December 21, 2018

Shenzhen Caremed Medical Technology 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: K182755
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: December 3, 2018
Received: December 3, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182755

Device Name
Disposable Temperature Probe

Indications for Use *(Describe)*
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 use by qualified medical personnel only.
Skin Temperature Probe:
The Disposable Skin Temperature Probes are intended to be used for monitoring temperature from skin. 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 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.

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.

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"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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2018/09/25

1. Submission sponsor

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3. Subject Device Information

Trade/Device Name	Disposable Temperature Probe
Model	Disposable Temperature Probe: TDAC75-MQ and TDAS75-MQ.
Common Name	Temperature Probe
Regulatory Class	Class II
Classification	21CFR 880.2910 / Thermometer, electronic, clinical / FLL
Submission type	Traditional 510(K)

4. Predicate Device

Draeger Medical GmbH, General Purpose Temperature Probe, Skin Temperature Probe under K121999.

5. Device Description

Disposable temperature probes are used during patient temperature measurement. These probes consist of a plug connector on the adapter cable end and a thermistor on the patient end. Temperature probes measure temperature by a resistor that is sensitive to temperature changes. These probes are connected to the patient monitor by using an interconnect cable. These probes have a skin or rectal contact with adult patients. Both the skin and rectal probe are single use and provided non-sterile.

These temperature probes are typically used with legacy Nihon Kohden monitors BSM-5135A.

Products are packed individually into a plastic bag in non-sterile condition. Package label describes product

LOT codes, CE-mark, legal entity information and a caution "Rx Only ".

6. Indication for use

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 use by qualified medical personnel only.

Skin Temperature Probe:

The Disposable Skin Temperature Probes are intended to be used for monitoring temperature from skin. 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 use by qualified medical personnel only.

7. Comparison to the Predicate Device

Features	Subject Device Caremed Disposable Temperature Probe	Predicate Device Draeger Temperature Probe K121999	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	Skin & Rectum	Skin & Rectum	Same
Population	Adult	Adult	Same
Material contact to body	Skin Probe: PVC, Foam, Epoxy adhesive Rectum Probe: PVC	Skin Probe: Stainless steel, TPE Rectum Probe: TPO, TPE	Different (1)
Length	3.75m	1.6m & 3m	Different (2)
Cable material	PVC	TPE	Different (3)
Plug material	PVC	TPS	Same
Operational Principles	Continual	Continual	Same

Components	Temperature Probe Interconnect Cable	Temperature Probe	Different (4)
Indication for Use	**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 use by qualified medical personnel only. **Skin Temperature Probe:** The Disposable Skin Temperature Probes are intended to be used for monitoring temperature from skin. 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 use by qualified medical personnel only.	**General Purpose Temperature Probes:** Draeger disposable general-purpose temperature probes are intended for patient core body temperature measurement in combination with Draeger and Siemens patient monitoring systems. The probes are inserted into the oesophagus or the rectum. **Skin Temperature Probes**: Draeger disposable skin temperature probes are intended for patient skin temperature measurement in combination with Draeger and Siemens patient monitoring systems. The probes are affixed on the patient's skin with an adhesive cover.	Different (5)

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

Different (1): It's different with the patient contacted material of predicate device. However, it's conformed with ISO 10993 series standard. According to analysis results, all the Patient Contacting Materials shows no cytotoxicity, irritation response was negligible and no sensitization. Thus, different material will not raise any safety or biocompatibility issues.

Different (2): The cable length of proposed device is different with predicate device. All subject devices were conducted performance testing according to ISO 80601-2-56. Thus, different cable length will not raise any safety or performance issues.

Different (3): It's different with the cable material of predicate device. However, it's conformed with ISO 10993 series standard. According to analysis results, all the cable shows no cytotoxicity, irritation response was negligible and no sensitization. Thus, different material will not raise any safety or biocompatibility issues.

Different (4): The subject device contains an interconnect cable which is designed to connect the monitor and the temperature probe. All components were conducted safety, EMC and performance testing. Thus, this different will not raise any question of safety and effectiveness.

Different (5): The compatible monitors of proposed devices are different from the predicate device. The

proposed devices are intended to use with Nihon Kohden monitors and the predicate devices are intended to use with Draeger and Siemens monitors. 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. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the Caremed 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 skin temperature probes are considered surface contacting for a duration of exceed 24 hours but not 30 days.

The rectal temperature probes are considered mucosal contacting for a duration of not exceed 24 hours.

Non-clinical data

The following standard and test requirements have been applied to Caremed Temperature probes with adaptor cable and compatible patient monitor Nihon Kohden Model BSM-5135A.

Test	Description	Result
Safety	Ensures the temperature probes meet the requirements of IEC 60601-1 electrical safety	Pass
EMC	Ensures the temperature probes meet the requirements of IEC 60601-1-2 and ISO 80601-2-56 electromagnetic compatibility	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

The thermometer testing followed ASTM E1112 and ASTM 80601-2-56

9. Conclusion

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