February 26, 2021

Hunan Honggao Electronic Technolofy Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou Kinda Biological Technology Co., Ltd
6F, No.1 TianTai road, Science City, LuoGang District,
GuangZhou, Guangdong
China

Re: K202111
Trade/Device Name: Medical infrared forehead thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 12, 2021
Received: January 25, 2021

Dear Jet Li:

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
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)*
K202111

Device Name
Medical infrared forehead thermometer

Indications for Use *(Describe)*
The Medical infrared forehead thermometer (Model: HGO1, HGO1 VI, HGO6 ) is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one year old and above. 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.***

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**510(k) Summary**

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

**Date Prepared:** February 26, 2021

## 1. Submitter Information

**Sponsor Company Name:** *Hunan Honggao Electronic Technology Co., Ltd.*

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E-mail: hgdztechnology@126.com

**Application Correspondent:** Guangzhou KINDA Biological Technology Co., Ltd.
**Address:** 6F, No.1 TianTai road, Science City, LuoGang District, Guang Zhou City, China
**Contact Person:** Mr. JetLi
**Tile:** Regulation Manager
**Tel:** +86-18588874857
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## 2. Subject Device Information

Type of 510(k) submission: Traditional
Common Name: Clinical Electronic Thermometer
Trade Name: Medical infrared forehead thermometer
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

Sponsor: Shenzhen Jumper Medical Equipment Co., Ltd.
Trade Name: Non-contact Forehead Thermometer
510(k) number: K131243
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Regulation Class: 2

## 4. Device Description

The proposed device, Medical infrared forehead thermometer, which includes model HGO1, HGO1 VI, HGO6 are hand-held, reusable, battery powered device, which are intended to detect body temperature from forehead of people aged over 1 year.

The proposed devices 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 object temperature [human body temperature], environment temperature and temperature of sensor itself; 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 devices have the following features: About one-second measuring time, measuring Body or Ambient temperature, 32-memory recalls, ℃ and ℉ 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, and the buzzer will tell the operator that the measurement has been completed. The device will display 3 different background colors according to the result.

The power supply of Medical infrared forehead thermometer is 3.0V DC, it is powered by two AAA batteries.

The package includes the following parts:

2×AAA batteries, 1×Manual and 1 pcs thermometer

## 5. Intended Use

The The Medical infrared forehead thermometer (Model: HGO1, HGO1 VI, HGO6 ) is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one year old and above. The device is reusable for home use and clinical use.

## 6. Material

The Medical infrared thermometer (Model: HG01,HG01 V1,HG06) are with non-contact to measurement forehead temperature at home or hospital. The device is consists of plastic enclosure, PCB circuit and Infrared sensor. There are operator or patient contacting components in the subject device as the following list.

| Operator/ Patient contacting components | Material | Body Contact Location | Contact Duration |
|---|---|---|---|
| Main enclosure (including Chassis-R, Chassis-L) | PC | Intact Skin | Less than 24 hours |
| Front cover | ABS w ith blue Colorant 0.4% | Intact Skin | Less than 24 hours |
| Button | ABS w ith blue Colorant 0.4% | Intact Skin | Less than 24 hours |
| Trigger | ABS w ith blue Colorant 0.4% | Intact Skin | Less than 24 hours |
| Battery Cover | ABS w ith blue Colorant 0.4% | Intact Skin | Less than 24 hours |
| Display screen | ABS | Intact Skin | Less than 24 hours |

## 7. Test Summary

**Biocompatibility testing**

- The biocompatibility evaluation for the Medical infrared forehead thermometer (Model: HG01,HG01 V1,HG06 ) was conducted in accordance with 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.

The tests included the following:

- Cytotoxicity
- Sensitization
- Irritation

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the Medical infrared forehead thermometer (Model: HG01,HG01 V1,HG06 ). The device complies with the IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, 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.
The device complies with the IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility for EMC.

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." and IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes.

**Performance Testing**

- ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature test
- 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 for Electrical safetytest
- Lifetime shelf life performance test

**Clinical Data:**

Clinical tests were conducted on representative model (HG01 V1), since the software and infrared sensor theory is the same between all the models: HG01, HG01 V1,HG06 .

The clinical tests evaluated 100 subjects which were divided into two group age ranges- children (greater than 1 to 5 years old) and adult (greater than5 years old). Each group has 30% of subjects got temperature equalling or exceeding37.5℃.

Based on the result, the clinical performance of the subject device complied with the requirement of ISO 80601-2-56:2017.

