July 21, 2023

Shen Zhen Rong Feng Technology Co., Ltd
Iris Fung
Regulation Manager
3/F R Building ShaSi Industrial Park, Shajing Town
BaoAn district
Shenzhen, Guangdong
China

Re: K223037
Trade/Device Name: Infrared Thermometer, Model: IR8807
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 18, 2023
Received: June 20, 2023

Dear Iris Fung:

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,

Porsche Bennett

Porsche Bennett
For David Wolloscheck, Ph.D.
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)*
K223037

Device Name
Infrared Thermometer, Model: IR8807

Indications for Use *(Describe)*
The Infrared Thermometer (Model: IR8807) is intended for the intermittent measurement of human body temperature from the forehead. It is a non-contact clinical thermometer and intended for use on people of all ages except for neonates/newborns.

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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510(k) Summary-K223037

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Sponsor Company Name: SHEN ZHEN RONG FENG TECHNOLOGY CO., LTD

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- Contact Person (including title): Hong Xiao Lan (Engineer)
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Application Correspondent: SHEN ZHEN RONG FENG TECHNOLOGY CO., LTD

Address: 3/F R building ShaSi Industrial Park, Shajing Town, BaoAn district, ShenZhen city, GuangDong Province, China

- **Contact Person:** Iris Fung
- **Tile:** Regulation Manager
- **Tel: +86-13211147965**
- **Email:** mdc-fs@foxmail.com； med-jl@foxmail.com
- **Summary Prepared Date**
  July 21, 2023

2. Subject Device Information:

- Type of 510(k) submission: Traditional
- Common Name: Infrared Thermometer
- Trade Name: Infrared Thermometer, Model: IR8807
- Classification Name: Clinical Electronic Thermometer
- Review Panel: General Hospital
- Product Code: FLL
- Regulation Number: 21 CFR 880.2910
- Regulation Class: 2

3. Predicate Device Information:

- 510(k) number: K173048
- Sponsor: Dongguan SIMZO Electronic Technology Co., Ltd.

- Trade Name: Non-contact Forehead Thermometer, Model: HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303
- Common Name: Infrared Thermometer
- Review Panel: General Hospital
- Product Code: FLL
- Regulation Number: 21 CFR 880.2910
- Regulation Class: 2

4. Device Description

The Infrared Thermometer (Model: IR8807) is an electronic thermometer using an infrared sensor to measure infrared energy radiated from the forehead. This energy is collected through the lens and converted to a temperature value. The Infrared Thermometer (Model: IR8807) has a forehead measurement mode and an object measurement mode.

The Infrared Thermometer (Model: IR8807), consists of the following parts:

a) Thermopile Sensor
b) Application-Specific Integrated Circuitry
c) Erasable Programmable Read-Only Memory Integrated Circuit
d) Capacitance-touch Integrated Circuit
e) LCD display
f) 2 buttons (Scan button, Setting button,)
g) 2×1.5V AAA dry batteries

The operation principle is based on infrared sensor technology. The sensor in the thermometer detects the infrared energy, and the device processes the data to body temperature result with its internal microcontroller unit. It operates in an adjusted mode.

The main functions of Infrared Thermometer (Model: IR8807) are as followings:

- Forehead temperature measure functions
- Wide range of temperature readings: from 32.0℃to 42.9℃ (89.6°F ~ 109.2°F)
- The measurement results can be displayed in either ℃or °F units
- The LCD display showing clear measurement result.
- Memory data reading/removal function: The device can store a total of 32 groups of memorable values. All memory values can be removed after the battery is removed
- Low battery indicator
- Buzzer reminder function
- Users can set temperature alarm value
- Environment or object temperature measurement function

The reference body site of the output temperature is Oral.

5. Indications for use

The Infrared Thermometer (Model: IR8807) is intended for the intermittent measurement of human body temperature from the forehead. It is a non-contact clinical thermometer and intended for use on people of all ages except for neonates/newborns.

