Yibin Junxin Electronics Technology Co., Ltd.
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu
District, Guangzhou, China
Guangzhou, Guangdong 510000
China

Re: K203662
Trade/Device Name: Infrared thermometer, Models: YRK-002A, T8, T9, T10, T11
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 23, 2021
Received: August 27, 2021

Dear Cassie Lee:

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)*
K203662

Device Name
Infrared thermometer, Models: YRK-002A, T8, T9, T10, T11

Indications for Use *(Describe)*
Infrared thermometer (Models: YRK-002A, T8, T9, T10, T11) is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead at a distance of 2-5cm for people of all ages. The device is reusable for home use and clinical use.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary for K203662

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

**1. Submitter's Information**

510(k) Owner's Name: Yibin Junxin Electronics Technology Co., Ltd.
Establishment Registration Number: 3017015806
Address: Building B2, No. 136, West Section Of Xinggang Road, Lingang Economic And Technological Development Zone, Yibin Sichuan, China
Tel: +86-831-3602202
Phone: +86-13530731921
Contact Person: Chaoze Guan
Email: peter@tablet-china.com

**Application Correspondent:**
Contact Person: Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: regulatory@share-info.com

**Date of the summary prepared: September 23, 2021**

**2. Subject Device Information**

Trade Name: Infrared thermometer
Models: YRK-002A, T8, T9, T10, T11
Common Name: Clinical Electronic Thermometer
Regulation Name: Clinical electronic thermometer
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Regulatory Class: II

**3. Predicate Device Information**

Trade/Device Name: Infrared Forehead Thermometer
Model: JZK-601, JZK-602, JZK-603
510(K) Number: K203707

**4. Device Description**

Infrared thermometer (Models: YRK-002A, T8, T9, T10, T11) is a hand-held, battery powered, infrared Thermometer that coverts a user's forehead temperature, using the infrared energy emitted in the area around the user's forehead temperature when measure from 2-5 cm of the subject's forehead with no contact.

It uses a thermopile sensor with integrated thermistor for the target reading and a thermistor mounted in the head of the thermometer for ambient temperature readings.
It composed by a measuring sensor, PCB, 4 buttons, an LCD and an enclosure. The functions of the five models are same. Press the measurement key to turn on the device. The screen of the device lights up. The LCD screen has the power status, measurement mode, temperature unit and measurement temperature. Press the "Setting" key to open the F1: The function of “Temperature Unit” can be set. When measuring body temperature, users need to measure in body mode from 2-5 cm from their forehead. Press the trigger, after 1 second with the sound of "beep", the measurement is completed and the temperature is displayed on the LCD screen. Without any operation, it will close automatically in 17 sec.
The difference between these models is only the model’s name.

**5. Intended Use / Indications for Use**
Infrared thermometer (Models: YRK-002A, T8, T9, T10, T11) is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead at a distance of 2-5cm for people of all ages. The device is reusable for home use and clinical use.

