February 17, 2026

Jiangsu Yuyue Medical Equipment & Supply Co., LTD.
Fang (Fawn) Zhang
No.1 Baisheng Road Development Zone
Danyang, Jiangsu 212300
China

Re: K252805
Trade/Device Name: YUWELL® Finger Pulse Oximeter (YX105, YX106, YX110, YX310)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 9, 2026
Received: January 9, 2026

Dear Fang (Fawn) Zhang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K252805

Please provide the device trade name(s).

YUWELL® Finger Pulse Oximeter (YX105, YX106, YX110, YX310)

Please provide your Indications for Use below.

YUWELL® Finger Pulse Oximeters are non-invasive, non-sterile, reusable, and spot-checking devices that measure and display SpO_2 and pulse rate (PR) via the patient's finger. They are indicated for use in adults and children (weight > 30 kg) and are intended for professional and home settings. These devices are unsuitable for continuous monitoring, use during motion, or in patients with low perfusion.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date 510k summary prepared: 10 DEC 2025

1. SUBMITTER

510(k) Submitter:	Jiangsu Yuyue Medical Equipment & Supply Co., LTD.
Address:	No.1 Baisheng Road Development Zone Danyang Jiangsu 212300 China
Company Contact Person:	Dr. Fang (Fawn) Zhang
Phone:	(206) 639-1311
Email:	fawn.zhang@yuwell.com

2. DEVICE

Device Common Name:	Finger Pulse Oximeter
Device trade or proprietary name:	YUWELL® Finger Pulse Oximeter
Model:	YX105, YX106, YX110, YX310
Classification Name:	Oximeter
Classification Regulation:	21 CFR §870.2700
Device Classification:	Class II
Device Product Code:	DQA

3. PREDICATE DEVICE

Device Trade Name:	YUWELL® Finger Pulse Oximeter
510(k):	K212385
Product Code:	DQA

4. REFERENCE DEVICE

Device Trade Name:	Pulse Oximeter
510(k):	K232975
Product Code:	DQA

5. DEVICE DESCRIPTION

YUWELL® Finger Pulse Oximeter (the Oximeter) is a finger pulse oximeter designed to measure functional oxygen saturation (SpO_2) of arterial hemoglobin and pulse rate (PR) in adults and children (weight > 30 kg). The device operates by detecting changes in light absorption caused by blood pulsation in the vascular bed, which are used to determine SpO_2 and PR. It contains light-emitting diodes (LEDs) and a photodetector, with the photodetector positioned on the opposite side of the probe from the LEDs. SpO_2 and PR are displayed on the device's LED/OLED screen, providing a visual pulse indicator that blinks in sync with the detected PR.

The Oximeter is powered by two AAA alkaline batteries and does not feature alarms. The YX310 and YX110 models can transfer data to a mobile device wirelessly whereas the YX105 and YX106 models do not transfer data.

6. INTENDED USE/PROPOSED INDICATIONS FOR USE

YUWELL® Finger Pulse Oximeters are non-invasive, non-sterile, reusable, and spot-checking devices that measure and display SpO_2 and pulse rate (PR) via the patient's finger. They are indicated for use in adults and children (weight > 30 kg) and are intended for professional and home settings. These devices are unsuitable for continuous monitoring, use during motion, or in patients with low perfusion.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Description	Subject Device	Predicate Device (K212385)	Reference Device (K232975)	Comparison
Manufacturer	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.	Beijing Choice Electronic Technology Co., Ltd.	/
Product Name	Finger Pulse Oximeter	Finger Pulse Oximeter	Pulse Oximeter	/
Models	YX105, YX106, YX110, YX310	YX102, YX306	MD300C228	/
Classification Regulation	21 CFR 870.2700, Class II	21 CFR 870.2700, Class II	21 CFR 870.2700, Class II	Same
Product Code	DQA	DQA	DQA	Same
Intended Use/Proposed Indications for Use	YUWELL® Finger Pulse Oximeters are non-invasive, non-sterile, reusable, and spot-checking devices that measure and display SpO_2 and pulse rate (PR) via the patient's finger. They are indicated for use in adults and children (weight > 30 kg) and are intended for professional and home settings. These devices are unsuitable for continuous monitoring, use during motion, or in patients with low perfusion.	YUWELL® Finger Pulse Oximeters are non-invasive, non-sterile, reusable, and spot-checking devices that measure and display SpO_2 and pulse rate (PR) via the patient's finger. They are indicated for use in adults and children (weight > 30 kg) and are intended for professional and home settings. These devices are unsuitable for continuous monitoring, use during motion, or in patients with low perfusion.	The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent child and infant patients in hospitals, hospital-type facilities and homecare. The device can be used by the people whose finger thickness is between 8mm. and 22mm (0.3 inches to 0.9 inches).	Same as the predicate device.
Intended patient population	Adults and children (weight >30 kg)	Adults and children (weight >30 kg)	Adult, adolescent, child and infant patients	Same as the predicate device.