6. Comparison to Predicate Device

Elements of Comparison	Subject Device	Predicate Device	Comparison
Manufacturer	SHEN ZHEN RONG FENG TECHNOLOGY CO.,LTD.	Dongguan SIMZO Electronic Technology Co.Ltd.	–
510 (k) Number	K223037	K173048	–
Product Name	Infrared Thermometer	Non-contact Forehead Thermometer	–
Models	Model: IR8807	HW-2/HW-2S/HW-3/HW-4 /HW- 4S/HW-302/HW-303	–
Intended Use	The Infrared Thermometer (Model: IR8807) is intended for the intermittent measurement of human body temperature from the forehead. It is a non-contact clinical thermometer and intended for use on people of all ages except for neonates/newborns.	The Non-contact Forehead Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	Note 1
Sensor	Infrared Sensor	Infrared Sensor	Same
Measurement Mode	Forehead measurement Mode	Forehead measurement Mode	Same
Measurement contact type	Non-contact type	Non-contact type	Same
Measurement type	Adjusted	Adjusted	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Measurement time	≤3S	1S	Note 2
Measurement Distance	2-5cm	HW-2/HW-2S/HW-3/HW-302/ HW- 303:5-8cm HW-4/HW-4S:1-2cm	Note 3
Measuring Range	32°C ~ 42.9°C	Forehead mode: 35.5°C ~42.9°C (95.9°F ~109.2°F)	Note 4
Accuracy	Forehead mode:±0.2°C , for range 35.0°C ~ 42.0°C ±0.3°C, outside this temperature range	Forehead mode: ±0.2°C (0.4°F) within 35.5°C ~42.9°C (95.9°F ~109.2°F), ±0.3°C(0.5°F) other range	Note 5
Display Resolution	0.1℃/0.1℉	0.1℃/0.1℉	Same
Sensor type	Thermopile	Thermopile	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
High temperature indication	Yes	Yes	Same
Buzzer	Yes	Yes	Same
Display screen	LCD	LCD	Same
Auto power-off while no operation	Yes	Yes	Same
℃/℉switchable	Yes	Yes	Same
Memory	32 sets	HW-2/2S:32 sets HW-3/4/4S: 1 set HW-302/303:64 Sets	Note 6
Power Supply	2 x AAA batteries	2 x AAA	Same
Operating Conditions	Temperature: 10°C ~ 40°C Relative humidity: ≤85% RH	Temperature: 10~40°C Relative humidity: ≤85% RH	Same
Storage Conditions	Temperature: -20°C ~55°C Relative humidity: ≤93%RH, non-condensing	Temperature: -25℃- +55℃ Relative humidity: ≤90%	Note 7
Dimension	182(L) x 54(W) x 47(H) mm	93*153*41mm	Note 8
Weight	Approximately 125 g	90-125 g	Note 8
Conformance standard	EN60601-1(Safety), IEC60601-1-2(EMC) ASTME1965-98(performance)	EN60601-1(Safety), IEC60601-1-2(EMC) ASTME1965-98(performance)	Same
Biocompatibility	ISO 10993-10 Skin Irritation test ISO 10993-10Skin Sensitization test ISO 10993-5 Vitro Cytotoxicity test	ISO 10993-10 Skin Irritation test ISO 10993-10Skin Sensitization test ISO 10993-5 Vitro Cytotoxicity test	Same
Sensor and patient contact materials	Infrared Sensor ABS plastic shell	Infrared Sensor ABS plastic shell	Same

Note 1

The Intended Use of subject device and predicate device is non-contact measurement of human body temperature from the forehead. The target population of the subject device is a subset of the predicate. This difference does not raise new or different questions of safety and effectiveness.

Note 2

Measurement time of the subject device is ≤3 seconds, the predicate device is 1 second. Both the subject and predict devices comply with ASTM E 1965-98. It is demonstrated that

the measure time does not affect the measurement accuracy. This difference does not raise new or different questions of safety and effectiveness.

Note 3

Measurement distance of the subject devices is 2-5cm, the predicate device measurement distance is 5- 8cm (models HW-2/HW-2S/HW-3/HW-302/ HW-303) or 1-2cm (models HW-4/HW-4S). Performance testing of the of the subject device demonstrates the accuracy meets the requirements within the distance range. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Note 4

Both devices have different measurement ranges; however, the measurement range of the subject device meets the requirements of ASTME1965-98. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Note 5

Both devices have different accuracy requirements.; however, the measurement accuracy of the subject device and the predicate device meet the requirements of ASTME1965-98. Performance testing was conducted on the subject device according to ASTM E1965-98. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Note 6

The memory capacity of the subject device is the same as the predicate device model: HW-2/2S. The memory capacity is only an auxiliary function. Software verification and validation testing conducted on the subject device demonstrates that the difference does not raise any new or different safety and effectiveness questions.

Note 7

There is a difference between the storage conditions of the predicate device and the subject device; however, both devices comply with IEC60601-1-11 and ASTM E1965-98. Therefore, the difference does not raise new or different questions of safety and effectiveness.

Note 8

There is a difference between the dimensions and weight of the predicate device and the subject device, however, the differences do not affect the safety and effectiveness as the subject device demonstrated adequate performance to requirements.

7. Test Summary - Non-Clinical Test

The subject device conforms to applicable standards that include:

- ASTM E 1965-98:2016 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- IEC 60601-1:2012, 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
- IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes
- IEC60601-1-11:2015 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 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity,
- ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

8. Summary of Clinical Test

Clinical tests were conducted on Model: IR8807. The study excluded subjects with medical conditions such as inflammation at the measuring sites and subjects using medications known to affect body temperature. The clinical tests evaluated 169 subjects which were divided into three age groups: infant (less than 1 year), children (1 t o 5 years old) and adult (greater than 5 years old). No less than 50 subjects in each group and 30% of them had temperature equaling or exceeding 37.5 ℃.

Based on the result, the clinical performance of the subject device complied with the requirement of ASTM E1965-98 (2016).

9. Summary of software verification and validation Test

According to Software Safety Classification of IEC 62304, the infrared forehead thermometer IR8807 software shall be Class B. The Infrared Thermometer (model: IR8807) display data about the patient's body temperature supported by the software. According to the software unit level test, integration test and system level test, we hereby certify that all the functions those support the infrared forehead thermometer system specifications are proper. The Infrared Thermometer (model: IR8807) can be used safely and effectively to measure body temperature.

10. Conclusion

After analyzing the intended use, technological characteristics, verification and validation testing, it can be concluded that the differences between the subject and predicate device do not raise any new or different questions of safety and effectiveness. Therefore, subject device, Infrared Thermometer, Model: IR8807 is substantially equivalent to the predicate device, Non-contact Forehead Thermometer, Model: HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303, cleared under K173048.