March 1, 2022

Shenzhen Envisen Industry Co., Ltd
% Kevin Wang
Consultant
Shenzhen Chonconn Medical Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K212945
Trade/Device Name: Sterile Disposable Temperature Probe/Model: TGMS-1691 and TSMS-1191
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 26, 2022
Received: January 28, 2022

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,

Gang Peng for
Payal Patel
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)*
K212945

Device Name
Sterile Disposable temperature probe/Model: TGMS-1691 and TSMS-1191

Indications for Use *(Describe)*
The Sterile Disposable Temperature Probe is to be used with Mindray uMEC10 to monitor core temperature or skin temperature. The device is for use by licensed healthcare practitioners only.

The probe is offered in the following two configurations:
- Body cavity Temperature Probe TGMS-1691 for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal or rectal cavities.
- Skin contact Temperature Probe TSMS-1191 for monitoring of skin temperature by application of the probe's adhesive cover to an adult and pediatric patient's skin surface.

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.

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510(K) Summary for K212945

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/2/25

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
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Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Sterile Disposable Temperature Probe
Model	TGMS-1691 and TSMS-1191
Common Name	Temperature Probe
Regulatory Class	Class II
Regulation Number	21CFR 880.2910
Regulation Name	Clinical Electronic Thermometer
Product Code	FLL

4. Predicate Device

1. DeRoyal Industries, Inc., DeRoyal Temperature Monitoring Probe under K200631.

5. Device Description

Sterile Disposable Temperature Probes are used during patient temperature measurement. These probes consist of a phone 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 which is also included in the submission as an accessory. These probes

have a skin or core contact with a patient.
These temperature probes are typically used with Mindray uMEC10, which was cleared under K171901.
Products are packed individually into a paper pouch in sterile condition.

6. Indications for use

The Sterile Disposable Temperature Probe is to be used with Mindray uMEC10 to monitor core temperature or skin temperature. The device is for use by licensed healthcare practitioners only.

The probe is offered in the following two configurations:

- Body cavity Temperature Probe TGMS-1691 for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal or rectal cavities.

- Skin contact Temperature Probe TSMS-1191 for monitoring of skin temperature by application of the probe's adhesive cover to an adult and pediatric patient's skin surface.

7. Comparison to the Predicate Device

Features	Configuration	Subject Device Sterile Disposable Temperature Probe K212945	Predicate Device DeRoyal Temperature Monitoring Probe K200631	Comparison
Classification Name	Body cavity Skin contact	Temperature Probe	Temperature Probe	Same
Product Code	Body cavity Skin contact	FLL	FLL	Same
Regulation Number	Body cavity Skin contact	880.2910	880.2910	Same
Panel	Body cavity Skin contact	General Hospital	General Hospital	Same
Class	Body cavity Skin contact	II	II	Same
Indications for Use	Body cavity Skin contact	The Sterile Disposable Temperature Probe is to be used with Mindray uMEC10 to	The DeRoyal Temperature Monitoring Probe is used for routine monitoring of the patient's core body or skin surface	Different 1

		monitor core temperature or skin temperature. The device is for use by licensed healthcare practitioners only. The probe is offered in the following two configurations: - Body cavity Temperature Probe TGMS-1691 for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal or rectal cavities. - Skin contact Temperature Probe TSMS-1191 for monitoring of skin temperature by application of the probe's adhesive cover to an adult and pediatric patient's skin surface.	temperature. The probe is offered in the following three configurations: - General Purpose Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion into the nasopharyngeal, esophageal, or rectal cavities. - Adult Skin Temperature Sensor for routine monitoring of skin temperature by application of the probe's adhesive cover to an adult patient's skin surface. - Tympanic Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion of the ear piece into the aural canal. The device is single use and for use by licensed	

			healthcare practitioners only. The probes are designed to interface with DeRoyal- branded cables for connection with YSI 400 or 700 series compatible monitors, including the following patient monitors and equivalent models: Mindray Passport, Philips IntelliVue, Siemens/Draeger Infinity, and GE Datex-Ohmeda brands.	
Application Population	Body cavity	adult and pediatric	adult and pediatric	Same
	Skin contact		adult	Different 2
Prescription Only	Body cavity Skin contact	Yes	Yes	Same
Mode of operation	Body cavity Skin contact	Direct mode	Direct mode	Same
Measure site	Body cavity	Rectum, Esophagus	Rectum, Esophagus, Nasopharynx	Different 3
	Skin contact	Skin Surface	Skin Surface	Same
Sensor	Body cavity Skin contact	Thermistor which is sensitive to temperature change.	Thermistor which is sensitive to temperature change.	Same
Reference Body Site	Body cavity	Core Body	Core Body	Same
	Skin contact	Skin Surface	Skin Surface	Same
Principle of operation	Body cavity Skin contact	Thermistor resistance based	Thermistor resistance based	Same

