June 23, 2025

Shenzhen AOJ Medical Technology Co., Ltd.
Jack Wang
Deputy Chief
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Park,Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an Dis
Shenzhen, Guangdong 518126
China

Re: K250470
Trade/Device Name: Ear Thermometer (EAR-E101); Ear Thermometer (EAR-E102); Ear Thermometer (EAR-E103)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 23, 2025
Received: May 23, 2025

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.

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 P. BENNETT -S

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)*
K250470

Device Name
Ear Thermometer (EAR-E101);
Ear Thermometer (EAR-E102);
Ear Thermometer (EAR-E103)

Indications for Use *(Describe)*
The Ear Thermometer is intended to measure human body temperature of people over three months from surface of eardrum. It applies to both professional use and home use.

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

Prepared Date: 2025/06/20

1. Submission sponsor

Name: Shenzhen AOJ Medical Technology Co., Ltd.

Address: Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Contact person: Jack Wang

Title: Deputy Chief

TEL: 86 755-27786026

2. Subject Device Information

Trade/Device Name	Ear Thermometer (EAR-E101); Ear Thermometer (EAR-E102); Ear Thermometer (EAR-E103)
Common Name	Clinical Electronic Thermometer
Model	models EAR-E101, EAR-E102, EAR-E103
Regulation Number	21 CFR 880.2910
Regulatory Class	Class II
Product Code	FLL
Submission type	Traditional 510(K)

3. Predicate Device

Manufacturer: Jiangsu Yuyue Medical Equipment & Supply Co., Ltd

Device name: Infrared Ear Thermometer, models YHT101 and YHT200.

510(K) Number: K203583.

4. Device Description

The ear thermometer is a handheld device that displays the temperature of the measured patient by measuring the thermal radiation of the eardrum. Measurement unit: ℃ or ℉.The results can be displayed on LCD.

The thermometers are powered by 1.5V×2 (AAA or AA) alkaline batteries, which can be used for people over three months.

A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the eardrum, which is converted into temperature measurement with the unit of ℃ or ℉.

All the models share the same critical components, intended use, working principle and similar product design, and compose of a sensor, PCB, buttons, LCD display and housing. Functions include

temperature measurement, memory reading recall, unit switch, low battery detection and high temperature indicator.

The major difference is the mechanical and the corresponding hardware adjustment.

5. Intended use & Indication for use

The Ear Thermometer is intended to measure human body temperature of people over three months from surface of eardrum. It applies to both professional use and home use.

6. Comparison to the Predicate Device

ITEM	**Subject Device (K250470)**	**Predicate Device (K203583)**	**Comparison Result**
Common Name	**Ear Thermometer**	**Infrared Ear Thermometer**	--
Model	EAR-E101, EAR-E102, EAR-E103	YHT101, YHT200	--
Manufacturer	Shenzhen AOJ Medical Technology Co., Ltd.	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd	--
Product Code	FLL	FLL	Same
Regulation No.	21 CFR 880.2910	21 CFR 880.2910	Same
Classification	II	II	Same
Indications for Use / Intended Use	The Ear Thermometer is intended to measure human body temperature of people over three months from surface of eardrum. It applies to both professional use and home use.	The YUWELL® Infrared ear thermometer is a non-sterile, reusable clinical thermometer. The device is to display the body temperature in the ear cavity by thermal radiation for people of all ages except preterm babies and newborns (1-29 days old).	Note 1
Patients population	people over three months	People of all ages except preterm babies and newborns (1-29days old)	Note 2
Operation	Hand held-Manually operated	Hand held-Manually operated	Same
Sensor	Infrared	Infrared	Same
Rx/OTC Use	OTC	OTC	Same
Measurement Technology	Thermopile	Thermopile	Same
Operating Mode	Adjusted mode	Adjusted mode	Same
Measurement Site	eardrum	ear	Same
Measurement Range	32.0℃~42.9℃ (89.6°F-109.2°F)	34.0 °C to 42.2 °C (93.2°F~108.0°F)	Note 3
Accuracy	±0.2℃/±0.4°F	34.0℃~34.9℃(93.2°F~94.8°F), ±0.3℃(±0.5°F) 35.0℃~42.0℃(95.0°F~107.6°F), ±0.2℃(±0.4°F) 42.1℃-42.2℃(107.7°F~108.0°F), ±0.3℃(±0.5°F)	Note 4
Display	LCD	LCD	Same
Memory	40 values	YHT101: 7 groups of measured	Note 5

