June 17, 2021

Shenzhen Sonida Digital Technology Co., Ltd
% Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co.,Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town
Shenzhen, Guangdong 518000
China

Re: K202440
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 8, 2020
Received: December 8, 2020

Dear Yoyo Chen:

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,

CAPT Alan M. Stevens
Acting 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)*
K202440

Device Name
Infrared Thermometer, Models HT-101, HT-102, HT-103, HT-104

Indications for Use *(Describe)*
The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.

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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K202440 510(k) Summary

1. Administrative Information

Prepared Date	June 14, 2021
Manufacturer information	Shenzhen Sonida Digital Technology Co., Ltd Address: 6F./3F-B., Building B, Zhengchangda Technopark, Tangwei Jianan Road, Fuhai Street, Baoan, Shenzhen, Guangdong, China, 518103 Contact person: Vivi Wey TEL Number: +(86) 0755-29607298 FAX Number: +(86) 0755-85259480 E-Mail: 2609815717@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Ms. Yoyo Chen E-Mail: yoyo@cefda.com; field@cefda.com

2. Device Information

Type of 510(k) Submission:	Traditional
Device Name:	Infrared Thermometer
Model:	HT-101, HT-102, HT-103, HT-104
Classification Name:	Thermometer, Electronic, Clinical
Device Class:	Class II
Regulation Number:	21 CFR 880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer	Guangzhou Berrcom Medical Device Co., Ltd.
Device name	Infrared Thermometer
Model	MD-H30
510(K) Number:	K191570
Product Code	FLL

4. Device Description

HT series infrared thermometers (includes model HT-101, HT-102, HT-103 and HT-104) measure the body temperature through receiving infrared energy radiation via the ear or forehead. These thermometers have the capability to measure temperature via forehead temperature mode or ear temperature mode, and the temperature is directly shown on the LCD display. These thermometers have the following features:

1) The device is intended to be used by consumers in the household environments and by healthcare providers;
2) The device is mainly composed of infrared sensor, signal receiving processor, buttons, buzzer, LCD display. It is powered by 2*1.5 AAA batteries;
3) It focuses the infrared energy received from the human's forehead or ear by using the Fresnel lens of the thermometer;
4) Switching between °C and °F;
5) Multi-functional, can measure ear and forehead temperature;
6) Automatic range selection; resolution is 0.1°C (0.1°F);
7) The latest 35 measurement data can be memorized and stored; the user can view the previous measurement results;
8) High temperature alarm function, displayed in green, orange and red backlight;
9) Switching between mute and un-mute mode;
10) Low battery indication, and auto shut-down.

5. Intended Use/Indication for Use

The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.

6. Substantial Equivalence Comparison

Items	Subject Devices	Predicate Device (K191570)	Comments
Product Code	FLL	FLL	Same

Items	Subject Devices	Predicate Device (K191570)	Comments
Regulation number	880.2910	880.2910	Same
Manufacturer	Shenzhen Sonida Digital Technology Co., Ltd	Guangzhou Berrcom Medical Device Co., Ltd.	/
Indications for use	The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.	The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.	Same
Thermometer type	Digital thermometer	Digital thermometer	Same
Sensor	Thermopile	Thermopile	Same
Operational principle	Infrared radiation detection	Infrared radiation detection	Same
Display type	LCD	LCD	Same
Measurement site	Forehead and ear	Forehead and ear	Same
Measurement Range	Ear & Forehead: 32.0°C~43.0°C (89.6°F~109.4°F)	Ear & Forehead: 32.0°C~43.0°C (89.6°F~109.4°F)	Same
Measurement accuracy	34.0°C~43.0°C (89.6°F~109.4°F): ±0.2°C(0.4°F) 32.0 °C~34.0°C(89.6°F~93.2°F): ±0.3°C(0.5°F)	±0.4°F (0.2°C) within 95~107.6°F (35.0~42.0°C), ±0.5°F (0.3°C) for other range.	Comparable (Note 1)
Display resolution	0.1°C (0.1°F)	0.1°C (0.1°F)	Same
Power supply	d.c.3.0V (2pcs AAA batteries)	2pcs AAA batteries	Same
Measurement time	1 second	1 second	Same
Measurement data memories	35 sets	20 sets	Comparable (Note 2)
Beeper setting	Yes	Yes	Same
Date and time setting	No	No	Same
Backlight	Yes	Yes	Same
Auto-off time	15s±1s	30s	Similar (Note 3)
Operation Condition	Temperature: 10°C~40°C Relative Humidity: ≤95% Atmospheric Pressure: 70kPa~106kPa	Temperature: 10°C~40°C Relative Humidity: ≤85% AtmosphericPressure: 70kPa~106kPa	Comparable (Note 4)
Storage and	Temperature: -20°C~50°C	Temperature: -20°C~55°C	Comparable

