June 5, 2026

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory Affairs Specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan
Baoan District
Shenzhen, 518108
China

Re: K253162
Trade/Device Name: Temperature probes (T2252-PG); Temperature probes (TCMA-AG); Temperature probes (TCMA-PG); Temperature probes (TMQ-DAG); Temperature probes (THP-DAG)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 7, 2026
Received: May 7, 2026

Dear Huanyu Zeng:

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,

DAVID WOLLOSCHECK -S

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

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.	K253162

Please provide the device trade name(s).

Temperature probes (T2252-PG);
Temperature probes (TCMA-AG);
Temperature probes (TCMA-PG);
Temperature probes (TMQ-DAG);
Temperature probes (THP-DAG)

Please provide your Indications for Use below.

Reusable Temperature Probes:
Unimed Reusable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are reusable and designed for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider. Probes must be cleaned, disinfected, and inspected for damage before use.

Disposable Temperature Probes:
Unimed Disposable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are disposable and designed for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider.

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)

K253162 - 510(K) Summary

1. Submitter

Submitter/Manufacturer:	Unimed Medical Supplies Inc. Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, Baoan District, Shenzhen, China 518108 FDA Establishment Number: 3007307487
Contact:	Zeng Huanyu Regulatory Affairs Specialist Tel: +86-755 26695165 E-mail: zenghy@unimed.cn
510(k) Submission Type	This is a traditional 510(k).

2. Proposed Device

Trade Name:	Temperature Probes (T2252-PG; TCMA-AG; TCMA-PG; TMQ-DAG; THP-DAG)
Common Name:	Continuous Measurement Thermometer
Classification:	Medical Specialty: General Hospital Regulation: 21 CFR 880.2910 – Clinical electronic thermometer Product Code: FLL Class: II

3. Predicate Device

510(K) No.	Trade Name
K121427	UNIMED TEMPERATURE PROBE

4. Device Description

This 510(k) submission includes five temperature probe models: three reusable models (T2252-PG, TCMA-AG, and TCMA-PG) and two disposable models (TMQ-DAG and THP-DAG). The reusable models are intended for repeated use after validated cleaning and disinfection. The disposable models are single-use devices.

The probes consist of a monitor-end connector, cable, and NTC thermistor at the patient end. The subject models are applied to the esophageal or rectal site, depending on model. T2252-PG and TCMA-PG are pediatric reusable models. TCMA-AG and the two disposable models are adult models.

The subject probes are designed for use with model-specific compatible patient monitors

using the YSI 400 series compatible temperature measurement approach.

5. Intended Use/Indications for Use

Reusable Temperature Probes:

Unimed Reusable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are reusable and designed for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider. Probes must be cleaned, disinfected, and inspected for damage before use.

Disposable Temperature Probes:

Unimed Disposable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are disposable and designed for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider.

6. Comparison to Predicate Device

Feature	**Subject Device (K253162)**	**Predicate Device (K121427)**	**Comparison to Predicate Device**
Device name	Unimed Reusable and Disposable Temperature Probes	UNIMED TEMPERATURE PROBE	Different (Note 3)
Classification Regulation/ Product Code	21 CFR 880.2910 Class II/FLL	21 CFR 880.2910 Class II/FLL	Same
Intended use	Reusable Temperature Probes: Unimed Reusable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are reusable and designed	Unimed Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors	Different (Note 1)

	for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider. Probes must be cleaned, disinfected, and inspected for damage before use. Disposable Temperature Probes: Unimed Disposable Temperature Probes are intended to be used for monitoring temperature by applying them to the esophageal or rectal site, depending on model. The temperature probes are disposable and designed for use with compatible patient monitors. These probes should be applied to a patient only under direct supervision of a licensed physician or health care provider.	compatible with YSI 400 series temperature probes. These devices are indicated for use by qualified medical personnel only.	
Patient population	Pediatric reusable models: T2252-PG and TCMA-PG. Adult models: TCMA-AG, TMQ-DAG, and THP-DAG. Neonatal use is not claimed.	Adult; the K121427 summary does not separately stratify pediatric subgroups.	Different (Note 2)
Measurement type	Continuous temperature monitoring.	Continuous temperature monitoring.	Same