function		values can be memorized YHT200: 10 groups of measured values can be memorized	
Scale	°C/°F	°C/°F	Same
Resolution of display	0.1 °C/°F	0.1 °C/°F	Same
Automatic power off time	Within 30s	60s±10s	Note 6
Operating Environments	Temperature: 15°C~ 40°C Humidity:≤ 85% RH, non-condensing Atmospheric pressure: 70–106 kPa	Temperature: 10 °C~ 40 °C (50°F-104°F) Humidity: 15%–90% (Non-Condensing) Atmospheric pressure: 70–106 kPa	Note 7
Transport and Storage Environments	Ambient Temperature: -20°C to 55°C Relative Humidity:≤ 93% RH, non-condensing Atmospheric pressure: 50 kPa to 106 kPa	Ambient Temperature: -20°C to +55°C (-4°F-131°F) Relative Humidity:15%–90% (Non-Condensing) Atmospheric pressure: 70 kPa - 106 kPa	Note 8
Power supply	2x1.5 V AA Alkaline battery (EAR-E101,EAR-E102) 2x1.5 V AAA Alkaline battery (EAR-E103)	Two (2) AAA alkaline batteries	Note 9
Dimensions (mm×mm×mm)	EAR-E101: 149mm x 80.4mm x 38.2mm EAR-E102: 152.3mm x 55.6mm x 36mm EAR-E103: 140 mm x 35mm x 40mm	YHT101: 145mm x 37mm x 57mm YHT200: 143mm x 39 mm x 57mm	Note 10
Electrical Safety	IEC 60601-1 IEC 60601-11 ISO 80601-2-56	IEC 60601-1 IEC 60601-11 ISO 80601-2-56	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Patient Contacting Materials	ABS, PP, LLDPS	YHT101:Shell: ABS material Button: PC material YHT200: Shell: ABS material Button: ABS material	Note 11 Both were validated for cytotoxicity, irritation and sensitization
Biocompatibility	ISO 10993-1 ISO 10993-5, ISO 10993-10, ISO 10993-23	ISO 10993-1 ISO 10993-5, ISO 10993-10	Equivalent

Justification for the differences:

No.	Difference	Justification
Note 1 Note 2	Indications for Use / Intended Use & Patients population	The scope of the applicable group of people has been narrowed down to exclude pediatric patients under 3 months (predicate device applicable population is also included). The subject device has a narrower intended population and it does not raise any new or different questions of safety or effectiveness.
Note 3 Note 4	Measurement range & accuracy	The measurement range of the predicate device is different from that of the subject device. The scale of clinical thermometer like Mercury thermometer reads temperature from 35℃ to 42℃. The subject device measurement range is 32.0℃ to 42.9℃ meet the normal clinical use. For the normal clinical measurement range of 32.0℃ to 42.9℃, the accuracy of the subject device and the predicate device are same or even stricter than the predicate device. And the performance test and clinical accuracy test showed that the subject device do not raise any new questions of safety and effectiveness.
Note 5	Memory function	In terms of the memory function, it is to help patients remember and check the previous results, so this minor difference would not raise any safety and effectiveness questions.
Note 6	Automatic power off time	The design purpose is to give the user time to review or record the data if needed. The difference will not raise any new safety or effectiveness questions.
Note 7 Note 8	Operation Environments & Storage Environments	Although the operation and storage conditions of the subject device are slightly different from the predicate device, they meet the same standard requirements of ISO 80601-2-56 and IEC 60601-1-11.Therefore, the operating and storage conditions do not raise new questions of safety and effectiveness.
Note 9	Power supply	The subject device powered by internal battery (AA or AAA) ,which both belong to alkaline battery. The test results have been verified by electrical safety and EMC testing. It does not affect the safety and effectiveness of subject device.
Note 10	Dimensions	The subject and the predicate are has slight difference in dimensions due to different outlook. Moreover, such engineering design has been verified against international standards, so such minor differences will not raise any safety and effectiveness questions.
Note 11	Patient Contacting Materials	The materials used for subject device and predicate device are similar, and it is validated for cytotoxicity per ISO10993-5 and irritation as well as sensitization per ISO 10993-10&10993-23, and it is demonstrated that the subject device does not raise any new questions of safety and effectiveness.

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The differences between the subject and predicate devices do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the bench testing, the different technological characteristics do not affect the safety and effectiveness of the subject device.

7. Non-clinical Data

Biocompatibility testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Bench testing

The device has been tested according to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 80601-2-56 Medical electrical equipment—Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- 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
- FDA Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

8. Clinical data

The clinical testing has been conducted per ISO 80601-2-56 Medical electrical equipment—Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

9. Conclusion

It is concluded from the non-clinical and clinical tests that the subject devices are substantially equivalent to the legally marketed predicate device identified above.