February 10, 2023

Zhejiang Rongsheng Industrial Co., Ltd.
Wu Bentuan
Chief Engineer
2 Jinheng Road
Xiaoshun Town, Jinhua, Zhejiang 321035
China

Re: K220657
Trade/Device Name: Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 5, 2023
Received: January 12, 2023

Dear Wu Bentuan:

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,

David Wolloscheck, Ph.D.
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)*
K220657

Device Name
Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001)

Indications for Use *(Describe)*
The Medical Infrared Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in no touch mode on the center of the forehead as the measurement site on people of one month and above.

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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K220657

510(k) Summary

SUBMITTER

Name: Zhejiang Rongsheng Industrial Co., Ltd.

Address: NO. 2 Jinheng Road, Xiaoshun Town, Jindong District Jinhua City Zhejiang, CN 321035

Name of contact person: Wu Bentuan

Telephone: +86-579-82953477

Preparation date: 2/1/2023

Device

Device trade name: Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001)

Classification name: Clinical Electronic Thermometer

Regulation class: II

Regulation number: 21CFR 880.2910

Panel: General Hospital

Product code: FLL

Predicative device

Predicate Submission Number: K163516

Predicate Device Trade Name: Braun No Touch + Forehead NTF3000 Thermometer

Classification name: Clinical Electronic Thermometer

Regulation class: II

Regulation number: 21CFR 880.2910

Panel: General Hospital

Product code: FLL

Device description

The Medical Infrared Thermometer is a non-contact, hand-held, battery powered device designed to measure human body temperature, which has the feature of simple and easy use, rapid measurement and accurate temperature feedback. The Medical Infrared Thermometer is an infrared thermometer to measure human body temperature using the infrared energy emitted in the area around the subject's forehead. The reference body site of the temperature measurement is axillary. The temperature

measurement distance is 1-5 cm.

The product is composed of enclosure, control panel, LCD screen, infrared sensor, PCB board, battery pack and USB charging inlet.

The thermometer has three functions of digital LCD display, buzzer indication for measurement results and three color back light indication for temperature (32.0°C to 37.3°C with green back light; 37.4°C to 38.0°C with yellow back light; 38.1°C to 43.0°C with red back light).

The device is powered by Li-ion Battery (3.7VDC; 30mAh), which can be recharged through a computer with USB port or by switching power supply (100-240V, 50/60Hz) connected with a USB charging cable. The switching power supply is not provided with the subject device and the USB charging cable will be provided with the subject device as an accessory.

There are two models RST-TC59-1001 and RST-TC60-1001 included in this document. Both models share the same construction except differences on product structure including appearance of enclosure, PCB design, sensor, MCU and working condition (ambient temperature). There are three buttons on control panel of both models, the first button is for power on/off and temperature measurement function, the second button is for temperature unit shift (℃ and ℉) function, the third button is for memory function.

Indication for use

The Medical Infrared Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in no touch mode on the center of the forehead as the measurement site on people of one month and above.

Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicative device	Verdict
Device trade name	Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001)	Braun No Touch + Forehead NTF3000 Thermometer	/
Product model	RST-TC59-1001, RST-TC60-1001	NTF3000	/
510(k) number	K220657	K163516	/
Device classification name	Class II	Class II	Same
Classification	880.2910	880.2910	Same

Attribute	Subject device	Predicative device	Verdict
regulations			
Product code	FLL	FLL	Same
thermometer type	skin IR thermometers	skin IR thermometers	Same
Intended use(s)/ Indication for use	The Medical Infrared Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in no touch mode on the center of the forehead as the measurement site on people of one month and above.	The Braun No Touch + Forehead NTF3000 Thermometer is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode on the center of the forehead as the measurement site on people of all ages.	Similar
Operational principle	The optical system gathers the infrared radiation energy of the target in its field of view, size of which depends on the optical parts and their positions. The gathered infrared energy is focused on the photoelectricity detector and converted to be the electrical signal accordingly. After passing through the amplifier and signal processing circuit, the electrical signal will be converted to be the temperature of the measured target according to the algorithm internally contained in the device and target emissivity correction.	The thermometer uses a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead, and an infrared proximity sensor for detection of contact or non-contact use and compensation of the temperature reading.	Same
Sensor type	thermopile	thermopile	Same
signal processing and display	MCU and LCD	MCU and LCD	Same
Low power indication	yes	yes	Same
Measurement site	forehead	forehead	Same
Operation mode	Adjusted mode	Adjusted mode	Same
ºC/ºF switchable	yes	yes	Same
Temperature measurement range	32 ºC~43 ºC (89.6 ºF~109.4	34.4°C (93.9°F) – 42.2°C (108°F)	Similar

