September 6, 2019

Shenzhen Caremed Medical Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, Nanshan Medical Devices Industrial Park
Nanshan District
Shenzhen, 518067
China

Re: K182751
Trade/Device Name: Reusable Temperature Probe (Model: TRAG-2252, TRAS-2252, TRCG-2252 and TRCS-2252)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 8, 2019
Received: August 8, 2019

Dear Kevin 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Alan Stevens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182751

Device Name
Reusable Temperature Probe (Model:TRAG-2252, TRAS-2252, TRCG-2252 and TRCS-2252)

Indications for Use *(Describe)*
The Reusable Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Nihon Kohden model BSM-5135A. These devices are indicated for used by qualified medical personnel 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2019/08/25

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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3. Subject Device Information

Trade/Device Name	Reusable Temperature Probe
Model	Reusable Temperature Probe: TRAG-2252, TRAS-2252, TRCG-2252 and TRCS-2252
Common Name	Temperature Probe
Regulatory Class	Class II
Classification	21CFR 880.2910 / Thermometer, electronic, clinical / FLL
Submission type	Traditional 510(K)

4. Predicate Device

510(k) Number: K121427
Applicant: UNIMED MEDICAL SUPPLIES INC.
Device name: UNIMED TEMPERATURE PROBE

5. Device Description

Reusable temperature probes are used during patient temperature measurement for multi-patient use. These probes consist of a phone plug connector on the monitor end and a thermistor on the patient end. Temperature probes measure temperature by a resistor that is sensitive to temperature changes. These probes are connected to the patient monitor either directly by using a phono plug or by an interconnect cable. These

probes have a skin or core contact with a patient.

These temperature probes are typically used with legacy Nihon Kohden monitors BSM-5135A.

Products are packed individually into a plastic bag in non-sterile condition. Package label describes product LOT codes, CE-mark, legal entity information and a caution "Rx Only ".

Model	Application site	length	Compatible monitors	Measurement range	Accuracy	Time response	Minimum measuring time
TRAG-2252	Adult Rectum	3.0m	Nihon Kohden, model: BSM-5135A	25-45°C	±0.2°C	⩽150S	5mins
TRAS-2252	Adult Skin						
TRCG-2252	Pediatric Rectum						
TRCS-2252	Pediatric Skin						

6. Intended use & Indication for use

The Reusable Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Nihon Kohden model BSM-5135A. These devices are indicated for used by qualified medical personnel only.

7. Comparison to the Predicate Device

Features	Subject Device Reusable Temperature Probe K182751	Predicate Device Unimed Temperature Probe K121427	Comparison
Classification Name	Temperature Probe	Temperature Probe	Same
Product Code	FLL	FLL	Same
Regulation Number	880.2910	880.2910	Same
Panel	General Hospital	General Hospital	Same
Class	II	II	Same
Thermistor	NTC resistance (2252 Ohms in 25℃)	NTC resistance (2252 Ohms in 25℃)	Same
Accuracy range	25-45℃	25-45℃	Same
Accuracy	±0.2℃	±0.1℃	Different (1)
Measure site	Skin & Rectum	Skin & Rectum	Same
Population	Adult & Pediatric	Adult	Different (2)
Material contact to body	PVC, TPU, Epoxy & Stainless steel	PVC, TPU & Stainless steel	Different (3)
Length	3m	1.5m & 3m	Same
Cable material	PVC & TPU	PVC & TPU	Same
Plug material	PA66	ABS	Different (4)
Operational Principles	Continual	Continual	Same
Indication for Use	The Reusable Temperature	Unimed Temperature Probes	Different (5)

	Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Nihon Kohden model BSM-5135A. These devices are indicated for used by qualified medical personnel only.	are intended to be used for monitoring temperature. The temperature probes are 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.	
Biocompatibility	Cytotoxicity Sensitization Irritation Rectal Irritation (Rectum probes only)	Cytotoxicity Sensitization Irritation Rectal Irritation (Rectum probes only)	Same
Justifications for differences between Reusable Temperature Probe and the predicate device are shown as below: Different (1): The accuracy is different from the predicate device. All subject devices were conducted performance testing according to ISO 80601-2-56. The accuracy is within the requirement from the standard. Thus, different accuracy does not raise new questions of safety and effectiveness for the subject device. Different (2): The only difference between adult probe and pediatric probe is physical size of the cable diameter. All subject devices were conducted performance testing according to ISO 80601-2-56. Thus, different patient population does not raise new questions of safety and effectiveness for the subject device. Different (3): It's different with the patient contacted material of predicate device. However, it's conformed with ISO 10993 series standard. According to analysis results, all the Patient Contacting Materials shows no cytotoxicity, irritation response was negligible and no sensitization. Thus, different material does not raise new questions of safety and effectiveness for the subject device. Different (4): It's different with the plug material of predicate device. However, it's conformed with ISO 10993 series standard. According to analysis results, all the materials shows no cytotoxicity, irritation response was negligible and no sensitization. Thus, different material of plug does not raise new questions of safety and effectiveness for the subject device. Different (5): The compatible monitors of proposed devices are different from the predicate device. The proposed devices are intended to use with Nihon Kohden monitors and the predicate devices are intended to use with Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors. The core component of temperature probe is Negative Temperature Coefficient (NTC)			

which is identical to the NTC used in predicate device. The NTC determines the accuracy and range of temperature measurement. All subject devices were conducted performance testing according to ISO 80601-2-56. The difference does not raise new questions of safety and effectiveness for the subject device.

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the Reusable Temperature Probes 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 battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation
- Rectal Irritation (Rectum probes only)

The Reusable Temperature Probes are considered surface contacting for a duration of less than 24 hours.

Non-clinical data

Test	Description	Result
Safety	Ensures the temperature probes meet the requirements of IEC 60601-1 electrical safety	Pass
EMC	Ensures the temperature probes meet the requirements of IEC 60601-1-2 and ISO 80601-2-56 electromagnetic compatibility	Pass
Laboratory accuracy	Not greater than 0.3 °C for a continuous clinical thermometer that is not an adjusted mode clinical thermometer	Pass
Time response	Heating transient time < 150s	Pass
Disinfection validation	Low-level disinfection validation; High-level disinfection validation	Pass
Chemical Disinfection Agent Residue Validation	According to ISO 10993-5, non- Cytotoxicity.	Pass

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed devices are substantially equivalent to the predicate device.