**8. Comparison to Predicate Device**

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

| Elements of Comparison | Subject Device<br>Medical infrared forehead thermometer (K202111) | Predicate Device<br>Non-contact Forehead Thermometer (K131243) | Remark |
|---|---|---|---|
| Manufacturer | Hunan Honggao Electronic Technology Co., Ltd. | Shenzhen Jumper Medical Equipment Co., Ltd | -- |
| Models | HG01, HG01 V1, HG06 | JPD-FR100 | -- |
| Intended Use | The The Medical infrared forehead thermometer (Model: HGO1, HGO1 Vl, HGO6) is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one year old and above. The device is reusable for home use and clinical use. | The non-contact infrared thermometer, model JPD-FR100, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference | Note 1 |
| Sensor | Infrared Sensor | Infrared Sensor | SE |
| Measurement Mode | Forehead measurement Mode | Forehead measurement Mode | SE |
| Measurement type | Non-contact type | Non-contact type | SE |
| Measurement Distance | 3-5cm | 1-6 cm | Note 2 |
| Measuring Range | 32～43 ℃ (89.6℉～109.4℉) | 32.2℃~43.3℃ (90.0℉~109.9℉) | Note 3 |
| Laboratory Accuracy | Forehead mode ±0.3°C | Forehead mode: ±0.2°C (0.4°F) | |
| Sensor type | Thermopile | Thermopile | SE |
| Fever alarm | Yes | Yes | SE |
| Buzzer | Yes | Yes | SE |
| Display type | LCD | LCD | SE |
| Auto power-off while no operation | Yes | Yes | SE |
| ℃/℉ switchable | Yes | Yes | SE |
| Memory | 32 sets | 20 sets | Note 4 |
| Power Supply | DC 3V, 2×AAA Batteries | Two 1 .5V AAA batteries | SE |

| Elements of Comparison | Subject Device<br>Medical infrared forehead thermometer (K202111) | Predicate Device<br>Non-contact Forehead Thermometer (K131243) | Remark |
|---|---|---|---|
| Operating Conditions | Temperature：+15℃~+40℃<br>Humidity：≤95% non-condensing<br>Atmospheric pressure：70kPa~106kPa | 10~40°C (50°F ~104 °F)<br>RH <95% | Note 5 |
| Storage Conditions | Temperature：-20℃~+55℃<br>Humidity：≤95% non-condensing<br>Atmospheric pressure：70kPa~106kPa | -25℃ - +55℃（-13° F- +131F）<br>RH≤90% | SE |
| Dimension (Lx W x H) | 149 × 77 × 43 mm | 145X60X50 mm | Note 6 |
| Weight | 127 g (excluding battery) | 180 g | |
| Safety | Complied with IEC 60601-1 | Complied with IEC 60601-1 | SE |
| EMC | Complied with IEC 60601-1-2 | Complied with IEC 60601-1-2 | SE |
| Performance | Complied with ISO 80601-2-56 | Complied with ISO 80601-2- 56 | SE |
| | Complied with ASTM E 1965 -98 (2003) | Complied with ASTM E 1965-98 (2003) | SE |
| Biocompatibility | Complied with ISO 10993-5<br>Complied with ISO 10993-10 | Complied with ISO 10993-5<br>Complied with ISO 10993-10 | SE |
| Contact location and duration | Intact skin (Less than 24 hours) | Intact skin (Less than 24 hours) | SE |
| Material | PC and ABS material | ABS material | Note 7 |

**Note 1**

The subject device is used for ages 12 months and older. However, the predicate is used for infants and adults. The user population of the subject device is subset of the predicate. And the manufacturer had conducted clinical accuracy trial to verify measurement accuracy for declared patient population according to ISO 80601-2-56. Therefore, this difference does not raise new safety and effectiveness questions.

**Note 2**

Measurement distance of the subject devices is 3-5cm, the predicate device's will be in the range of 1-6cm. And the manufacturer had conducted clinical accuracy trial to verify measurement accuracy for declared patient population according to ISO 80601-2-56 based on the measurement distance 3-5 cm. The performance test result of subject device shows the accuracy meets the requirements within the distance range. Therefore, this difference does not raise new safety and effectiveness questions.

**Note 3**

The subject devices and predicate device have different measurement range and different laboratory accuracy specification, but the laboratory accuracy and the measurement range of subject devices meet the requirements of ASTME1965-98. And clinical accuracy also had been validated according to ISO 80601-2-56. Therefore, the difference does not raise new safety and effectiveness questions.

**Note 4**

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

**Note 5**

There is minor difference on the temperature operation condition between predicate device and subject device. But the subject device also had pass IEC60601-1-11 and the labelling will indicate the operation condition. Therefore, this difference does not impact of safety and effectiveness.

**Note 6**

There is minor difference on the size and weight between predicate device and subject device. But this difference does not impact of safety and effectiveness.

**Note 7**

There is minor difference on the material of device case and enclosure between predicate device and subject device. But the operator or patient contacting parts' in the subject device all complied with ISO 10993-5, ISO 10993-10. Therefore, the difference would not cause issue of safety and effectiveness.

## 9. Summary of Clinical Test

Clinical study for non-contact thermometer was performed to determine the clinical accuracy and to provide comparison with predicate device. 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 100 subjects which were divided into two group age ranges- children (1 to 5 years old) and adult (greater than 5 years old). The clinical accuracy of the proposed device was evaluated by ISO 80601-2-56 - clinical bias with stated uncertainty and clinical repeatability. The clinical test results showed that the accuracy of the proposed device is within acceptable scope specified in ISO 81061-2-56.

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

## 10. Conclusion

Based on the performance testing, comparison and analysis provided it was concluded that the subject device Medical infrared forehead thermometer (Model: HG01, HG01 V1,HG06) is substantially equivalent to the cleared predicate Non-contact Forehead Thermometer (K131243) Model JPD-FR100.