June 18, 2019

Shenzhen Med-link Electronics Tech Co., Ltd.
Baihan Feng
Regulatory Affairs Specialist
4th Floor, Building A, Yingtailong Industrial Park
Dalang South Road, Longhua District
Shenzhen, Guangdong 518109
China

Re: K182667
Trade/Device Name: Med-link Temperature Probes
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 14, 2019
Received: May 16, 2019

Dear Baihan Feng:

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 Tina Kiang, Ph.D
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)*
K182667

Device Name
Med-link Temperature Probes

Indications for Use *(Describe)*
Med-link Temperature Probes are intended to be used for monitoring temperature for multi-patient use. The temperature probes are reusable and designed for use with monitors of Philips Model IntelliVue MP50, Mindray Model PM-9000, Datex-Ohmeda Model Cardiocap II, Drager Model Infinity Gamma XL.

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.

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Shenzhen Med-link Electronics Tech Co., Ltd.

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Type of submission: Traditional

The assigned 510(k) number is: K182667

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.

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Tel: 0086-755-61568825

Fax: 0086-755-61120055

Establishment Registration Number: 3006636961

2. Correspondent

Baihan Feng (Regulatory Affairs Specialist, Primary Contact)

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Liu Fei

E-mail: USER22@med-linket.com

3. Data of Preparation

14th, May 2019

4. Identification of the Device

Trade Name: Med-link Temperature Probes

Common Name: Temperature Probe

Classification Regulation: 21 CFR 880.2910

Classification Name: Clinical Electronic Thermometer

Product Code: FLL

Class: II

Review Panel: General Hospital

5. Identification of the Predicate Device

Table 1 Predicate Device Information

No.	Device Name	Common Name	Manufacture	Classification and Code	Classification regulation	510(k) number
1	Unimed Temperature Probe (Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe)	Temperature Probe	Unimed Medical supplies Inc.	Class II, FLL	21 CFR 880.2910	K121427

6. Indications for Use of the Subject device

Med-link Temperature Probes are intended to be used for monitoring temperature for multi-patient use. The temperature probes are reusable and designed for use with monitors of Philips Model IntelliVue MP50, Mindray Model PM-9000, Datex-Ohmeda Model Cardiocap II, Drager Model Infinity Gamma XL.

These devices are used by qualified medical professional only.

7. Device Description

The proposed devices are used for patient temperature measurement for multi-patient use. The temperature probes are reusable and 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.

No	Model	Description	Measurement range	Accuracy	Compatible monitors
1	W0003A	Adult Reusable Skin-surface Probe	25-45℃	±0.1℃	Philips IntelliVue MP50 (K040304)
2	W0003B	Adult Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	
3	W0001A	Adult Reusable Skin-surface Probe	25-45℃	±0.1℃	Mindray

4	W0001B	Adult Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	PM-9000 (K070791)
5	W0013A	Adult Reusable Skin-surface Probe	25-45℃	±0.1℃	Mindray BeneVision N12 (K182075)
6	W0013B	Adult Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	
7	W0007A	Adult Reusable Skin-surface Probe	25-45℃	±0.1℃	Datex-Ohmeda Cardiocap II (K912530)
8	W0007B	Adult Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	
9	W0008A	Adult Reusable Skin-surface Probe	25-45℃	±0.1℃	Drager Infinity Gamma XL (K053484)
10	W0008B	Adult Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	

8. Non-clinical Test

A series of safety, essential performance and biocompatibility tests were performed to assess the safety and effectiveness of Med-link Temperature Probes. The tests listed below were conducted in accordance with

IEC 60601-1 Medical electrical equipment-Part 1:General requirements for basic safety, and essential performance.

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: Test for in vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests For Irritation And Skin Sensitization

- Cytotoxicity Test
- Irritation Test
- Sensitization Test

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

9. Comparison to the Predicate Device

Item	Proposed Device	Predicate Device	Verdict
Trade name	Med-link Temperature Probes	Unimed Temperature Probe (Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe)	/

Item	Proposed Device	Predicate Device	Verdict
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Unimed Medical supplies Inc.	/
510(K) Number	K182667	K121427	/
Classification Regulation	21CRF 880.2910	21CRF 880.2910	SE
Classification and Code	Class II, FLL	Class II, FLL	SE
Common name	Temperature Probe	Temperature Probe	SE
Type of Use	Prescription	Prescription	SE
Intended use	Med-link Temperature Probes are intended to be used for monitoring temperature for multi-patient use. The temperature probes are reusable and designed for use with monitors of Philips Model IntelliVue MP50, Mindray Model PM-9000, Datex-Ohmeda Model Cardiocap II, Drager Model Infinity Gamma XL. 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.	SE 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.	SE
Measurement Site	Skin, Esophageal and Rectal	Skin, Esophageal and Rectal	SE
Measurement	25-45℃	25-45℃	SE

Item	Proposed Device	Predicate Device	Verdict
Range			
Accuracy	±0.1℃	±0.1℃	SE
Component	Reusable	Reusable	SE
Thermistor resistance	2.25K@25℃	2.252K@25℃	SE
Material	Cable: PVC Probe end：Epoxy，S304 Stainless Steel	Not-provided	SE Note 2
Compatible Monitors	Philips Model IntelliVue MP50, Mindray Model PM-9000, Datex-Ohmeda Model Cardiocap II, Drager Model Infinity Gamma XL.	Philips,Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.	SE Note 1
Sterilization	Non-sterile	Non-sterile	SE
Operation Environment	Temperature: +5°C~+40°C; Atmospheric Pressure: 86 kPa to 106 kPa Relative humidity range:0 % to 80 %, non-condensing (% RH)	Not-provided	SE Note 3
Storage Environment	Temperature: -10°C to +40°C	Not-provided	SE Note 3
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
Performance	ISO 80601-2-56	EN 12470-4	SE Note 4
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-5, ISO 10993-10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	SE

Note 1

The compatible monitors of proposed devices are different from the predicate device. The core component of temperature probe in the subject device 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. The performance bench testing in accordance with ISO 80601-2-56 for all models of the subject device with compatible monitors was conducted and the results met the requirements. Therefore, the intended use of proposed devices is the same as predicate device. This difference does not raise different questions of safety or effectiveness for the subject devices.

Note 2

Although patient contact material are different for proposed device and predicate device, they are both complied with ISO 10993-5 and ISO 10993-10. The differences do not affect the safety and effectiveness.

Note 3

Although some specifications of operating & storage conditions are different for proposed device and predicate device, they are both complied with IEC 60601-1 and ISO 80601-2-56. The differences do not affect the safety and effectiveness.

Note 4

EN 12470-4 as old performance standard was replaced by new performance standard ISO 80601-2-56. Therefore, both of them met the applicable performance requirements. The differences do not affect the safety and effectiveness.

10. Conclusion

Based on the comparison and analysis in this submission, it can be concluded that: Med-link Temperature Probes are substantially equivalent to the predicate devices.