May 22, 2025

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

Re: K250878
Trade/Device Name: YUWELL® Infrared Ear Thermometer (YHT100); YUWELL® Infrared Ear Thermometer (YHT107)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 17, 2025
Received: March 24, 2025

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 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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

510(k) Number *(if known)*
K250878

Device Name
YUWELL® Infrared Ear Thermometer (YHT100); YUWELL® Infrared Ear Thermometer (YHT107)

Indications for Use *(Describe)*
The Infrared Ear Thermometer is indicated for intermittent measurement of human body temperature from the ear canal. The device can be used by people of all ages except preterm babies or babies who are small for gestational age. The thermometer is intended for use in professional settings and the home environment. It is not for emergency clinical conditions.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K250878- 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: May 22, 2025

I. 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

II. DEVICE

Device Common Name:	Clinical electronic thermometer
Device trade or proprietary name:	YUWELL® Infrared Ear Thermometer (YHT100); YUWELL® Infrared Ear Thermometer (YHT107)
Classification Name:	Thermometer, Electronic, Clinical
Classification Regulation:	21 CFR §880.2910
Device Classification:	Class II
Device Product Code:	FLL

III. PREDICATE DEVICE

Device Trade Name:	Braun Thermoscan® PRO 6000 Ear Thermometer
510(k):	K152748
Product Code:	FLL

IV. DEVICE DESCRIPTION

YUWELL® Infrared Ear Thermometer is designed to measure human body temperature. This hand-held, no-contact device is battery-powered and utilizes infrared energy emitted in the subject's tympanic membrane to determine human body temperature. The thermometer provides temperature readings in just 2 seconds. It is suitable for individuals of all ages except preterm babies or babies who are small for gestational age. The Infrared Ear Thermometer YHT107 can transmit the temperature readings via Bluetooth, whereas the YHT100 does not have data transmission capability.

V. INDICATIONS FOR USE

The Infrared Ear Thermometer is indicated for intermittent measurement of human body temperature from the ear canal. The device can be used by people of all ages except preterm babies or babies who are small for gestational age. The thermometer is intended for use in professional settings and the home environment. It is not for emergency clinical conditions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristics	**Predicate Device** **K152748**	**Subject Device** **K250878**	**SAME/DIFFERENT** **Comment**
Type of Thermometer	IR Thermometer	IR Thermometer	Same
Product Code	FLL	FLL	Same
Regulation	880.2910	880.2910	Same
Indications for use	The Braun Thermoscan® PRO 6000 Ear Thermometer is indicated for the intermittent measurement and monitoring of human body temperature for patients of all ages in a professional use environment. The probe cover is used as a sanitary barrier between the infrared thermometer and the ear canal.	The Infrared Ear Thermometer is indicated for the intermittent measurement of human body temperature from ear canal for people of all ages except for pre-term babies or babies who are small for gestational age. The device can be used in professional and home environments. The thermometer is not for emergency clinical conditions. The probe cover is used as a sanitary barrier between the infrared ear thermometer and the ear canal.	Different; see Note (1) below the table
Patient Population	All populations	All populations except for premature babies and	Different; see Note (2) below the table

		babies small for their gestational age	
RX/OTC Use	OTC	OTC	Same
Measurement Sensor	IR	IR	Same
Measurement Site	Ear	Ear	Same
Contact/Non-contact	Non-contact	Non-contact	Same
Temperature Range	20℃-42.2℃	34.0-42.2℃ (93.2-108.0°F	Similar; the temperature range conforms with ASTM E1965 and the subject device's temperature range is within that of the predicate device, which does not introduce new questions of safety and effectiveness.
Accuracy (C/F)	0.3℃ for <35℃ 0.2 deg C for 35℃ to 42 deg C 0.3℃ for >42℃	±0.2℃ (±0.4°F), 35.0℃–42.0℃ (95.0°F–107.6°F); ±0.3℃ (±0.5°F), 34.0℃–34.9℃ (93.2°F–94.8°F), 42.1℃–42.2℃ (107.8°F–108.0°F)	Same
Display Resolution	0.1℃/0.1°F	0.1℃/0.1°F	Same
Cel/Fahrenheit	Both	Both	Same
Response Time	2-3s	< 12 sec	Different; see Note (3) below the table
Memory	Temp sets (Storage of temps)	Temp sets (Storage of temps)	Same
Material	ABS, PC, PP, Resins	ABS: Housing Keys PC: Display panel	Similar; no discussion is required as al the materials in the subject device are contained in the predicate device. No new questions of safety and effectiveness are raised; and the biocompatibility review is appropriate

