September 15, 2021

Longnan RenZhong Medical Equipment Co., Ltd.
% Iris Fung
Regulation Manager
SGS-CSTC Standards Technical Services Co., Ltd.
198 KEZHU Road, SCIENTECH Park
Guangzhou Economic & Technology Development District
Guangzhou, Guangdong, 510000
China

Re: K210118
Trade/Device Name: Infrared Body Thermometer (Model: YK-001)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 6, 2021
Received: August 16, 2021

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,

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)*
K210118

Device Name
INFRARED BODY THERMOMETER (Model: YK-001)

Indications for Use *(Describe)*
INFRARED BODY THERMOMETER (Model: YK-001) is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature using the center of the forehead as the measurement site. The device is indicated for use by people over one month old. It can be used by consumers in household environment and doctors in clinic as reference.

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

1. Summary Prepared Date

15 September 2021

2. Submitter Information

Sponsor Company Name: Longnan Renzhong Medical Equipment Co., Ltd.

- Address: Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi Province, 341000, China
- Phone: +86-13715212441
- Contact Person (including title): Liangping Liao (Manager)
- E-mail: ln@akkord.com.cn

Application Correspondent: SGS-CSTC Standards Technical Services Co., Ltd.

- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, 510000, China
- Contact Person: Ms. Iris Fung
- Tel: +86-20-32136908
- Email: Iris.Fung@sgs.com

3. Subject Device Information

Trade Name: INFRARED BODY THERMOMETER (Model: YK-001)

Common Name: Clinical Electronic Thermometer

Regulation Name: Clinical Electronic Thermometer

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Regulation Class: II

4. Predicate Device Information

Sponsor: Shenzhen Jumper Medical Equipment Co., Ltd.

Trade Name: Non-contact Infrared Thermometer

510(k) number: K131243

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Regulation Class: II

5. Device Description

The proposed device, INFRARED BODY THERMOMETER, which includes model YK-001 hand-held, reusable, battery powered device, which is intended to detect body temperature from forehead.

The proposed device measure temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. The distance of the measurement is 3cm~5cm.

The proposed device uses a temperature sensor, which can detect the human forehead temperature, object temperature and environment temperature; these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature, and then transfer to screen for display.

The device has the following features: About two-second measuring time, measuring Body or Ambient temperature, 99-memory recalls, ℃/℉ unit switchable, over range message (Hi/Lo), low battery indication, auto shut-off when the device is idle for 15 seconds. When completes, the results will be displayed on the LCD display screen. The device will display 3 different background colors according to the result.

The power supply of INFRARED BODY THERMOMETER (YK-001) is 3.0V DC, it is powered by two AAA batteries.

The reference body site of INFRARED BODY THERMOMETER (Model: YK-001) is armpit.

6. Indications for Use

INFRARED BODY THERMOMETER (Model: YK-001) is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature using the center of the forehead as the measurement site. The device is indicated for use by people over one month old. It can be used by consumers in household environment and doctors in clinic as reference.

7. Comparison to Predicate Device

A comparison of key technological characteristics between the subject device and predicate device was listed as below:

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Longnan Renzhong Medical Equipment Co.,Ltd.	Shenzhen Jumper Medical Equipment Co., Ltd	--
510 (k) Number	K210118	K131243	--
Product Name	INFRARED BODY THERMOMETER	Non-contact Infrared Thermometer	--
Models	YK-001	JPD-FR100	--
Intended Use	INFRARED BODY THERMOMETER (Model: YK-001) is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature using the center of the forehead as the measurement site.	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

