2017, and the FDA Guidance Document for Pulse Oximeters. The subject device of this study was to evaluate the SpO2 accuracy performance of the subject device during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry. After Institutional Review Board (IRB) approval, 11 healthy adult volunteer subjects (ages 21-47yr, with skin tones varying from Fitzpatrick 2-6) were included in the study conducted November 2021 to December 2021 to evaluate the SpO2 accuracy performance. The SpO2 accuracy performance results showed that the subject device have an ARMS<2 during steady state conditions over the range of 70-100%.

Based on the non-clinical performance data and clinical data as documented in the device development, the subject devices were found to be as safe, as effective, and perform as well as the legally marketed devices identified above.