Key performance specifications/ characteristics			
Prescription or OTC	Rx Only	Rx only	Same
Thermometer type / application site	Esophageal/rectal temperature probe	General purpose temperature probe	Different (Note 1)
Use type	Reusable/Disposable	Reusable	Different (Note 3)
Sensor Structure Composition	Plug, cable, thermistor	Plug, cable, thermistor	Same
Materials	Reusable models: PVC, stainless steel, and epoxy resin. Disposable models: PVC.	Reusable models: PVC, stainless steel, and epoxy resin.	Different (Note 3)
Length	Reusable models: 3.00 m. Disposable models: 0.76 m.	3.00 m	Different (Note 3)
Nominal probe diameter	Esophageal/rectal probes: 2.6 mm.	Esophageal/rectal probes: 2.6 mm.	Same
Compatible devices	Model-specific compatible monitors include GE Dash 5000/YSI400, Philips IntelliVue X2, and Comen C60.	Monitors of Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.	Different (Note 4)
Response time	The IFUs instruct users to allow the displayed temperature reading to stabilize for at least 35 seconds after probe placement and monitor connection before recording the value.	/	Different (Note 5)
Performance			
Temperature range	25 °C to 45 °C	25 °C to 45 °C	Same
Accuracy	±0.1 °C	±0.1 °C	Same

Thermistor resistance	NTC thermistor 2.252 kΩ	NTC thermistor 2.252 kΩ	Same
Environmental			
Operating environment conditions	Operating ambient temperature: 0 °C to +40 °C.	Operating ambient temperature: 0 °C to +40 °C.	Same
Biocompatibility	Pass ISO 10993 cytotoxicity, skin irritation and skin sensitivity tests	Pass ISO 10993 cytotoxicity, skin irritation and skin sensitivity tests	Same

Notes for differences identified in the comparison table:

Note 1 - Intended use and application site: The subject devices have the same temperature-monitoring purpose as the predicate device. The subject labeling limits use to model-specific esophageal/rectal measurement. This clarification does not introduce a new temperature-measurement principle. The difference is addressed through model-specific labeling and performance testing according to ISO 80601-2-56.

Note 2 - Patient population: The subject device includes identified pediatric reusable models and adult models, and neonatal use is not claimed. The pediatric models are controlled through model identification, probe dimensions, professional-use labeling, biocompatibility testing, and performance testing.

Note 3 - Reusable/disposable configuration, materials, and length: The subject models use the same temperature-measurement principle, NTC thermistor approach, plug/cable/thermistor construction, YSI 400-series compatible interface, temperature range, and accuracy specification as the predicate. The disposable configuration, materials for disposable models, and model-specific cable length do not raise new questions of safety or effectiveness. These differences are addressed by biocompatibility testing, performance testing, accelerated-aging/shelf-life evaluation, and simulated-shipping evaluation.

Note 4 - Compatible devices: The subject models identify compatible monitors by model while maintaining the YSI 400-series compatible temperature-measurement approach. Electrical safety, electromagnetic compatibility, and displayed-temperature performance testing support the compatible-monitor approach.

Note 5 - Response/stabilization time: The subject IFUs instruct users to allow the displayed temperature reading to stabilize for at least 35 seconds before recording the value. Post-conditioning and post-shipping displayed-temperature testing support the stated performance

specification.

7. Non-clinical Test Data

Non-clinical tests were conducted to verify that the proposed devices meet the applicable design specifications and support substantial equivalence to the predicate device. The non-clinical testing conformed to the following recognized standards, as applicable:

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 disturbances - 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

ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

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

ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

8. Substantial Equivalence Statement

Based on the comparison, analysis, and submitted non-clinical data, Unimed believes that the Unimed Disposable and Reusable Temperature Probes are as safe and effective as, and substantially equivalent to, the predicate device.