August 31, 2021

JKH USA, LLC
Bill Quanqin Dai
Manager
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K203636
Trade/Device Name: PlusCare Temperature Probe, Skin Types: PT2252-AS, PTHP-AS, PTMQ-AS, PTSW-AS, PTSM-15AS, PTSL-AS, PTMR-AS; General Purpose Types: PT2252-AG, PTHP-AG, PTMQ-AG, PTSW-AG, PTSM-15AG, PTSL-AG, PTMR-AG
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 20, 2021
Received: July 28, 2021

Dear Bill Quanqin Dai:

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 Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203636

Device Name
PlusCare Temperature Probe
Skin Types: PT2252-AS, PTHP-AS, PTMQ-AS, PTSW-AS, PTSM-15AS, PTSL-AS, PTMR-AS;
Rectum Types: PT2252-AG, PTHP-AG, PTMQ-AG, PTSW-AG, PTSM-15AG, PTSL-AG, PTMR-AG

Indications for Use *(Describe)*
PlusCare 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 use 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.

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K203636 - 510(k) Summary

Submitter:	Name: JKH USA, LLC Mailing Address: 14271 Jeffrey Rd. #246, Irvine, CA 92620
Contact Person:	Name: Bill Quanqin Dai Phone Number: 909-929-9896 Email Address: Bill@jkhUSA.com
Date Prepared:	08/31/2021
Device Trade Name:	PlusCare Temperature Probe
Device Common Name:	Clinical electronic thermometer
Model:	Skin Types: PT2252-AS, PTHP-AS, PTMQ-AS, PTSW-AS, PTSM-15AS, PTSL-AS, PTMR-AS; Rectum Types: PT2252-AG, PTHP-AG, PTMQ-AG, PTSW-AG, PTSM-15AG, PTSL-AG, PTMR-AG
Regulation Name: **Regulation Number:** **Product Code:** **Device Class:**	Clinical electronic thermometer 21 CFR 880.2910 FLL Class II
Predicate Device: **510(k) Number:** **Device Name:** **Manufacturer:**	 K121427 Unimed Temperature Probe UNIMED MEDICAL SUPPLIES INC

Description of Devices:

The Skin Temperature Probe and Rectum Temperature Probe are used during patient temperature measurement. These probes consist of a connector on the monitor end and a thermistor on the patient end. These probes are to be used with compatible temperature measurement systems only.

Temperature probes measure temperature through a resistor that is sensitive to temperature changes.

The probe is connected to the monitor either directly by using the connector or by an extension cable. These probes have a skin or core contact with a patient.

Table 1. Basic information of devices

Model	Application site	length
PT2252-AS	Skin	3.0m
PTHP-AS	Skin	3.0m
PTMQ-AS	Skin	3.0m

PTSW-AS	Skin	3.0m
PTSM-15AS	Skin	1.5m
PTSL-AS	Skin	3.0m
PTMR-AS	Skin	3.0m
PT2252-AG	Rectum	3.0m
PTHP-AG	Rectum	3.0m
PTMQ-AG	Rectum	3.0m
PTSW-AG	Rectum	3.0m
PTSM-15AG	Rectum	1.5m
PTSL-AG	Rectum	3.0m
PTMR-AG	Rectum	3.0m

Operating Principle:

The operating principle is resistance based on the metal conductor increases with temperature decrease, and the linear changes to the characteristics of the temperature measurement. It is to measure differences in resistance and equates that to changes in temperature.

Indications for Use:

PlusCare 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 use by qualified medical personnel only.

Substantial Equivalence Discussion:

The subject and predicate devices are exactly the same. They have the same intended use, the same design principle, the same production process, and the same material composition. See the detailed comparison in the table below.

Table 2. Comparison of Technological Characteristics

Description	**Subject Device (K203636)**	**Predicate Device (K121427)**	Comparison
Trade name	PlusCare Temperature Probe	Unimed Temperature Probe	N/A

Population	Adult	Adult	Same
Indications for Use	PlusCare 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 use by qualified medical personnel 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.	Same
Contact duration period of use	Skin-Type Probe: less than 30 days Rectum-Type Probe: less than 24h	Skin-Type Probe: less than 30 days Rectum-Type Probe: less than 24h	Same
Prescription/ OTC use	Prescription	Prescription	Same
Energy source	Powered by compatible devices	Powered by compatible devices	Same
Operating Principle	Thermistor resistance based on the metal conductor increase with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	Thermistor resistance based on the metal conductor increase with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	Same
Technology	Temperature sensitive resistor	Temperature sensitive resistor	Same
Application site	Skin, rectum	Skin, rectum	Same
Material	ABS, copper, PA6, PVC, Gilded copper needle, TPU, NTC thermistor, Epoxy resin, Stainless steel plate	ABS, copper, PA6, PVC, Gilded copper needle, TPU, NTC thermistor, Epoxy resin, Stainless steel plate	Same
Measurement range	25-45℃/77-113°F	25-45℃	Same
Thermistor resistance	NTC resistance 2.25KΩ@25°C	NTC resistance 2.25KΩ@25°C	Same
Accuracy	±0.1℃/±0.18°F	±0.1℃	Same
Component	plug, cable and temperature sensing probe	plug, cable and temperature sensing probe	
Usage	Reusable	Reusable	Same

Operation Environment	Temperature: 0°C~40°C (32°F ~104°F); Relative humidity range: 15% to 85%	Temperature: 0°C~40°C (32°F ~104°F); Relative humidity range: 15% to 85%	Same
Storage environment	Temperature: -25℃~55℃ (-13°F ~131°F) Relative humidity range: ≤85%	Temperature: -25℃~55℃ (-13°F ~131°F) Relative humidity range: ≤85%	Same
Biocompatibility	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	Same
Sterile	Non-sterile	Non-sterile	Same
Standards met	IEC 60601-1 ISO 80601-2-56 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1 ISO 80601-2-56 ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Non-Clinical Test Data:

The subject device meets the following recognized standards:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety
- 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 10993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
- 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 irritation and delayed-type hypersensitivity

The subject device is classified as a skin contacting device with a contact duration of less than 30 days. Biocompatibility tests have been conducted on the subject device, including cytotoxicity, sensitization, and skin irritation. The test results show that the subject device met the requirements of the standards.

Substantial Equivalence:

The subject and predicate devices are exactly the same. Therefore, the PlusCare Temperature Probe is substantially equivalent to the Unimed Temperature Probe cleared under K121427 with respect to the intended use, target populations, treatment method, and technological characteristics.