Attribute	Subject device	Predicative device	Verdict
	ºF)		
Measuring accuracy	35.0 ºC~42.0 ºC (95.0 ºF ~107.6 ºF): ±0.2 ºC(±0.4 ºF); 32.0 ºC ~ 34.9 ºC (89.6 ºF ~94.8 ºF): ±0.3 ºC (±0.5ºF); 42.1 ºC~43.0 ºC (107.8 ºF ~109.4 ºF): ±0.3 ºC (±0.5 ºF)	35-42 ºC (95-107.6 ºF):± 0.2 ºC (± 0.4 ºF); Outside the range 35-42 ºC (95-107.6 ºF): ± 0.3 ºC (± 0.5 ºF)	Same
Measurement precision	0.1°C (0.1°F)	0.1°C (0.1°F)	Same
Electric Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62133-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Different
Biocompatibility	Meets ISO 10993 and FDA guidance "Use of International Standard ISO 10993-1" ISO 10993-5 ISO 10993-10	Meets ISO 10993 and FDA Bluebook memo G95-1 ISO 10993-5 ISO 10993-10	Same
Performance	ASTM E1965-98 ISO 80601-2-56	ASTM E1965-98 ISO 80601-2-56	Same
Power requirements	rechargeable li-ion battery pack; 3.7 V; 300 mAh; recharged through USB port by external power source, e.g. compatible charger or computer with USB port etc.	2 AA batteries	Different
Patient contact materials	RST-TC59-1001: ABS with colorants (white and green) for device housing including handle, PMMA for buttons RST-TC60-1001: ABS with colorants (white and blue) for device housing including handle, PMMA for Transparent LCD cover, silicone rubber for buttons	Patient contacting materials include ABS (device housing / handle and power button) and TPR (temperature button and nose / forehead touch bumper).	Similar
Memory	20 sets	Not available	Different

Attribute	Subject device	Predicative device	Verdict
Ambient temperature environment - Operating condition	RST-TC59-1001: 15ºC ~ 40ºC (59 ºF~104 ºF); Relative humidity: ≤85%; non-condensing RST-TC60-1001: 0ºC ~ +40ºC (32ºF~104ºF); Relative humidity: ≤85%; non-condensing	15 °C – 40 °C (59 °F –104 °F), 15–95% non-condensing	Similar
Ambient temperature environment - Storage condition	RST-TC59-1001: temperature: -25ºC ~ +50ºC (-13 ºF~+122 ºF); Relative humidity: ≤90% non-condensing; Atmospheric pressure: 70kPa~106 kPa RST-TC60-1001: -25ºC ~ +70ºC (-13ºF~+158ºF); Relative humidity: ≤90% non-condensing; Atmospheric pressure: 70kPa~106 kPa	temperature: –25°C to 60°C (–13°F to 140°F) Humidity: 15–95% non-condensing Pressure: 700-1060hPA	Similar
Measurement distance	1cm ~ 5cm	0-5cm	Similar
Response time	1 second	2 seconds	Different

Discussion for similarities and differences:

1. Intended use(s)/Indication for use: indication for use of the subject device has the similar meaning with different words as the predicate device. In addition, the subject device has more restricted people age range than the predicate device. Such difference will not affect the safety and effectiveness of the subject devices.
2. Temperature measurement range: the subject devices measurement range from 32 ºC~43 ºC (89.6 ºF~109.4 ºF), which is different from the predicate device's measurement range, 34.4°C (93.9°F) – 42.2°C (108°F). While the subject devices have been tested and validated according to standard ISO 80601-2-56 including clinical accuracy and the measuring range of the subject devices meet the minimum rated output range of clinical thermometer requirement, from 35°C to 42°C, therefore, such difference will not affect the safety and effectiveness of the subject devices.