Elements of Comparison	Subject Device	Predicate Device	Verdict
	The device is indicated for use by people over one month old. It can be used by consumers in household environment and doctors in clinic as reference.		
Sensor	Infrared Sensor	Infrared Sensor	Identical
Principle operation	The proposed device measure temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. The proposed device uses a temperature sensor, which can detect the human forehead temperature, object temperature and environment temperature; these temperatures are then transfer to electronic signal and amplified; and then it is transferred to digital signal by AD module in MCU of the proposed device. MCU will calculate the body temperature, and then transfer to screen for display.	The device uses infrared sensor(thermopile)to detect the radiated infrared energy emitted by the object, solid, liquid or gas. The intensity of the emitted energy depends on the temperature of the object and the infrared sensor can recognize it to transfer to the proper electronic signal. The signal can be processed in the subject device to convert to the temperature reading.	Identical
Measurement Mode	Forehead measurement Mode	Forehead measurement Mode	Identical
Measurement type	Non-contact type	Non-contact type	Identical
Measurement Distance	3-5cm	1-6 cm	Note 2
Measuring Range	32℃～42.9℃ (89.6℉～109.2℉)	32.2℃~43.3℃ (90.0℉~109.9 ℉)	Note 3
Accuracy	Forehead mode: ±0.2°C (± 0.4°F) , for range 35.0°C ~ 42.0°C(95°F ~107.6°F); ±0.3°C(±0.5°F), outside this temperature range	Forehead mode: ±0.2°C (0.4°F)	
Sensor type	Thermopile	Thermopile	Identical
High temperature prompt	Yes	Yes	Identical
Buzzer	Yes	Yes	Identical
Display type	LCD	LCD	Identical
Auto power-off while no operation	Yes	Yes	Identical
℃/℉ switchable	Yes	Yes	Identical
Memory	99 sets	20 sets	Note 4
Power Supply	DC 3V, 2×AAA Batteries	DC 3V, 2 x AAA Batteries	Identical

Elements of Comparison	Subject Device	Predicate Device	Verdict
Operating Conditions	Temperature：+15℃~+40℃ (59°F ~104°F) Humidity：15% to 95% non-condensing Atmospheric pressure：70kPa~106kPa	10~40°C(50°F ~104 °F) RH < 85%	Note 5
Storage Conditions	Temperature：-20℃~50℃(-4°F ~122 °F) Humidity：≤95% non-condensing Atmospheric pressure：70kPa~106kPa	-25℃ - +55℃（-13° F-+131 ° F） RH ≤ 90%	Note 5
Dimension (Lx W x H)	138x95x40mm（L* W * H）	145X60X50 mm	Note 6
Weight	About 90g(without battery)	180 g	Note 6
Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Identical
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Identical
Performance	Complied with ISO 80601-2- 56:2017	Complied with ISO 80601-2-56	Identical
	Complied with ASTM E 1965 -98 (2016)	Complied with ASTM E 1965 - 98 (2003)	Identical
Components	It composed by a measuring sensor, set buttons, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.	It composed by a measuring sensor, set buttons, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.	Identical
Biocompatibility	All the patient contacting materials are compliance with ISO 10993-5; ISO10993-10	All the patient contacting materials are compliance with ISO 10993-5; ISO10993-10	Identical
Materials	ABS for enclosure	ABS for enclosure	Identical
Labeling	OTC	OTC	Identical

Note 1

The patient population between the subject device and predicate is different. The clinical accuracy test was conducted in accordance with ISO 80601-2-56:2017. The test result complies with the standard. The difference does not raise new safety and effectiveness questions.

Note 2

Measurement distance of the subject device is 3-5cm whereas the predicate device's is in the range of 1- 6cm. But the performance test result of subject device shows the accuracy meets the requirements within the distance range. The difference does not raise new safety and effectiveness questions.

Note 3

The subject device and predicate device have different measurement range, but they have the same accuracy. The measurement range of subject device meet the requirements of ASTM E1965-98. The difference does not raise new safety and effectiveness questions.

Note 4

The memory capacity of predicate device and subject device is different, but the memory function does not affect accuracy of measurement and does not impact the performance of subject device.

Note 5

The operating condition and storage condition are different between the subject device and predicate. The operating condition and storage condition met the requirements of ISO 80601-2-56 and performance test was conducted in accordance with the standard. The difference does not impact the performance of subject device.

Note 6

There is minor difference on the size and weight between predicate device and subject device. But they both are portable device; such minor difference would not cause issue of safety and effectiveness.

8. Test Summary

Non-clinical test:

INFRARED BODY THERMOMETER conforms to applicable standards that include:

- ASTM E 1965-98 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
- ISO 10993-1:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- 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
- IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes
- 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/AMD 1:2018 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

Clinical Data:

The clinical accuracy study for the non-contact thermometer was performed to determine the clinical accuracy. The three groups of subjects being tested were: 1) over 1 month to under 1 year old, 2) children between 1 and 5 years old, and 3) patients over 5 years old.

The study includes 137 subjects. For each age group, the ratio of febrile subjects was more than 30% and less than 50%. 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 test results showed that the accuracy of the proposed device is within acceptable scope specified in ISO 81061-2-56.

9. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the performance testing, comparison and analysis, the subject device INFRARED BODY THERMOMETER (Model: YK-001) is substantially equivalent to the Non-contact Infrared Thermometer cleared under K131243.