		PP: Probe cover	
Power Supply	Battery	Battery	Same
Sound	Beeps	Beeps	Same
Probe Cover	Yes	Yes	Same
Auto Power on/off	Yes; 10s	Yes; 60 ± 10s	Different; see Note (4) below the table
Operating Mode	Adjusted	Adjusted	Same
Display Screen	LCD	LCD	Same
Operation Environment (Temp/Humidity)	10 - 40℃ ambient temperature (amb) and up to 95% RH	+10℃–+40℃ (50°F–104°F) and 15-90% RH	Similar; the operating temperature range conforms with ASTM E1965. The difference does not raise new questions of safety and effectiveness.
Storage Environment (Temp/Humidity)	Temperature: -25 ºC ~ +55 ºC (-13 ºF-131 ºF) Humidity: 15% RH ~ 95% RH (no condensation)	Temperature: -20 ºC–+55 ºC (-4 ºF–131 ºF) Humidity: 15-90% RH no condensation	Similar; the storage conditions conform with ASTM E1965. The difference does not raise new questions of safety and effectiveness.
Dimension	150mm x 60 mm x 35mm	6"×2.3"×1.5" (153 mm×59 mm×37.5 mm)	Similar; the difference does not impact device performance and does not raise new questions of safety and effectiveness.
Weight	Unknown	0.176 lbs. (80g) without battery	Different; the difference does not impact device performance and does not raise new questions of safety and effectiveness
Conformance Standards	Same	ISO 80601-2-56:2017, AMD1:2018 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential	Same

		performance of clinical thermometers for body temperature measurement ASTM E1965-98(2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature ASTM E1104-98 Standard Specification for Clinical Thermometer Probe Covers and Sheaths IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC TS 60601-4-2 Medical electrical equipment –Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical	

		electrical systems IEC 62304:2006+A1:2015 Medical device software — Software life cycle processes IEC 60601-1-11:2015 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	Same	ISO 10993-1: 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization	Same

		ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation	

Notes:

Note (1) Indications for Use and Note (2) Patient Population: The intended patient population of the subject device is a subset of that of the predicate device, because the subject device excludes pre-term babies or babies small for gestational age. This does not raise new or different questions of safety and effectiveness of the device.

Note (3) Response Time: The subject device takes about 10 seconds longer to provide a temperature reading. The difference in time is minimal. Performance testing was reviewed where appropriate. No new or different questions of safety and effectiveness are introduced.

Note (4) Auto Power on/off: The subject device takes about 60 seconds to automatically shut down. The purpose of this duration is to give the user more time to review or record the measurements if needed. This does not raise new questions of safety and effectiveness.

VII. 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.

Performance Testing-Bench
Performance bench testing for the YUWELL® Infrared Ear Thermometer 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® Infrared Ear Thermometer YHT107 is provided with Bluetooth connectivity to support the wireless communication of the measurement data. 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
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.

VIII. 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 80601-2-56: 2017+ A1:2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

2) ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometer for Intermittent Determination of Patient Temperature

This clinical study consisted of 154 subjects, of which 50 subjects are infants, 50 subjects are children, and 54 subjects are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five years old). The clinical validation results demonstrated that the clinical data, represented by clinical bias, limits of agreement and clinical repeatability met the acceptance criteria of the clinical validation protocol.

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.

IX. CONCLUSIONS

The subject device has substantially equivalent intended use, technological characteristics, and principles of operation as the predicate. Any differences between the subject and predicate devices were evaluated through design verification and validation testing which demonstrated device performance and safety, and do not raise any new questions of safety and effectiveness.