Intended application site	Finger	Finger	Finger	Same
Performance Specifications				
SpO_2 Display Range	0%~100%	0%~100%	0%~100%	Same
SpO_2 Measurement Range	70%~100%	70%~100%	70%~100%	Same
SpO_2 Accuracy	70%~80%,80%~90%, 90%~100%, ± 2%; ＜70%, no definition	70%~80%,80%~90%, 90%~100%, ± 2%; ＜70%, no definition	70%~100%, ± 2%; 0~69% no definition	Same as the predicate device.
SpO_2 Resolution	1%	1%	1%	Same
PR Display Range	25bpm~250bpm	25bpm~250bpm	30 bpm~250 bpm	Same as the predicate device.
PR Measurement Range	25bpm~250bpm	25bpm~250bpm	30 bpm~250 bpm	Same as the predicate device.
PR Accuracy	±1% or ±1 bpm (whichever is greater)	±1% or ±1 bpm(larger)	30 bpm~99 bpm, ± 2 bpm; 100 bpm~250 bpm, ± 2%	Same as the predicate device.
PR Resolution	1bpm	1bpm	1 bpm	Same as the predicate device.
Safety Specifications				
Performance	ISO 80601-2-61	ISO 80601-2-61	ISO 80601-2-61	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Operation environment	Ambient temperature: 41°F~104°F (5°C~40°C); Relative humidity: 15%~90%, no condensation; Atmospheric pressure: 700hPa~1060hPa.	Ambient temperature: 41°F~104°F (5°C~40°C); Relative humidity: ≤80%; Atmospheric pressure: 860hPa~1060hPa.	Ambient temperature: 32°F~104°F (0°C~40°C); Relative humidity: 15%~93% no condensation; Atmospheric pressure: 70kPa~106kpa.	Different. The operating environment of the subject device is recommended by IEC 60601-1-11, with a larger range of relative humidity and atmospheric pressure than that of the predicate. Safety testing was

				conducted to demonstrate the safety and effectiveness of the subject device under the claimed conditions. Thus, the difference will not affect substantial equivalence between the subject and the predicate devices.
Storage & Transport environment	Ambient temperature: -13°F~+158°F (-25°C~＋70°C); Relative humidity: ≤93%, no condensation; Atmospheric pressure: 500hPa~1060hPa.	Ambient temperature: -4°F~+131°F (-20°C~＋55°C); Relative humidity: ≤93%, no condensation; Atmospheric pressure: 500hPa~1060hPa.	Ambient temperature: -13°F~+158°F (-25°C~＋70°C); Relative humidity: ≤93%, no condensation; Atmospheric pressure: 70kPa~106kpa.	Different. The storage & transport environment of the subject device is recommended by IEC 60601-1-11, and testing has been performed accordingly. Test results showed that the subject device is safe and effective under the claimed environment. Therefore, the difference in storage and transport environment between the subject and the predicate devices will not affect their substantial equivalence.
Contacting material	Enclosure: ABS Screen protect film: PC Fingertip Cushion: Medical Silicone Gel **YX110** Button: None **YX105, YX106** Button: Medical Silicone Gel **YX310** Button: ABS	Enclosure: ABS Screen protect film: PC Fingertip Cushion: Medical Silicone Gel **YX102** Button: None **YX306** Button: ABS	Enclosure, Battery Cover and Button: ABS Screen protect film: PMMA Fingertip Cushion: Silica gel	Same as the predicate device.
Features				
Measuring characteristics	Spot-checking Not suitable for continuous monitoring, use during motion, or in patients with low perfusion.	Spot-checking Not for continuous monitoring, use during motion or for patients with low perfusion.	Spot-checking	Same as the predicate device.