3. Electric safety and EMC: the batteries used in the subject device are rechargeable batteries, different from the predicate device, and tested according to IEC 62133-2. Such difference between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.
4. Power requirements: the subject devices are powered with rechargeable li-ion battery pack and different from the predicate device, which is powered with 2 AA batteries. The rechargeable battery pack has been tested according to IEC 62133-2: 2017, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.
5. Patient contact materials: there are some material differences between the subject devices and the predicate device, but biocompatibility of both the subject devices and the predicate device has been evaluated and tested according to ISO 10993 series and FDA guidance. The patient contact materials have passed the biocompatibility testing in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010. Such difference between the predicate device and subject device will not affect the safety and effectiveness of the subject device.
6. Memory function: The subject devices have the memory function to store 20 sets history measurement records while the predicate device has not such memory function. The validation test of the software used in the subject device was conducted in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The difference will not raise safety or effectiveness issues on the subject device.
7. Ambient temperature environment operating condition: there are differences between ambient temperature of the subject devices and the predicate device, but performance and safety tests of the subjective device have been conducted and passed under the specific operating condition according to standards IEC 60601-1, ISO 80601-2-56 and ASTM E1965-98, and the user manuals of the subjective devices provide the operating and storage condition as well. Therefore, such difference will not affect the safety and effectiveness of the subject devices.
8. Ambient temperature environment - Storage condition: Performance and safety tests of the subjective device have been passed under the specific storage condition, and the user manual of the subjective device provides the storage condition as well, therefore, the difference of the storage conditions between subject device and predicate device will not affect the safety and effectiveness of subject device.

9. Measurement distance: there is slight difference between the subject devices and the predicate device on measurement distance and the subject devices have more restricted measurement range (1cm-5cm) than the predicate device (0cm-1cm). The performance tests of the subject device are conducted in accordance with standard ISO 80601-2-56 and ASTM E1965-98, and the test results showed that the measurement accuracy of the subject device is in conformity with the standard requirement. In addition, clinical accuracy testing of the subject devices was validated according to standard ISO 80601-2-56, therefore, such difference will not affect the safety and effectiveness of the subject devices.
10. Response time: there is slight difference between the subject devices and the predicate device on response time and the subject devices are faster in response than the predicate device. The performance tests of the subject device are conducted in accordance with standard ISO 80601-2-56 and such difference will not affect the safety and effectiveness of the subject devices.

Summary of non-clinical testing (Performance testing-bench)

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971:2019.
- Software Evaluation according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The software validation and verification tests are conducted at unit level, integration level and system level. The software and hardware system is verified that no defects are found.
- IEC 60601-1: 2005+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 disturbances – Requirements and tests
- IEC 60601-1-11: 2015 Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 80601-2-56: 2017+A1: 2018 medical electrical equipment part 2-56: particular

requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

- ASTM E1965-98(2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- IEC 62133-2: 2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

  Biocompatibility Tests are carried out in accordance with ISO 10993-1: 2018, summary level biocompatibility information sees below table:

Name of test	Endpoint	Result
In vitro cytotoxicity test	Quantitative evaluation according to ISO 10993-5: there shall be no reduction of cell viability by more than 30 %, which is considered a cytotoxic effect.	Pass
Skin sensitization test	According to ISO 10993-10: Magnusson and Kligman grades shall not be of 1 or greater in the test group, provided grades of less than 1 are seen in control animals.	Pass
Skin irritation test	According to ISO 10993-10: the primary irritation index (PII) determined on the test group shall be 0-0.4	Pass

Summary of clinical Accuracy Validation Test

Clinical accuracy validation for the Medical Infrared Thermometer is designed and performed according to standard ISO 80601-2-56: 2017+A1: 2018 and ISO 14155: 2011 under clinical setting.

Both models RST-TC59-1001 and RST-TC60-1001 are selected to implement clinical accuracy validation respectively. A blackbody radiator and a Platinum resistance thermometer are selected to validate the laboratory accuracy of the infrared thermometer under testing before and after the clinical trial. And total of 165 subjects are selected to be subjected to temperature measurement with the infrared thermometer under testing (DUT) and the reference clinical thermometer (RCT) respectively. RCT used

in this clinical trial is mercury axillary thermometer (Geratherm classic, Getatherm Medical AG). The whole trial procedure and the clinical accuracy validation is in accordance with ISO 80601-2-56: 2017+A1: 2018.

The clinical tests were evaluated on 165 subjects and the thermometer was evaluated in three age groups including subgroup A1 and A2: A1 – one month up to three months; A2 - three months to one year; B - older than one years and younger than five years; and C - older than five years old.

Subjects selected for each model in this clinical trial are: A1) group 26 A2) group 29 b) group: 55 c) group: 55. Total number of subjects is 165.

The clinical performance test protocol and data analysis were conducted in accordance with the requirement of ISO 80601-2-56: 2017+A1: 2018. The test report showed the clinical performance of the subject devices complied with the requirement of ISO 80601-2-56: 2017+A1: 2018.

Conclusions

Based on comparison of the intended use, technological characteristics, applicable safety standards, verification and validation testing, the differences between Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001) and the predicate device do not raise new issues of safety and effectiveness. it can be concluded that Medical Infrared Thermometer (Model: RST-TC59-1001, RST-TC60-1001) is substantially equivalent to the legally marketed predicate device.