October 10, 2018

Orantech Inc.
% Kevin Wang
Chonconn Medical Device Consulting Co., Ltd.
22A, Haijing Square, No. 18, Taizi Road
Nanshan District, Shenzhen, 518067
China

Re: K173194
Trade/Device Name: Temperature Probe (Models:
TS-Y400-AG30, TS-Y400-AS30, TS-PH-AG30 and TS-PH-AS30)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 13, 2018
Received: September 13, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173194

Device Name
Temperature Probe (Model: TS-Y400-AG30, TS-Y400-AS30, TS-PH-AG30 and TS-PH-AS30)

Indications for Use *(Describe)*
Orantech Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips Model MP30 and Nihon Kohden Model BSM-6301A. 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.

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Orantech

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2018/02/05

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Temperature Probe
Model	TS-Y400-AG30, TS-Y400-AS30, TS-PH-AG30 and TS-PH-AS30
Common Name	Temperature Probe
Regulatory Class	Class II
Classification	21CFR 880.2910 / Clinical electronic thermometer / FLL
Submission type	Traditional 510(K)

4. Predicate Device

1. Unimed Medical Supplies Inc. Temperature Probe under K121427.

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 Philips monitor model MP30 and Nihon Kohden monitor model BSM-6301A.

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

Product Specification

Model	Application site	length	Compatible monitors	Measurement range	Accuracy
TS-PH-AG30	Rectum	3.0m	Philips Model: MP30	25-45℃	±0.1℃
TS-PH-AS30	Skin	3.0m	Philips Model: MP30	25-45℃	±0.1℃
TS-Y400-AG30	Rectum	3.0m	Nihon Kohden Model: BSM-6301A	25-45℃	±0.1℃
TS-Y400-AS30	Skin	3.0m	Nihon Kohden Model: BSM-6301A	25-45℃	±0.1℃

6. Indication for use

Orantech Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips Model MP30 and Nihon Kohden Model BSM-6301A.

These devices are indicated for used by qualified medical personnel only.

7. Comparison to the Predicate Device

Orantech Model	Predicate Model	Description
TS-PH-AG30	THP-AG	Reusable Temperature Probe, adult rectum, 3.0M
TS-PH-AS30	THP-AS	Reusable Temperature Probe, adult skin, 3.0M
TS-Y400-AG30	T2252-AG	Reusable Temperature Probe, adult rectum, 3.0M
TS-Y400-AS30	T2252-AS	Reusable Temperature Probe, adult skin, 3.0M

Features	Subject Device Orantech Temperature Probe	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	±0.1℃	±0.1℃	Same
Measure site	Skin & Rectum	Skin & Rectum	Same
Patient population	Adult	Adult	Same
Material contact to body	Thermistor Sensor Tip: Epoxy & Stainless steel	Thermistor Sensor Tip: Stainless steel	Different (1)
Length	3m	1.5m & 3m	Same
Cable material	PVC & TPU	PVC & TPU	Same
Plug material	PA66	ABS	Different (2)
Biocompatibility	Cytotoxicity Sensitization Irritation	Cytotoxicity Sensitization Irritation	Same
Operational Principles	Continual	Continual	Same
Indication for Use	Orantech Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips Model MP30 and Nihon Kohden Model BSM-6301A. These devices are indicated for used by qualified medical personnel only.	Unimed Temperature Probes 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.	Different (3)

Justifications for differences between Orantech Temperature Probe and the predicate device are shown as below:

Different (1): 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 will not raise any safety or biocompatibility issues.

Different (2): 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 will not raise any safety or biocompatibility issues.
Different (3): The compatible monitors of proposed devices are different from the predicate device. The proposed devices are intended to use with Philips and 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. Therefore, the indication for use of proposed devices is essentially the same as predicate device.

8. Performance Data

Biocompatibility testing

The biocompatibility evaluation for the Orantech Temperature Probe was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Orantech Temperature Probe is considered surface contacting for a duration of exceed 24 hours but not 30 days.

Non-clinical data

The Orantech Temperature Probe has been tested according to the following standards:

Test	Description	Result
Safety	Ensures the temperature probes meet the requirements of IEC 60601-1 electrical safety	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
Use life testing	Ensures the temperature probes meet the requirements of the expected service life of the probe.	Pass
Cleaning and Disinfection	Validate the cleaning and disinfection method is effective. The study was conducted based on following documents: 1) AAMI TIR 30: 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices; 2) AAMI TIR 12: 2010 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers;	Pass

	3) FDA Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling document issued on: March 17, 2015.	

9. Conclusion

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