August 25, 2023

Shenzhen SINO-K Medical Technology Co., Ltd.
℅ Kevin Wang
Consultant
Shenzhen Chonconn Medical Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K223807
Trade/Device Name: Reusable Temperature Probe, Disposable Temperature Probe
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 25, 2023
Received: July 26, 2023

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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K223807

Device Name
Reusable Temperature Probe, Disposable Temperature Probe

Indications for Use *(Describe)*
Reusable Temperature Probes:
Reusable Temperature Probes are intended to be used for monitoring temperature for multi- patient use. The temperature probes are reusable and designed for use with monitor of GE-Marquette Model DASH3000.
These devices are used by qualified medical professionals only.

Disposable Temperature Probes:
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- Marquette Model DASH3000.
These devices are used by qualified medical professionals 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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510(K) Summary – K223807

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: August 25, 2023

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Reusable Temperature Probe, Disposable Temperature Probe
Regulatory Class	Class II
Regulation Number	21CFR 880.2910
Regulation/Common Name	Clinical Electronic Thermometer
Product Code	FLL
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer Name	Shenzhen Med-link Electronics Tech Co., Ltd.
510(k) Number	K193338
Trade/Device Name	Med-link Reusable Temperature Probes, Med-link Disposable Temperature Probes
Regulatory Class	Class II
Regulation Number	21CFR 880.2910
Regulation/Common Name	Clinical Electronic Thermometer
Product Code	FLL
Submission type	Traditional 510(K)

5. Device Description

The proposed devices are used for patient temperature measurement. The probes are reusable or disposable depending on the model. 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 increasing with temperature decrease, and the linear changes to the characteristics of the temperature measurement. The proposed devices are designed to be used in a healthcare facility and compatible with a monitor, GE-Marquette Model DASH3000.

The six models have two types of structure designs corresponding to reusable and disposable use which consists of different materials. The Negative Temperature Coefficient (NTC) of the six models are identical. Reusable models ST1304, ST2304, ST3304, ST4304 have a similar structure design with two different sensor shapes for different measure sites and consist of the same materials. Disposable models ST5105A and ST6105A have a similar structure design with two different sensor shapes for different measure sites and consist of the same materials.

No.	Model	Description
1	ST1304	Skin contact Temperature Probe, adult, reusable
2	ST2304	Body cavity Temperature Probe, Esophageal, adult, reusable
3	ST3304	Skin contact Temperature Probe, pediatric, reusable
4	ST4304	Body cavity Temperature Probe, Esophageal, pediatric, reusable
5	ST5105A	Skin contact Temperature Probe, adult, disposable
6	ST6105A	Body cavity Temperature Probe, Esophageal, adult, disposable

6. Indication for use

Reusable Temperature Probes:

Reusable Temperature Probes are intended to be used for monitoring temperature for multi-patient use. The temperature probes are reusable and designed for use with monitor of GE-Marquette Model DASH3000.

These devices are used by qualified medical professionals only.

Disposable Temperature Probes:

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-Marquette Model DASH3000.

These devices are used by qualified medical professionals only.

7. Comparison to the Predicate Device

Item	Subject Device, K223807	Predicate Device, K193338	Comparison
Trade name	Reusable Temperature Probe, Disposable Temperature Probe	Med-link Reusable Temperature Probes, Med-link Disposable Temperature Probes	/
510(k) submitter	Shenzhen SINO-K Medical Technology Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	/
510(k) Number	K223807	K193338	/
Models	Reusable adult/pediatric models: ST1304, ST2304, ST3304, ST4304 Disposable adult/pediatric models: ST5105A, ST6105A	Reusable pediatric models: W0003D,W0001C,W0001D, W00008C,W00008D Disposable adult/pediatric models: W0001E, W0001F, W0099F, W0003E, W0003F	SE Note 1
Type of use	Prescription/Rx	Prescription/Rx	Same
Indication for Use	Reusable Temperature Probes: Reusable Temperature Probes are intended to be used for monitoring temperature for multi-patient use. The temperature probes are reusable and designed for use with monitor of GE-Marquette Model DASH3000. These devices are used by qualified medical	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.	SE Note 1

Item	Subject Device, K223807	Predicate Device, K193338	Comparison
	professional only. Disposable Temperature Probes: 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-Marquette Model DASH3000. These devices are used by qualified medical professional only.	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.	
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.	Same
Measure site	Skin, Esophagus	Skin, Esophageal and Rectal	SE Note 2
Usage	Reusable, Disposable	Reusable, Disposable	Same
Measurement Range	25-45℃	25-45℃	Same
Measurement Time	60s	180s	SE Note 3
Accuracy	±0.1℃	±0.1℃	Same
Components	plug, cable and temperature sensing	plug, cable and temperature sensing	Same

