November 21, 2024

Shenzhen Smallsignal Technology Co., Ltd.
Qingliang Liu
General Manager
Room 901-7,Building 1, No.9, Jinxiu Middle Road,
Laokeng Community, Longtian Street, Pingshan
Shenzhen, Guangdong 518122
China

Re: K232520
Trade/Device Name: Fingertip Pulse Oximeter, models Alpine20, Alpine20A, Alpine20H, Alpine20HA, Alpine20B, Alpine20BA, Alpine20BH, Alpine20BHA, Alpine30, Alpine30A, Alpine30H, Alpine30HA, Alpine30B, Alpine30BA, Alpine30BH, Alpine30BHA, Alpine20L, Alpine20LB, Alpine20LH, Alpine20LBH, Alpine30L, Alpine30LB, Alpine30LH, Alpine30LBH
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 2, 2024
Received: October 22, 2024

Dear Qingliang Liu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232520

Device Name

Fingertip Pulse Oximeter (Models Alpine20, Alpine20A, Alpine20H, Alpine20HA, Alpine20B, Alpine20BA, Alpine20BH, Alpine20BHA, Alpine30, Alpine30A, Alpine30H, Alpine30HA, Alpine30B, Alpine30BA, Alpine30BH, Alpine30BHA, Alpine20L, Alpine20LB, Alpine20LH, Alpine20LBH, Alpine30L, Alpine30LB, Alpine30LH, Alpine30LBH)

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 healthcare environment. 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

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Shenzhen Smallsignal Technology Co., Ltd. Address: Room 40205, Building 1, Huahan Science and Technology Industrial Park, No. 19, Qiyun West Road, Heping Community, Pingshan Street, Pingshan District, Shenzhen, Guangdong Province, China, 518083 TEL: 86 755 23010489
Contact Person:	Qingliang Liu
Prepare date:	October 22, 2024
2. Device name and classification	**Device Name:** Fingertip Pulse Oximeter **Models:** Alpine20, Alpine20A, Alpine20H, Alpine20HA, Alpine20B, Alpine20BA, Alpine20BH, Alpine20BHA, Alpine30, Alpine30A, Alpine30H, Alpine30HA, Alpine30B, Alpine30BA, Alpine30BH, Alpine30BHA, Alpine20L, Alpine20LB, Alpine20LH, Alpine20LBH, Alpine30L, Alpine30LB, Alpine30LH, Alpine30LBH **Classification Name:** 21 CFR 870.2700 Oximeter **Product code:** DQA **Regulatory Class:** Class II
3. Reason for Submission	New submission. No prior submission associated with the current submission.
4. Predicate Device(s)	Shenzhen AOJ Medical Technology Co.,Ltd., AOJ-70A, AOJ-70B, AOJ-70C, AOJ-70D and AOJ-70E Pulse Oximeter / K202173
5. Device Description	The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation (SpO_2). The subject device is a reusable device, and need to reprocess as suggested in the user manual after each use. And the device is intended to be used on the finger, and powered by 2*1.5V AAA battery. Bluetooth function is available for Alpine20B, Alpine20BA, Alpine20BH, Alpine20BHA, Alpine30B, Alpine30BA, Alpine30BH, Alpine30BHA, Alpine20LB, Alpine20LBH, Alpine30LB and Alpine30LBH only.
6. Indications for Use	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 healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.

7. Predicate Device Comparison

Please refer to following table to find differences between the subject device and predicate device.

Table 1 Comparison between the predicate and the subject device

ITEM	**Proposed Device Alpine20 series Pulse Oximeter**	**Predicate Device AOJ-70A, AOJ-70B, AOJ-70C, AOJ-70D and AOJ-70E**	**Comparison Result**
Manufacture	Shenzhen Smallsignal Technology Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	----
Indications for Use	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 healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.	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 healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.	Same
Operational Specifications			
Intended patient population	Adult	Adult	Same
Intended application site	Finger	Finger	Same
use under motion and low perfusion conditions	No	No	Same
Measurement Principles	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Signal Detection Method	Photodetector	Photodetector	Same
SpO_2 Range	35~100%	0~100%	Different[1]
SpO_2 Resolution	1%	1%	Same
SpO_2 Accuracy	70~100%: ±2% 0% to 69%: unspecified	70~100%: ±2% 0% to 69%: unspecified	Same
Pulse Rate Range	25 bpm ~ 250 bpm	25 bpm ~ 250 bpm	Same
Pulse Rate Accuracy	±2 bpm	±2 bpm	
Pulse Rate Resolution	1 bpm	1 bpm	Same
Shipped Sterile	No	No	Same
Power suppler	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery	Same

