July 24, 2020

Shenzhen Changke Connect Electronics Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical Devices Industrial Park
Nanshan District
Shenzhen, Guangdong 518067
China

Re: K193625
Trade/Device Name: Disposable Temperature Probe
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 22, 2020
Received: June 22, 2020

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,

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

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)*
K193625

Device Name
Disposable Temperature Probe

Indications for Use *(Describe)*
The disposable rectal temperature probes are intended to be used for continually monitoring temperature for up to 10 minutes from the rectum of adults, the probes may be used for up to 24 hours.
The temperature probes are non-sterile and designed for single patient use with monitors of EDAN model iM50. These devices are indicated for use by qualified medical personnel in hospital environment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary - K193625

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/07/17

1. Submission sponsor

Name: Shenzhen Changke Connect Electronics Co., Ltd.
Address: A2-4th floor of Xiang dali Technology Park, No.87 of HengPing Road, Henggang, Longgang District, Shenzhen, P.R. China
Contact person: Yahui Zhou
Title: General Manager
E-mail: zhouyahui@szcklt.com
Tel: +86 136 1301 2560

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: No. A415, Block A, NanShan Medical devices Industrial Park Nanshan District, Shenzhen, Guangdong, P.R. China 518067
Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Disposable Temperature Probe
Model	CK-TP-882121-611D
Common Name	Temperature Probe
Regulatory Class	Class II
Classification	21CFR 880.2910 / Thermometer, electronic, clinical / FLL
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Shenzhen Caremed Medical Technology Co., Ltd.
Device: Disposable Temperature Probe
K#: K182755

5. Device Description

Disposable temperature probe is used during patient temperature measurement. The probe consists of a phone plug connector on the adapter cable end and a thermistor on the patient end. The probe measures temperature by a resistor that is sensitive to temperature changes. The probe is connected to the patient monitor by using an interconnect cable.

The probe is used with legacy Edan Instruments, Inc. patient monitors iM50, which was cleared under K113623.

The probe is packed individually into a plastic bag in non-sterile condition. The package label describes product LOT codes, CE-mark, legal entity information and a caution "Rx Only ".

6. Intended use & Indication for use

The disposable rectal temperature probes are intended to be used for continually monitoring temperature for up to 10 minutes from the rectum of adults, the probes may be used for up to 24 hours.

The temperature probes are non-sterile and designed for single patient use with monitors of EDAN model iM50. These devices are indicated for use by qualified medical personnel in hospital environment.

7. Comparison to the Predicate Device

Features	Subject Device Changke Disposable Temperature Probe	Predicate Device Caremed Disposable Temperature Probe K182755	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	Rectum	Skin & Rectum	Same
Population	Adult	Adult	Same

Material contact to body	Rectum Probe: PVC	Skin Probe: PVC, Foam, Epoxy adhesive Rectum Probe: PVC	Same
Length	3.75m	3.75m	Same
Cable material	PVC	PVC	Same
Plug material	PVC	PVC	Same
Operational Principles	Continual	Continual	Same
Connector type	Male, Mono Plug Connector	Male, Mono Plug Connector	Same
Features	Subject Device Changke Disposable Temperature Probe	Predicate Device Caremed Disposable Temperature Probe K182755	Comparison
Time period of use	Rectum Probe: less than 24h	Skin Probe: less than 30 days Rectum Probe: less than 24h	Same
Indication for Use	The disposable rectal temperature probes are intended to be used for continually monitoring temperature for up to 10 minutes from the rectum of adults, the probes may be used for up to 24 hours. The temperature probes are nonsterile and designed for single patient use with monitors of EDAN model iM50. These devices are indicated for use by qualified medical personnel in hospital environment.	**Rectal Temperature Probe:** The Disposable Rectal Temperature Probes are intended to be used for monitoring temperature from the rectum. The temperature probes are non-sterile and designed for single patient use with monitors of Nihon Kohden model BSM-5135A. These devices are indicated for used by qualified medical personnel only. **Skin Temperature Probe:** The Disposable Temperature Probes are intended to be used for monitoring temperature from skin. The temperature probes are nonsterile and designed for single patient use with monitors of Nihon Kohden model BSM-5135A. These devices are indicated for used by qualified medical personnel only.	Different (1)

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

Different (1): The proposed device only includes the rectal probes which is in the scope of the predicate and the IEC80601-2-56 demonstrated compatibility. In addition, the compatible monitors of proposed devices are different from the predicate device. The proposed devices are intended to use with EDAN monitor and the predicate devices are intended to use with Nihon Kohden monitor. 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. Non-Clinical Testing

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the proposed Temperature Probes was 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Rectal Irritation (Rectum probes only)

The following standard and test requirements have been applied to Temperature probes with adaptor cable and compatible patient monitor EDAN Model iM50.

Test	**Description**	**Result**
Safety	Ensures the temperature probes meet the requirements of IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Pass
EMC	Ensures the temperature probes combined with the iM50 monitor meet the requirements of IEC 60601-1-2	Pass
Usability	IEC 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	Pass
Performance	ISO 80601-2-56 Medical Electrical Equipment: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement	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

9. Conclusion

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