DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 4, 2017

Rudolf Riester GmbH
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
7th Floor, Jingui Business Building
No.982 Congyun Rd, Baiyun District
Guangzhou, 510420
CHINA

Re: K171182
Trade/Device Name: ri-former Predictive Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 25, 2017
Received: August 28, 2017

Dear Mike Gu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171182

Device Name
ri-former® Predictive Thermometer

Indications for Use *(Describe)*

The device is used for measuring body temperature in the mouth (oral) in the anus (rectal) and in the armpit (axillary). It is intended for adults, children and infants.

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

K171182

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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Date Prepared:	Apr 21, 2017

II. DEVICE

Name of Device:	ri-former® Predictive Thermometer
Common/Usual Name:	Clinical electronic thermometer
Classification Names:	Clinical electronic thermometer (21 CFR 880.2910)
Regulation Class:	II
Product Code:	FLL

III. PREDICATE DEVICE

FILAC FAS TEMP ELECTRONIC THERMOMETER, K003313

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ri-former® Predictive Thermometer is a fast, highly accurate, and easy to use clinical instrument for measuring patient temperatures by oral, axillary or rectal means. The thermometer is driven by the power supply of our ri-former® diagnostic station.

There are rectal (red) and oral, axillary (blue) probes available.

To prevent from cross contamination the thermometer needs to be used with disposable probe covers. The thermometer can be used for the temperature measurement of all patients and is designed for the use in hospitals, clinics, medical practices or similar facilities.

V. INDICATION FOR USE

The device is used for measuring body temperature in the mouth (oral) in the anus (rectal) and in the armpit (axillary). It is intended for adults, children and infants.

VI. SUBSTANTIAL EQUIVELENCE

Specification	Predicate Device	Proposed Device	Discussion of Differences
Device name	FILAC FAS TEMP ELECTRONIC THERMOMETER	ri-former PREDICTIVE THERMOMETER	
K number	K003313	——	
Classification	Class Ⅱ	Class Ⅱ	Identical
Product code	FLL	FLL	Identical
Intended use	The device is used as a predictive measurement of temperature by Oral, Axillary, or Rectal means. It is intended for use on people of all ages.	The device is used for measuring body temperature in the mouth (oral) in the anus (rectal) and in the armpit (axillary). It is intended for adults, children and infants.	Identical
Mechanism of action	The electronic thermometer is detected by thermistor and calculated to provide fast and accurate temperature measurements.		Identical

Specification	Predicate Device	Proposed Device	Discussion of Differences
Power source	Battery	ri-former diagnostic station is designed as a base unit for the power supply.	Different, the proposed product was demonstrated electromagnetic compatibility and electrical safety by the testing. The difference does not raise the issues of product's safety and effectiveness.
Components	Probe	Probe	Identical
	Plastic enclose	Plastic enclose	Identical
	LCD	LCD	Identical
	Button	Button	Identical
	battery	AC power	Different, the proposed device is validated to be electrical safety, refer to the test report of IEC 60601-1 and IEC 60601-1-2.
	Probe cover	Probe cover	Identical
	Probe cable	Probe cable	Identical
	Circuit Board	Circuit Board	Identical
	No mounting	Wall mounting plates	Similar. The predicate is a handle device. The proposed device is designed to be mounted on the wall, so the mounting plates are required.

Specification	Predicate Device	Proposed Device	Discussion of Differences
Materials	Enclose cover: Flame retardant polycarbonate-polyester blend	Enclose cover: Acrylonitrile butadiene styrene copolymers (ABS D-1000)	The material of the enclose cover is different. The ABS material is widely used in medical devices
	Probe Handle: Flame retardant polycarbonate-polyester blend	Probe Handle: Flame retardant polycarbonate-polyester blend	Identical
	Probe Shaft: Flame retardant polyester	Probe Shaft: Flame retardant polyester	Identical
	Probe Cable: Polyurethane jacket with TPE over mold	Probe Cable: Polyurethane jacket with TPE over mold	Identical
	Tip: Aluminum	Tip: Aluminum	Identical
	Probe cover: High density polyethylene (HDPE)	Probe cover: High density polyethylene (HDPE)	Identical
	The device is constructed with non-latex materials	The device is constructed with non-latex materials	Identical
Sensor	Thermistor		Identical
Anatomic site	Oral, axillary, rectal		Identical
Environment of Use	Hospital, clinics, medical practices or similar facilities. No use in MR environment.		Identical
Temperature range	30 °C to 43 °C (86 °F to 109 °F)		Identical

Specification	Predicate Device	Proposed Device	Discussion of Differences
Ambient temperature environment	10 °C to 40 °C (50 °F to 104 °F)		Identical
Accuracy	Water Bath Accuracy (35.5 °C to 42.0 °C): Direct Mode (All Sites): ± 0.1 °C (±0.2 °F) Standard Prediction Mode (All Sites)**: ±0.1 °C (±0.2°F) Quick Prediction Mode (Oral Only)**: ±0.3 °C (±0.5°F) Patient Accuracy: In standard predict mode, thermometer accuracy meets EN 12470-3 A Standard Prediction Mode reading and a Direct Mode reading will differ by less than ±0.2°C (±0.4 °F) on 98% of tested patients		Identical
Precision and repeatability	A Standard Prediction Mode reading and a Direct Mode reading will differ by less than ± 0.2 °C (± 0.4 °F) on 98% of tested patients		Identical
Response time	Oral (Quick Mode): 3-5 seconds (non-fever temps), 8-10 seconds (fever temps) Oral (Standard Mode): 6-10 seconds Axillary Mode: 8-12 seconds Rectal Mode: 10-14 seconds Direct Mode (All Sites): 60-120 seconds		Identical
Probe	The probe used in proposed device is the identical one of the predicate device.		Identical

Specification	Predicate Device	Proposed Device	Discussion of Differences
Patient contact materials	Probe cover: High density polyethylene (HDPE) The probe cover used in proposed device is the identical one of the predicate device.		Identical
User function	Direct Mode	Direct Mode	Identical
	Quick Mode	Quick Mode	Identical
	Cold Mode	Cold Mode	Identical

VII. NON-CLINICAL PERFORMANCE DATA

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

Biocompatibility:

The human contacting components, the probe and probe cover,

were tested in accordance with:

-ISO 10993-5:2009 biological evaluation of medical devices – Part

5: Tests for in vitro cytotoxicity

-ISO 10993-10:2013 biological evaluation of medical devices – Part

10: Tests for irritation and skin sensitization

Electrical Safety and EMC:

The device was tested accordance with:

- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

- IEC 60601-1-2:2007(Third edition), Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements and Tests

Performance Testing:

- ISO 80601-2-56 First Edition 2009-10-01 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

-ASTM E1112-00 (Reapproved 2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Riester has provided appropriate software documentation based on moderate Level of Concern. A system level software verification and validation protocol was developed to

test each requirement. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

VIII. CLINICAL TESTING DATA

No clinical testing data is included in this submission.

IX. CONCLUSION

ri-former® Predictive Thermometer and its application comply with the thermometer performance standards. Non-clinical tests determined that the ri-former® Predictive Thermometer performance is substantially equivalent to the predicate device.