**6. Comparison of indications for use and technological characteristics**
The technological characteristics, features, specifications, materials, mode of operation, and intended use of Thermometer is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Company | Yibin Junxin Electronics Technology Co., Ltd. | ShenZhen ZhengKang Technology Co., Ltd. | -- |
| Trade Name | Infrared thermometer | Infrared Forehead Thermometer | -- |
| Classification Name | Thermometer, Electronic, Clinical | Thermometer, Electronic, Clinical | Same |
| 510(k) Number | K203662 | K203707 | -- |
| Product Code | FLL | FLL | Same |
| Thermometer Type | Infrared Forehead | Infrared Forehead | Same |
| Indications for Use | Infrared thermometer (Models: YRK-002A, T8, T9, T10, T11) is a non-contact infrared | The Infrared forehead thermometer is a non-contact infrared thermometer (Models JZK-601, JZK- 602, JZK-603) intended for | Similar Note 1 |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| | thermometer intended for the intermittent measurement of human body temperature from forehead at a distance of 2-5cm for people of all ages. The device is reusable for home use and clinical use. | the intermittent measurement of human body temperature from forehead at a distance of 1-5cm for people of all ages. The device is reusable for home use and clinical use. | |
| Prescription/over-the-counter use | OTC | OTC | Same |
| Intended use environment | Home, Clinical | Home, Clinical | Same |
| Measurement method | Infrared radiation detection | Infrared radiation detection | Same |
| Measurement place | Forehead | Forehead | Same |
| Measurement mode | Adjusted | Not public | Different Note 2 |
| Reference Body Site | Oral | Not public | Different Note 2 |
| Measuring range | 32.0°C ~ 42.9°C (89.6°F to 109.2°F) | 32.0°C ~ 42.9°C (89.6°F to 109.2°F) | Same |
| Display resolution | 0.1°C/0.1°F | 0.1°C/0.1°F | Same |
| C/F switchable | YES | YES | Same |
| Measuring accuracy | 32°C ~ 39°C: ±0.2°C (89.6°F ~ 102.2°F: ±0.4°F)<br>39°C ~ 42.9°C: ±0.3°C (102.2°F ~ 109.2°F: ±0.5°F) | 32°C ~ 34.9°C: ±0.3°C (±0.5°F)<br>35°C ~ 42°C: ±0.2°C (±0.4°F)<br>42.1°C ~ 42.9°C: ±0.3°C (±0.5°F) | Similar Note 2 |
| Measurement distance | 2-5cm | 1-5cm | Similar Note 2 |
| Power Supply | DC3V (2 pieces 1.5V AAA) | JZK-601 and JZK-603: DC 3V (2x AA 1.5V Alkaline batteries)<br>JZK-602: DC 3V (2x AAA 1.5V Alkaline batteries) | Same |
| Dimensions | 136mm(L) x 87mm(W) x 40mm(H) | JZK-601 and JZK-603: 154 x 96 x 42mm<br>JZK-602: 143 x 81 x 36mm | Similar Note 3 |
| Weight | 88g | JZK-601 and JZK-603: | Similar |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| | | 93g<br>JZK-602: 86g | Note 3 |
| Auto Power off | Yes | Yes | Same |
| Memory | 30 sets | 32 sets | Similar<br>Note 3 |
| Display screen | LCD | LCD | Same |
| Operational environmental conditions | Temperature: 10°C ~ 40°C (50 ~ 104°F)<br>Humidity: ≤85% | Temperature: 10 ~ 40°C (50 ~ 104°F)<br>Humidity: ≤95% | Similar<br>Note 2 |
| Storage environmental conditions | Temperature: -25°C ~ 70°C (-13 ~ 219.2°F)<br>Humidity: ≤95% | Temperature: -20°C ~ 60°C (-4 ~ 140°F)<br>Humidity: ≤95% | Similar<br>Note 2 |
| Electric Safety and EMC | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-56<br>ASTM E1965-98 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-56<br>ASTM E1965-98 | Same |
| Materials of construction | ABS plastic | ABS | Same |
| Biocompatibility | ISO 10993-5<br>ISO 10993-10 | ISO 10993-5<br>ISO 10993-10 | Same |

**Discussion:**

**Note 1:**

Although there are a few differences in the Indications for Use, the intended user population is the same as the predicate device (K203707), and the measurement distance is within the measurement distance range of the predicate device (K203707), and the measurement positions of the subject device and the predicate device is the same, and they meet the requirement of safety and essential performance standards. The difference between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**Note 2:**

The “Reference Body Site”, “Reference Body Site”, “Measuring accuracy”, “Measurement distance”, “Operational environmental conditions” and “Storage environmental conditions” of subject device is similar to the predicate device, all of them meet the requirement of safety and essential performance standard ISO 80601-2-56 and ASTM E1965-98. The differences between the predicate devices and subject device will not affect the safety and effectiveness of the subject device.

**Note 3:**

The “Dimensions”, “Weight” and “Memory” of subject device is similar with predicate devices, both of them meet the requirement of safety and essential performance standard IEC 60601-1,

IEC 60601-1-2 and IEC 60601-1-11. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

**7. Summary of Non-Clinical Testing**

**7.1 Non-clinical testing was conducted to verify that the subject devices meet all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:**

A. Electromagnetic Compatibility, Electrical Safety, and Battery Safety:

The subject devices were tested for compliance with the following:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02 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 Edition 2.0 2015-01, 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 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards

B. Software Verification: Software documentation was provided in accordance with FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005.

C. Performance Testing:

- ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

**7.2 Discussion of Clinical Tests Performed**

The clinical performance test protocol and data analysis is conducted as a requirement of ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with ASTM E1965-98 (2016).

Clinical tests were conducted on the subject device Model YRK-002A, T8, T9, T10, T11. The clinical tests evaluated 240 of subjects. The proposed thermometer was evaluated in four groups: A1 - 0 up to 3 months, A2 - 3 months to 1 year; B1 -older than 1 year and younger than 5 years; and C - older than 5 years old. Test subjects included patients from the neonatal subgroup patient population (0 – 28 days). The clinical performance test protocol and data analysis were conducted in accordance with the ASTM E1965-98 (2016). The test report showed the clinical performance of the subject device complied with ASTM E1965-98 (2016).

**8. Final Conclusion**

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.The subject device Infrared thermometer (Models: YRK-002A, T8, T9, T10, T11) is substantially equivalent to the Infrared Forehead Thermometer, Model: JZK-601, JZK-602, JZK-603 cleared under K203707 with respect to the indications for use, target populations, and technological characteristics.