Measurement wavelength-Red light	660±8nm	660±8nm	660± 3nm	Same as the predicate device.
Measurement wavelength-Infrared light	905 ± 25nm	905 ± 25nm	905± 10nm	Same as the predicate device.
Display Type	**YX105, YX106, YX110:** LED **YX310:** OLED	**YX102:** LED **YX306:** OLED	LCD	Same as the predicate device.
Power Supply	Two (2) AAA alkaline batteries	Two (2) AAA alkaline batteries	Two (2) AAA alkaline batteries	Same
Display Content	**YX105, YX106, YX110:** SpO_2, PR, Pulse bar, Low battery **YX310:** SpO_2, PR, Pulse volume wave, Pulse bar, Battery level, and Symbol of gravity sensing mode	**YX102:** SpO_2, PR, Pulse bar, Low battery **YX306:** SpO_2, PR, Pulse volume wave, Pulse bar, Battery level, and Symbol of gravity sensing mode	SpO_2, PR, PI	Same as the predicate device.
User Interface	**YX105, YX106, YX110:** 1 display direction **YX310:** 4 display directions	**YX102:** 1 display direction **YX306:** 4 display directions	7 display modes	Same as the predicate device.
Bluetooth	**YX105, YX106:** No Bluetooth function **YX110, YX310:** with Bluetooth function	No Bluetooth function	With Bluetooth function	Two models (YX110 and YX310) of the subject device differ from the predicate device but they are the same with the reference device in this regard. The subject device has been verified for safety and effectiveness per IEC 60601-1, IEC 60601-1-2, IEC 60601-1- 11 and ISO 80601-2-61. Therefore, the difference will not affect the safety and effectiveness of the subject device.

8. SUMMARY OF NON-CLINICAL TESTS

Electromagnetic Compatibility (EMC) and Electrical Safety Testing

The subject device has been tested in compliance with the following standards:

1) IEC 60601-1:2015+A1:2012+A2:2020/ ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 and A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

2) IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3) IEC 60601-1-11:2015/AMD1:2020 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

Biocompatibility Testing

Biocompatibility testing in accordance with ISO 10993-1:2018 is included as part of this submission to support the acceptability of the biocompatibility risks. In addition, FDA Guidance "Use of International Standard ISO 10993-1" issued in 2023 is followed. The biocompatibility testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

Performance Testing-Bench

Performance bench testing for the YUWELL® Finger Pulse Oximeter is included in this submission to support performance and functionality.

Software Verification and Validation Testing

Software verification and validation were provided in compliance with FDA Guidance for "The Content of the Premarket Submission for Software Contained in Medical Devices."

The software was found to fit in the category of products that would require Basic Documentation Level because the failure or latent flaw of the device software function would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device or others in the

environment of use prior to the implementation of the risk controls. The software does not provide any data that is considered life-supporting.

Wireless Testing

The YUWELL® Finger Pulse Oximeter YX110 and YX310 are provided with Bluetooth connectivity to support the wireless communication of the measurement data. While this feature is not in the predicate device, it is in the reference device. The corresponding software and cybersecurity testing was conducted on the subject device. Specifically, wireless testing was conducted in accordance with the FDA Guidance, "Radio-Frequency Wireless Technology in Medical Devices" to support the Bluetooth feature provided as part of the device.

Cybersecurity

The YUWELL® Finger Pulse Oximeter YX110 and YX310 are provided with Bluetooth connectivity to support the wireless communication of the measurement data. While this feature is not in the predicate device, it is in the reference device. The corresponding software and cybersecurity testing was conducted on the subject device. Specifically, cybersecurity documentation was provided as part of this submission in accordance with the FDA Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Reprocessing

Validation of cleaning and disinfection instructions was performed in accordance with FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

9. PERFORMANCE DATA: CLINICAL TESTING

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per the following standards:

1) ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment

2) FDA Guidance "Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff"

The clinical test of the Finger Pulse Oximeters was conducted against a laboratory CO-oximeter within the range of 70% to 100%. There was a total of 12 healthy adult volunteers (8 males and 4 females) with skin

pigmentations ranging from light to dark. The subjects included 5 with light skin, 4 with medium skin, and 3 with dark skin. For each device, 268 data points were sampled for analysis. The clinical validation results demonstrated that the root mean square error (A_{rms} value) of the finger pulse oximeter was within ±2% SpO_2 over the claimed range of 70%–100%.

The subject device has the same intended use and similar performance, equivalence testing standards, and all testing results have come back as positive results or pass for the subject device, which the subject device is as safety and effectiveness as the predicate device.

10. CONCLUSIONS

The subject device has the same intended use, and similar technological characteristics as that of the predicate device. While there are differences between them, those differences do not raise safety or effectiveness concern as any of those differences has already been evaluated through design verification and validation. Furthermore, the difference in Bluetooth function is addressed by the reference device. Therefore, the subject device is substantially equivalent to products that have already received market clearance.