Item	Subject Device, K223807	Predicate Device, K193338	Comparison
	probe	probe	
Thermistor resistance	2.25KΩ@25℃	2.25KΩ@25℃	Same
Device Dimension	Reusable models:3m Disposable models: 0.8m	Unknown	SE Note 4
Material	Materials of reusable probe: Cable: PVC Probe end: Steel, Epoxy, PA66 Materials of disposable probe: Cable: PVC Probe end: Epoxy, Medical pressure-sensitive adhesive	Materials of reusable probe: Cable: TPU Probe end：Epoxy，S304 Stainless Steel; Materials of disposable probe: Cable: PVC Probe end: Epoxy, PVC	SE Note 5
Compatible Monitors	GE-Marquette Model DASH3000	Reusable temperature 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.	SE Note 1
Operating Environment	Temperature: +5 to+40°C Humidity: ≤80%(non-condensing) Atmospheric pressure：86kPa～106kPa	Temperature: +5°C~+40°C; Atmospheric Pressure: 86 kPa to 106 kPa Relative humidity range:0 % to 80 %, non-condensing (% RH)	Same
Storage Environment	Temperature: -10°C to +40°C	Temperature: -10°C to +40°C	Same

Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
Performance	ISO 80601-2-56	ISO 80601-2-56	Same
Biocompatibility	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-1	All the patient-contacting materials are evaluated by the biocompatibility standard ISO10993-5, ISO 10993-10.	Same
Sterilization	Non-sterile	Non-sterile	Same
Operational Type	Continual	Continual	Same
Shelf life	2 years	Unknown	SE Note 6

Note 1

The subject device is compatible with a different monitor than the predicate device. In addition, the intended patient population of both the subject device and the predicate device include adult and pediatric patient populations with the only difference being that the predicate device does not have a model that is intended to reusable for adult patients.

The core component of the temperature probes in the subject devices is Negative Temperature Coefficient (NTC) which is identical to the NTC used in the predicate devices. The NTC determines the accuracy and range of temperature measurement. The subject device performance was tested in accordance with ISO 80601-2-56 for all models, using the compatible monitor. All results met the requirements. Therefore, the differences do not raise new questions of safety and effectiveness.

Note 2

The subject device measurement sites are a subset of the predicate device measurement sites. The subject device performance and biocompatibility was tested in accordance to ISO 80601-2-56 and ISO10993-1, respectively. Therefore, the difference does not raise new questions of safety and effectiveness.

Note 3

The measurement time of the subject device is 60 seconds; however, the measurement time of the predicate device is 180 seconds. The subject device's measurement time is less than that of the predicate and the device performance of all models have been tested to ISO80601-2-56. Therefore, the differences do not raise new or different questions of safety and effectiveness.

Note 4

The device dimensions of the predicate device are unknown. The length of the cable of the subject device will provide flexibility for clinical use. The length of the cables does not affect the performance of the subject devices. The performance of the subject devices has

been verified with ISO 80601-2-56; the difference does not raise new questions of safety and effectiveness.

Note 5

Although patient-contacting materials are different between the subject devices and predicate devices, all of the subject device models were tested in accordance to and complied with ISO 10993-5 and ISO 10993-10. Therefore, the differences do not raise new questions of safety and effectiveness.

Note 6

The shelf life of the subject device is 2 years; however, the shelf life of the predicate device is unknown. The performance of the subject device has been verified for the claimed shelf life. Therefore, the difference does not raise new questions of safety and effectiveness.

8. Non- Clinical Testing

The following testing was conducted to demonstrate substantial equivalence.

Biocompatibility testing

The biocompatibility evaluation for the subject devices were 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 biocompatibility testing included the following tests:

- Cytotoxicity
  - ISO10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization
  - ISO10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Irritation
  - ISO10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Oral mucosa Irritation (Body cavity Temperature Probe only)

Performance Testing

Non-clinical testing has been conducted to verify that the subject devices meet all design specifications which support the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the targeted device complies with the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical

Equipment- Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 80601-2-56:2017+A1:2018 Medical electrical equipment – Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

9. Clinical Testing

No clinical testing was performed as this device does not require clinical studies to demonstrate substantial equivalence with the predicate device.

10. Conclusion

It can be concluded that the differences between the subject devices, Reusable Temperature Probe, Disposable Temperature Probe and predicate devices do not raise new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device, Med-link Reusable Temperature Probes, Med- link Disposable Temperature Probes, cleared under K193338.