May 11, 2026

Shenzhen IMDK Medical Technology Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K252655
Trade/Device Name: Pulse Oximeter (PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 3, 2026
Received: April 3, 2026

Dear Boyle 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252655

Please provide the device trade name(s).

Pulse Oximeter (PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT)

Please provide your Indications for Use below.

The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) through the fingertip. This portable device is indicated for use in adult patients in hospitals, professional healthcare facilities, and home environments.
The device is not intended for continuous monitoring, use during motion or use with low perfusion.
The device is intended for reuse.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K252655

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Shenzhen IMDK Medical Technology Co., Ltd.
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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: March.25th,2026

2.0 Device Information

Trade name: Pulse Oximeter
Common name: Pulse Oximeter
Classification name: Oximeter
Model(s): PO-A2AO,PO-A2AT, PO-A3AO,PO-H1AO,PO-B1AO, PO-C5AO,PO-C5AT,PO-C6AO, PO-C6AT
Production code: DQA
Regulation number: 21 CFR 870.2700
Classification: Class II
Panel: Anesthesiology

3.0 Predicate &Reference Device Information

Predicate#
Manufacturer: Shenzhen IMDK Medical Technology Co., Ltd.

Trade name: Pulse Oximeter,Model: C101H1
510(k) number: K173123

Reference#
Manufacturer: Shenzhen IMDK Medical Technology Co., Ltd.
Trade name: Pulse Oximeter,Model: C101A2, C101B1, C101A3
510(k) number: K221979

K221979 is only being used as a reference device for the materials it is made of and the biocompatibility testing associated with it.

4.0 Indication for Use Statement

The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) through the fingertip. This portable device is indicated for use in adult patients in hospitals, professional healthcare facilities, and home environments.
The device is not intended for continuous monitoring, use during motion or use with low perfusion.
The device is intended for reuse.

5.0 Device Description

These Pulse Oximeters intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (PR). The device measures SpO2 and PR with a SpO2 senor and can display the SpO2, pulse rate, Pulse Amplitude Index and other indication parameters, such as pulse amplitude bar and battery power status on the display screen. SpO2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO2 measuring unit. The light-electronic transducer in finger sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The PLETH curve and numeral value of SpO2 will be obtained. These pulse oximeter, models PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO,
PO-C6AT, are designed for spot checking of the pulse oxygen saturation and pulse rate for adults in a clinic environment.
This medical device can be reused. It is used for adult patients without motions.
Not for continuously monitoring.

6.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K252655	Predicated Device K173123	Remark
Product Name	Pulse Oximeter	Pulse Oximeter	**--**
Manufacturer	Shenzhen IMDK Medical Technology	Shenzhen IMDK Medical Technology	--

	Co., Ltd.	Co., Ltd.	
Product Code	DQA	DQA	Same
Regulation No.	21CFR 870.2700	21CFR 870.2700	Same
Class	Class II	Class II	Same
Model	PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT	C101H1	--
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 hospitals.	Fingertip Pulse Oximeter C101H1 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 hospitals.	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 perfuse 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
Applied Population	Adults	Adults in a clinic environment	Same
Overall Dimension	PO-H1AO: 60*36*35mm PO-A2AO/PO-A2AT: 60*36*33mm PO-A3AO: 58*36*33mm PO-B1AO: 66*36*33mm PO-C5AO/PO-C5AT: 60*38*55mm PO-C6AO/PO-C6AT: 60*38*38mm	60*36*35mm	--

Table 2 Performance Comparison

Item	**Subject Device K252655**	**Predicate Device K173123**	**Remark**
LED wavelength	Red= 660 nm; Infrared=905nm	Red= 660nm; Infrared= 905nm	Same
Power source	DC3.0V(2*AAA 1.5V batteries)	2 AAA alkaline batteries	Same
SpO2 Display Range	0-99%	0%-100%	Similar
SpO2 Measuring Range	35%-100%	0%-100%	Different
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	80~100%, ±2%; 70%~79%, ±3%; 0% to 69%: unspecified	70~100%, ±3%;	Different
PR Measuring Range	30bpm-240 bpm	30bpm-240 bpm	Same
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	± 3bpm	±1 bpm or ±1%, whichever is greater	Different

