June 20, 2025

Shenzhen Medke Technology Co., Ltd.
℅ Mrs. Jie Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K243000
Trade/Device Name: Reusable Temperature Probe (T1306, T2306, T3306, T4306);
Disposable Temperature Probe (T5106, T6106)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 26, 2024
Received: May 23, 2025

Dear Jie Yang:

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.

Submission Number *(if known)*

K243000

Device Name

Reusable Temperature Probe(T1306, T2306, T3306, T4306);
Disposable Temperature Probe(T5106, T6106)

Indications for Use *(Describe)*

Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable or for single patient use and designed for use with Mindray monitor Model PM-8000 and other monitors compatible with YSI 400 series temperature probes.
These devices are used by qualified medical professional only.

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- K243000

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/06/20

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Reusable Temperature Probe (T1306, T2306, T3306, T4306); Disposable Temperature Probe (T5106, T6106)
Common Name	Temperature Probe
Regulatory Class	Class II
Regulation & Name	21CFR 880.2910 / Thermometer, electronic, clinical
Product Code	FLL
Submission type	Traditional 510(K)

4. Predicate Device

Predicate	**Device name and model**	**K number**	**Manufacturer**
Primary Predicate device	Unimed Temperature Probe (Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe)	K121427	Unimed Medical Supplies Inc.
Reference device	ESOPHAGEAL RECTAL EMPERATURE PROBE ER400-9, ER400-12	K863646	RESPIRATORY SUPPORT PRODUCTS, INC. (owned by ICU Medical, Inc. now)

5. Device Description

The subject devices are used for patient temperature measurement. The probes are reusable or disposable depending on models. These probes consist of a connector on the monitor end and a thermistor on the patient end. The working principle is resistance based on the metal conductor increases with temperature decrease, and the linear changes to the characteristics of the temperature measurement. The subject devices are designed to be used in healthcare facilities like hospital and compatible with a monitor of Mindray Model PM-8000 and other monitors compatible with YSI 400 series temperature probes.

The six models have two types of structure designs corresponding to reusable and disposable use which consists of different materials. The NTC of the six models are identical. Reusable models T1306, T2306, T3306, T4306 have a similar structure design with two different sensor shapes for different measure sites and consist of the same materials. Disposable models T5106 and T6106 have a similar structure design with two different sensor shapes for different measure sites and consist of the same materials.

Model	Description
T1306	Skin contact Temperature Probe, adult, reusable
T2306	Body cavity Temperature Probe, Esophageal/Rectal, adult, reusable
T3306	Skin contact Temperature Probe, pediatric, reusable
T4306	Body cavity Temperature Probe, Esophageal/Rectal, pediatric, reusable
T5106	Skin contact Temperature Probe, adult/ pediatric, disposable
T6106	Body cavity Temperature Probe, Esophageal/Rectal, adult/ pediatric, disposable

6. Intended use & Indication for use

Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable or for single patient use and designed for use with Mindray monitor Model PM-8000 and other monitors compatible with YSI 400 series temperature probes.

These devices are used by qualified medical professional only.

7. Comparison to the Predicate Device

The following tabulation indicates the detailed differences between the subject devices and the predicate device.

Item	**Subject Device**	**Primary Predicate Device**	**Comparison**
Trade name	Reusable Temperature Probe (T1306, T2306, T3306, T4306); Disposable Temperature Probe (T5106, T6106)	Unimed Temperature Probe	/
510(k) submitter	Shenzhen Medke Technology Co., Ltd.	Unimed Medical Supplies Inc.	/
510(k) Number	K243000	K121427	/

Models	Skin Temperature Probe: Reusable: T1306, T3306 Disposable: T5106 Body cavity Temperature Probe: Reusable: T2306, T4306 Disposable: T6106	Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe	/
Item	**Subject Device**	**Primary Predicate Device**	**Comparison**
Classification Regulation	880.2910	880.2910	Same
Class	II	II	Same
Product Code	FLL	FLL	Same
Common Name	Temperature Probe	Temperature Probe	Same
Type of use	Prescription	Prescription	Same
Indication for Use	Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable or for single patient use and designed for use with Mindray monitor Model PM-8000 and other monitors compatible with YSI 400 series temperature probes. These devices are used by qualified medical professional only.	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 compatible with YSI 400 series temperature probes. These devices are indicated for used by qualified medical personnel only.	Similar, note 1
Operating Principle	Resistance of thermistor based on the metal conductor increases with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	Resistance of thermistor based on the metal conductor increases with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	Same

Measure site	Skin, Esophageal and Rectal	Skin, Esophageal and Rectal	Same
Operation mode	Direct mode	Direct mode	Same
Usage	Reusable, Disposable	Reusable	Similar Note 1
Item	**Subject Device**	**Primary Predicate Device**	**Comparison**
Measurement Range	25-45℃	25-45℃	Same
Accuracy	±0.1℃	±0.1℃	Same
Component	plug, cable and temperature sensing probe	plug, cable and temperature sensing probe	Same
Thermistor resistance	2.25KΩ@25℃	2.252KΩ@25℃	Same
Material	Materials of reusable probe: PVC, Copper nickel plated, Expoxy AB glue Materials of disposable probe: PVC, Foam, Aluminum foil	Not-provided	Similar Note 2
Compatible Monitors	Mindray Model PM-8000, and other monitors compatible with YSI 400 series temperature probes.	Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.	Similar, Note 1
Operating Environment	Temperature: +5 to+40°C Humidity: ≤80%(non-condensing) Atmospheric pressure：86kPa～106kPa	Not-provided	Similar Note 3
Storage Environment	Temperature range: -20℃ to 55℃(-4 to 131℉) Humidity (Operating): ≤93% Hyperbaric Pressure: 86kPa～106kPa	Not-provided	Similar Note 3
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
Performance	ISO 80601-2-56	EN 12470-4	Similar, Note 4

Biocompatibility	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10, ISO 10993-23	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	Similar, Note 4

Item	Subject Device	Primary Predicate Device	Comparison
Sterilization	Non-sterile	Non-sterile	Same
Operational Type	Continual	Continual	Same

Justification of differences:

Note 1

The subject device claims different compatible patient monitor compared with predicate device. However, they all compatible with monitors compatible with YSI 400 series temperature probes. The compatibility has been verified by bench testing. Besides, the subject device includes both reusable and disposable models while the predicate only include reusable models. The reusable models are considered higher risk models and can be used to cover both reusable and disposable models of the subject devices. Therefore, the difference does not raise any new or different safety and effectiveness questions.

Note 2

The materials information of the predicate is not available. However, the biocompatibility of the subject device has been evaluated per ISO 10993-1. The difference does not raise any new or different safety and effectiveness questions.

Note 3

Operating and Storage condition difference: The subject device has been tested and the test results met the requirements of IEC 60601-1 and ISO 80601-2-56. The difference does not raise any new or different safety and effectiveness questions.

Note 4

The subject device complies with the newest FDA recognized standard compared with the predicate device. The difference does not raise any new or different safety and effectiveness questions.

8. Non-clinical Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the subject devices were 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
- Oral mucosa/ Rectal Irritation (Body cavity Temperature Probe only)

Bench testing

Bench testing has been conducted to verify that the subject devices meet all design specifications which support the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the targeted device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 80601-2-56:2017+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.

9. Clinical study

No clinical study is needed for the subject device.

10. Conclusion

Substantial equivalence comparisons, performance testing and compliance with voluntary standards demonstrate that the differences between the subject and predicate device do not raise new questions of safety and effectiveness. The subject device is substantially equivalent to the predicate device.