Storage and Transport Environment	Temperature: -10℃- 40℃ Humidity: 15%-93% Atmospheric pressure: 50 kPa-106 kPa	Temperature: -20℃- 50℃ Humidity (non-condensing): 10%-95% Atmospheric pressure: 70 kPa-106 kPa	Different [2]
Operating Environment	Temperature: 5℃- 40℃ Humidity: 15%-80% Atmospheric pressure: 86 kPa-106 kPa	Temperature: 10℃- 40℃ Humidity (non-condensing): 15%-95% Atmospheric pressure: 70 kPa-106 kPa	
Compliance Standards			
Bio-compatibility	ISO 10993-1 ISO 109903-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 109903-5 ISO 10993-10	Different [3]
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	
Performance	ISO 80601-2-61	ISO 80601-2-61	
Physical Specifications			
Dimension (Width*Height* Depth)	Alpine20/ 20L series: 61mm×37mm×33mm Alpine30/ 30L series: 61mm×34mm×32mm	57mm×30mm×30 mm	Different [4]
Data Transmission			
Data transmission	Bluetooth is available for Alpine20B, Alpine20BA, Alpine20BH, Alpine20BHA, Alpine30B, Alpine30BA, Alpine30BH, Alpine30BHA, Alpine20LB, Alpine20LBH, Alpine30LB and Alpine30LBH	No available	Different [5]

Justification for the differences:

1) Different SpO2 Range
   The measuring range of the predicate is 0~100% , while that of the subject is 35~100%, and such specification is verified per the international standard ISO 80601-2-61, same as the standard complied with of the predicate, so the different range will be acceptable for the subject device.

2) Different operating, storage and transport environment

   Minor difference to operation, storage/transport environment for the subject device, but the system has been proved to be safe and effective since the safety testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as declared under the suggested conditions. So those changes will not cause any safety and effectiveness problem.

3) Different Biocompatibility test standard

The endpoints for the biocompatibility are the same, which include cytoxicity, skin irritation and sensitization, the difference happened due to the irritation was taken from ISO 10993-10 to ISO 10993-23 without no change for the parts applied in the subject device, both of which are used for evaluation for test of irritation. This difference will not raise any safety and effectiveness questions.

4) Different Physical Specifications

The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor different will not raise any safety and effectiveness questions.

5) Different data transmission function

Some models of the subject devices have Bluetooth data transmission function, and the wireless function has been verified to assure its data transmission and cybersecurity. No new safety and effectiveness questions raised.

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 as demonstrated in the non-clinical and clinical evidence.

8. Performance Testing

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 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 worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the IEC 60601-1: 2005+A1: 2012+A2: 2020 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the IEC 60601-1-2: 2015+A1:2020 *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 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 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.

Clinical data

Clinical testing is conducted per *Annex EE Guideline for evaluating and documenting SpO_2 ACCURACY in human subjects* of *ISO 80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment* and the FDA Guidance Document for Pulse Oximeters. The subject device of this study was to evaluate the Sp02 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. There were 12 adult healthy volunteers to validated the SpO2 accuracy of the pulse oximeter, aged 22-37 years old, with skin tones varying from Fitzpatrick I-VI,including five females and seven males. The measure results showed that the subject device perform as claimed during the measurement range of 70-100% with 2% accuracy.

9. Conclusion

Verification and validation testing was conducted on the subject device Fingertip Pulse Oximeter and all testing passed pre-specified criteria. The subject device and the predicate device have the same intended use and the differences in technological features do not raise different questions of safety and effectiveness. This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device.