August 25, 2020

Shenzhen Med-link Electronics Tech Co., Ltd.
Fei Liu
Regulatory Affairs Specialist
4th and 5th Floor, Building Two, Hualian Industrial Zone,
Xinshi Community
Shenzhen, 518109
China

Re: K193338
Trade/Device Name: Med-link Reusable Temperature Probes, Med-link Disposable Temperature Probes
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 16, 2020
Received: July 27, 2020

Dear Fei Liu:

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
Acting 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

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: K193338

1. Submitter information

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

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2. Correspondent

Fei Liu (Regulatory Affairs Specialist, Primary Contact)

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3. Data of Preparation

16th, July. 2020

4. Identification of the Device

Trade Name: Med-link Reusable Temperature Probes, Med-link Disposable Temperature Probes

Common Name: Temperature Probe

Classification Regulation: 21 CFR 880.2910

Product Code: FLL

Class: II

Review Panel: General Hospital

5. Identification of the Predicate Devices

Table 1 Predicate Device Information

No.	Device Name	Common Name	Manufacturer	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
2	Disposable Temperature Probe	Temperature Probe	Shenzhen Launch Electrical Co., LTD	Class II, FLL	21 CFR 880.2910	K181967

6. Indications for Use of the Subject Device

Med-link Reusable Temperature Probes:
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 IntelliVueMP50, Mindray Model PM-9000 and Drager Model Infinity Gamma XL.
These devices are used by qualified medical professional only.

Med-link Disposable Temperature Probes:
Med-link Disposable Temperature Probes are intended to be used for monitoring temperature for single patient use. The temperature probes are non-sterile and designed for use with monitors of GE Model B20 and Philips Model IntelliVueMP50.
These devices are used by qualified medical professional only.

7. Device Description

The proposed 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 proposed devices are designed to be used in healthcare facilities like hospital.

No	Model	Description	Measurement range	Accuracy	Compatible monitors
1	W0003D	Pediatric Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	Philips IntelliVue MP50 (K040304)
2	W0001C	Pediatric Reusable Skin-surface Probe	25-45℃	±0.1℃	Mindray PM-9000 (K070791)
3	W0001D	Pediatric Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	
4	W0008C	Pediatric Reusable Skin-surface Probe	25-45℃	±0.1℃	Drager Infinity Gamma XL (K053484)
5	W0008D	Pediatric Reusable Esophageal/Rectal Probe	25-45℃	±0.1℃	
6	W0001E	Adult /Pediatric Disposable Skin-surface Probe	25-45℃	±0.1℃	GE B20 (K122253)
7	W0001F	Adult /Pediatric Disposable Esophageal/Rectal Probe	25-45℃	±0.1℃	
8	W0099F	Adult /Pediatric Disposable Esophageal/Rectal Probe	25-45℃	±0.1℃	
9	W0003E	Adult /Pediatric Disposable Skin-surface Probe	25-45℃	±0.1℃	Philips IntelliVue MP50 (K040304)
10	W0003F	Adult /Pediatric Disposable Esophageal/Rectal Probe	25-45℃	±0.1℃	

8. Comparison to the Predicate Device

Item	Proposed Device	Predicate Device	Predicate Device	Verdict
Trade name	Med-link Reusable Temperature Probes, Med-link Disposable Temperature Probes	Unimed Temperature Probe (Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe)	Disposable Temperature Probe	/
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Unimed Medical supplies Inc.	Shenzhen Launch Electrical Co., LTD	/
510(K) Number	K193338	K121427	K181967	/
Classification Regulation	21CRF 880.2910	21CRF 880.2910	21 CRF 880.2910	Same
Classification and	Class II,	Class II,	Class II,	Same

Item	Proposed Device	Predicate Device	Predicate Device	Verdict
Code	FLL	FLL	FLL	
Common name	Temperature Probe	Temperature Probe	Temperature Probe	Same
Type of Use	Prescription	Prescription	Prescription	Same
Indications for use	Med-link Reusable Temperature Probes: 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 IntelliVueMP50, Mindray Model PM-9000 and Drager Model Infinity Gamma XL. These devices are used by qualified medical professional only. Med-link Disposable Temperature Probes: Med-link Disposable Temperature Probes are intended to be used for monitoring temperature for single patient use. The temperature probes are non-sterile and designed for use with monitors of GE Model B20 and Philips Model IntelliVueMP50. 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.	The Disposable Temperature Probe (body surface type) is to be used with a compatible medical monitor that has temperature measurement function to continuously measure the patient's skin temperature. The Disposable Temperature Probe (celomic type) is to be used with a compatible medical monitor that has temperature measurement function to continuously measure the patient's oral, rectal, nasopharyngeal cavity temperature.	Different Note 1