Analysis:

The differences in SpO_2 measuring range and SpO_2 accuracy, and PR accuracy between the Subject Device and Predicate Device do not affect the intended use, technological characteristics, or safety/effectiveness profile of the device. Both devices comply with the applicable requirements of ISO 80601-2-61:2017 and the FDA pulse oximeter guidance.

The Subject Device is therefore substantially equivalent to the Predicate Device.

Table 3 Safety Comparison

Item	Subject Device K252655	Predicate Device K173123	Remark
Electrical Safety	Comply with IEC 60601-1 IEC 60601-1-11	Comply with IEC 60601-1 IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Performance	ISO 80601-2-61	ISO 80601-2-61	Same
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

7.0 Non-clinical Testing Summary

The following performance data have been conducted to verify that the Oximeter meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Conclusions for Biocompatibility Testing

The biocompatibility evaluation for the oximeter was conducted in accordance with the FDA's Biocompatibility Guidance "Use of 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 permanent (>30 days).

Biocompatibility testing for the subject device leverages the biocompatibility data from the reference device (K221979), which has the same patient-contacting materials and contact characteristics.

The reference device K221979 is used specifically to support the material characterization and associated biocompatibility testing. Therefore, no additional biocompatibility testing was required for the subject device.

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1:2005/AMD2:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11:2020, 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

- ➢ IEC 60601-1-2:2020, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances - Requirements and tests
- ➢ IEC 60601-1-6:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ➢ IEC 62471:2006, Photobiological safety of lamps and lamp systems

Summary of Bench Testing

Bench testing was conducted and the results show that the subject device complies with the below standard:

➢ ISO 80601-2-61:2018, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Content of Premarket Submissions for Device Software Functions.

The Software Validation is in compliance with FDA Guidance.

Summary of Shelf Life and Cleaning Testing

The service life has been verified through accelerated aging. The service life is 3 years except the battery is reasonable and effective.

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17,2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the User manual.

8.0 Clinical Test Summary

The clinical study was conducted in accordance to ISO 80601-2-61. The subject device of this study was to verify the accuracy of pulse oximetry (SpO2) measured by the oximeter (model PO-H1AO) with a measurement range of 70-100% under no motion on 12 healthy adult volunteers, in which 5 females and 7 males.

Clinical hypoxia test results were obtained in human adult volunteers (the study population includes sufficient darkly pigmented subjects) to validate the accuracy of the subject devices versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Twelve subjects were enrolled for the clinical study. The Fitzpatrick Scale and Monk’s Scale were used to determine their skin pigmentation scores. 3 dark subjects (Fitzpatrick Type 5-6/Monk Type 08-09) in this study allow a proper

evaluation of the sensor accuracy in dark population. The study contains more than the minimum 200 data points, and the clinical study results support device accuracy claims for the specified saturation range.

The overall SpO_2 accuracy performance of the subject device demonstrated an ARMS of 2.10% during steady state conditions over the range of 70-100%.

Subgroup analyses were conducted to evaluate potential bias and performance differences with respect to gender and skin pigmentation (light, medium, and dark).

For skin pigmentation subgroups:

- Dark skin subjects (Fitzpatrick V–VI) demonstrated ARMS values of approximately 2.05–2.10% over the 70–100% range.
- Medium skin subjects (Fitzpatrick IV) demonstrated ARMS values of approximately 2.10%.
- Light skin subjects (Fitzpatrick I–III) demonstrated ARMS values ranging from approximately 1.48% to 2.33%.

Bias analysis across all subgroups showed no systematic deviation that would indicate reduced performance in any specific population group.

The clinical study results support that the device is safe and effective for use across the intended patient population.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.