		on the metal conductor increase with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	on the metal conductor increase with temperature decrease, and the linear changes to the characteristics of the temperature measurement.	
Rated Output Range	Body cavity Skin contact	0-50℃ (32°F- 122°F)	25-45℃	Different 4
Accuracy	Body cavity Skin contact	±0.1°C/0.2°F in the range 25°C/77°F to 45°C/113°F ±0.2°C/0.4°F in the range 0°C/32°F to 24.9°C/76.8°F and 45.1°C/113.2°F to 50°C/122°F	±0.2°C	
Operating Conditions	Body cavity Skin contact	5°C to 40°C(41°F to 104°F) 20% to 85%RH,	25°C to 45°C \	Different 5
storage conditions	Body cavity Skin contact	-20 to 55°C (-4°F to 131°F), 10% to 93%RH,	-25°C to +55°C \	Different 6
diameter	Body cavity	3mm	3mm,4mm	Same
Length	Body cavity	0.75m	\	Different 7
	Skin contact	0.95m	\	
Design	Body cavity	Wire set with a phone plug connector on the adapter cable end and a thermistor on	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. The wire set is	Same

		the patient end. The wire set is enclosed in a tube that may be inserted into the application site.	enclosed in a tube that may be inserted into the application site.	
	Skin contact	Wire set with a phone plug connector on the adapter cable end and a thermistor on the patient end. An adhesive probe cover applies the device to the patients' skin.	Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. An adhesive probe cover applies the device to the patients' skin.	Same
Materials	Body cavity	PVC Connector and Tube Cable (PVDF Material)	Tube: PVC Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC molded brass Strain Relief: PVC Cap: UV-cured adhesive	Different 8
	Skin contact	Cover: Release liner:(PET) and Foam(aluminum foil/PET) with 3M glue Wire: Copper with PVDF insulation Thermistor: Ceramic Connector: PVC molded brass Strain Relief:	Cover: Adhesive foam Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC molded brass Strain Relief: PVC Cap: UV-cured adhesive	

		PVC Cap: stainless steel and epoxy glue		
Biocompatibility	Body cavity	Cytotoxicity complied with ISO 10993-5 Sensitization complied with ISO 10993-10 Irritation complied with ISO 10993-10	Cytotoxicity complied with ISO 10993-5 Sensitization complied with ISO 10993-10 Irritation complied with ISO 10993-10	Same
	Skin contact			Same
Sterilization	Body cavity	Sterilized with Ethylene Oxide	Sterilized with Ethylene Oxide	Same
	Skin contact	Sterilized with Ethylene Oxide	Sterilized with Ethylene Oxide	Same
Disposable	Body cavity Skin contact	Yes	Yes	Same

Different 1:

The subject device has the same Intended use as the predicate device. However, there is some differences in the indications for use.

Predicate K200631 General purpose probe has one more application site nasopharyngeal compared with the subject body cavity probe. The esophageal and rectal cavities measurement sites of the subject body cavity temperature probe and predicate device general purpose temperature probe are the same. The measurement site of the subject body cavity temperature probe is a subset of the predicate device. The difference does not raise any new safety and effective questions.

Predicate K200631 skin probe is only appliable to adult while the subject skin probe is applicable to adult and pediatric. However, the skin contact probe design meets design requirements and is complied with ISO 80601-2-56 standard. The difference does not raise any new safety and effective questions.

The compatible monitors of proposed devices are different from the predicate device. The validate testing was conducted in accordance with the ISO 80601-2-56 standard. The difference does not raise any new safety and effective questions.

Different 2

Predicate K200631 skin probe is only appliable to adult while the subject skin probe is applicable to adult and pediatric. However, the skin contact probe design meets design

requirements and is complied with ISO 80601-2-56 standard. The difference does not raise any new safety and effective questions.

Different 3

K200631 General purpose probe has one more application site nasopharyngeal compared with the subject body cavity probe. The application site of the subject device is the subset of the predicate device and complies with ISO 80601-2-56 standard, the difference does not raise any new safety and effective questions.

Different 4

Although the measurement range and accuracy of the subject devices are different form the predicate device, the design meets the design requirement. The subject devices are complied with ISO 80601-2-56 standard. Therefore, the difference does not raise any new safety and effective questions.

Different 5

The operating conditions of the subject devices are different from the predicate device. According to ISO 80601-2-56, a clinical thermometer shall operate in normal use over the ranges of an ambient temperature operating range from 15℃ to 40℃. The ambient temperature of the subject device covers this range, it has also been tested according to ISO 80601-2-56, which has proved that the subject device functions well under specified ambient temperature environment.

Different 6

The storage temperature is the same while the humidity range information of the predicate is not available. However, the validation test was conducted according to ISO 80601-2-56 standard, which has proved that the subject device functions well under specified humidity environment.

Different 7

The information of the predicate is not available. However, the validation test was conducted according to ISO 80601-2-56 standard and the difference does not raise any new safety and effective questions.

Different 8

There are some differences in the materials used in the subject devices and the predicate devices. A biocompatibility testing was performed on the subject products. Electrical Safety and EMC testing also were performed on the subject devices. The results of the testing demonstrate the subject devices comply with ISO 10993-5 and ISO 10993-10 standard and the difference does not raise any new safety and effective questions.

8. Performance Data

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 (Body cavity Temperature Probe only)
- Oral mucosa Irritation (Body cavity Temperature Probe only)

The Sterile Disposable temperature probe is considered surface/mucosal contacting for a duration of not exceed 24 hours.

Non-clinical data

Non-clinical testing has been conducted to verify that the Sterile Disposable Temperature Probe meets 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.
- Stability and performance test of the skin temperature probe for 24hrs continues use.

9. Conclusion

Based on the performance testing, comparison and analysis, the proposed subject devices are substantially equivalent to the predicate device.