Item	Proposed Device	Predicate Device	Predicate Device	Verdict
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.	The Disposable Temperature Probe obtains temperature information through the influence degree that the thermal balance has on the resistance value of thermistor sensor after it has contacted human body.	Same Note 2
Measurement Site	Skin, Esophageal and Rectal	Skin, Esophageal and Rectal	Skin (mainly axilla), oral, rectal and nasopharyngeal cavity	Different Note 3
Usage	Reusable, disposable	Reusable	Disposable	Same
Measurement Range	25-45℃	25-45℃	25-45℃	Same
Accuracy	±0.1℃	±0.1℃	±0.1℃	Same
Component	plug, cable and temperature sensing probe	plug, cable and temperature sensing probe	plug, cable and temperature sensing probe	Same
Thermistor resistance	2.25KΩ@25℃	2.252KΩ@25℃	Not-provided	Same as the K121427 predicate device.
Material	Materials of reusable probe: Cable: TPU Probe end：Epoxy，S304 Stainless Steel; Materials of disposable probe: Cable: PVC Probe end: Epoxy, PVC	Not-provided	Foam and PVC	Different Note 4
Compatible	Reusable temperature	Philips,Marquette,	Model C30 (Manufacturer:	Different

Item	Proposed Device	Predicate Device	Predicate Device	Verdict
Monitors	probes are compatible with Philips Model IntelliVue MP50, Mindray Model PM-9000, Drager Model Infinity Gamma XL, and disposable temperature probes are compatible with GE Model B20 and Philips Model IntelliVue MP50.	Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.	COMEN)	Note 1
Operation Environment	Temperature: +5 ℃~+40 ℃; Atmospheric Pressure: 86 kPa to 106 kPa Relative humidity range:0 % to 80 %, non-condensing (% RH)	Not-provided	Temperature: +5 ℃~+40 ℃	Different Note 5
Storage Environment	Temperature: -10 ℃ to +40 ℃	Not-provided	Not-provided	Different Note 5
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
Performance	ISO 80601-2-56	EN 12470-4	ISO 80601-2-56	Different Note 6
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.	Passed the tests as per ISO 10993-5 and ISO 10993-10 (Cytotoxicity, sensitization, irritation)	Same
Sterilization	Non-sterile	Non-sterile	Non-sterile	Same
Operational Type	Continual	Continual	Continual	Same

Note 1

The compatible monitors of proposed devices are different from those of the predicate devices. The core component of temperature probes in the subject devices is Negative Temperature Coefficient (NTC) which is identical to the NTC used in the predicate devices. The performance bench testing in accordance with ISO 80601-2-56 for all models of the subject devices with compatible monitors were conducted and the results met the requirements. The NTC determines the accuracy and range of temperature measurement. The difference does not raise new questions of safety and

effectiveness.

Note 2
Both the subject device and the K181967 predicate device measure differences in resistance and equate that to changes in temperature. Therefore, the operating principles are actually the same.

Note 3
Although nasopharyngeal as a measurement site is excluded in the sites of proposed devices, our disposable temperature probes have been compared with the predicate disposable temperature probes in intended use, working principle, construct, material, safety and performance standard, etc., such a removal of measurement site doesn't affect the substantial equivalence among other items, nor does it affect the equivalent comparison between proposed device and predicate device in measurement sites including skin, esophageal and rectal. The difference does not raise new questions of safety and effectiveness.

Note 4
Although patient-contacting materials are different for proposed devices and predicate devices, all of them are complied with ISO 10993-5 and ISO 10993-10. The differences do not raise new questions of safety and effectiveness.

Note 5
Although some specifications of operating & storage conditions are different for proposed devices and predicate devices, they are all complied with IEC 60601-1 and ISO 80601-2-56. The differences do not raise new questions of safety and effectiveness.

Note 6
EN 12470-4 as old performance standard was replaced by new performance standard ISO 80601-2-56. Therefore, all of them met the applicable performance requirements. The differences do not raise new questions of safety and effectiveness.

9. 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 above were conducted in accordance with
IEC 60601-1 Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance,
Compatibility testing with monitors, 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.

In addition, shelf life testing was conducted to ensure the temperature probes meet the requirements of the expected life of the probe.

10. Clinical performance data

No clinical studies were performed to demonstrate substantial equivalence.

11. 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.