Items	Subject Devices	Predicate Device (K191570)	Comments
transportation condition	Relative Humidity: ≤95% Atmospheric Pressure: 70kpa~106kpa	Relative Humidity: 15%~93% Atmospheric Pressure: 70kpa~106kpa	(Note 4)
Protection against electric shock	Externally power supply, Type BF	Externally power supply, Type BF	Same
IP Class	IP22	IP22	Same
Mode of operation	Continuous Operation	Continuous Operation	Same
Materials of skin-contacting components	ABS/ PA757(+); PC/PC-110	ABS	Comparable (Note 5)
Physical Dimensions	HT-101:165*38*50 mm; HT-102:156*37*44mm; HT-103:155*52*38 mm; HT-104:154*39*50mm	Not available	Comparable (Note 5)
Weight	HT-101: 62.5g (Battery excluded) HT-102: 58g (Battery excluded) HT-103: 64.5g (Battery excluded) HT-104: 63g (Battery excluded)	Not available	Comparable (Note 5)

Note 1: Measurement accuracy:

The measurement accuracy of the subject devices has been verified to meet the requirements of ISO80601-2-56 and ASTM E1965-98 standard. The difference does not raise different safety and effectiveness issues.

Note 2: Measurement data memories

The purpose of function of measurement data memories is intended to store and view the previous readings. This function has been verified during software verification. The difference does not raise any issues on the device safety and effectiveness.

Note 3：Auto-off time

Although the time of auto-off time is less than the predicate device, both the subject devices and predicate device meet the basic safety requirement of IEC 60601-1:2005+AMD 1: 2012. The difference itself does not raise any issues on the device safety and effectiveness.

Note 4：Operation, Storage and transportation condition

The differences in operating and storage does not raise any safety and effectiveness questions. The subject device has been tested according to IEC 60601-1-2 EMC, IEC 60601-1, and ISO 80601-2-56 and ASTM E1965-98 standards. Therefore, the difference does not raise any issues on the device safety and effectiveness.

Note 5: Materials of skin-contacting components, Physical Dimensions, and weight

The subject devices and predicate device have different appearances, but the difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2 EMC, IEC 60601-1, and ISO 80601-2-56, ASTM E1965-98 and ISO 10993-1 standards.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject devices have passed safety testing in according to following standards.

1) IEC 60601-1:2005+AMD 1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) 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
3) 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

7.2. Biocompatibility Test

The subject devices have passed biocompatibility tests in according to following standards.

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7.3. Performance Test-Bench

The subject devices have passed performance testing in according to following standards.

1) ISO 80601-2-56:2017+AMD2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
2) ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

7.4. Software verification and validation

Software documentation consistent with moderate level of concern is submitted in this 510(k). System validation testing presented in this 510(k) demonstrates that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels

8. Clinical Accuracy Validation

Clinical accuracy validation testing was conducted according to ASTM E1965-98(Reapproved 2016). The clinical accuracy validation test report included temperature readings of 150 subjects, of which 50 subjects were infants, 50 subjects were children and the rest of the 50 subjects were adults (NOTE: Infants---newborn to one year; Children---greater than one to five years; Adults---greater than five years old.). The clinical accuracy validation test report demonstrates that the subject devices met the requirements for

clinical bias and clinical repeatability per ASTM E1965-98(Reapproved 2016).

9. Conclusion

The Infrared Thermometer (Model HT-101, HT-102, HT-103, HT-104) is substantially equivalent to the predicate device (K191570). This conclusion is based upon comparison of intended use, technological characteristics and applicable safety standards. Any differences in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.