June 4, 2021

Guandong Genial Technology CO., LIMITED
℅ Jet Li
Regulation Manager
Guangzhou KINDA Biology Technology Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K210014
Trade/Device Name: Infrared Forehead Thermometer (Model: T80, T81, T82, T83, T84, T85)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 19, 2021
Received: May 4, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210014

Device Name
Infrared Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85)

Indications for Use *(Describe)*
The Infrared Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85) is a non-contact thermometer used to measurement forehead temperature at home or hospital. The device is indicated 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

K210014

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

1. Submitter Information

Sponsor Company Name: GUANGDONG GENIAL TECHNOLOGY CO., LIMITED.

Establishment Registration Number: Applying

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- Phone: +86-020-37236838

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- Contact Person (including title): Jun Yu (General Manager)
- E-mail: admin@genial.cn

Application Correspondent: Guangzhou KINDA Biology Technology Co., Ltd.

- **Address:** 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhouCity, China
- **Contact Person:** Mr. Jet Li
- **Tile:** Regulation Manager
- **Tel:** +86-18588874857
- **Email:** med-jl@foxmail.com

3 Subject Device Information:

- Type of 510(k) submission: Traditional
- Common Name: Infrared Forehead Thermometer
- Trade Name: Infrared Forehead Thermometer(Model: T80、T81、T82、T83、T84、T85)
- Classification Name: Clinical Electronic Thermometer
- Review Panel: General Hospital
- Product Code: FLL
- Regulation Number: 21 CFR 880.2910
- Regulation Class: 2

4 Predicate Device Information:

- Sponsor: Dongguan SIMZO Electronic Technology Co.Ltd.

- Trade Name: Non-contact Forehead Thermometer
- 510(k) number: K173048
- Review Panel: General Hospital
- Product Code: FLL
- Regulation Number: 21 CFR880.2910
- RegulationClass: 2

2. Device Description

The Infrared Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85) 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 Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85), 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 and Backlight
f) 4 buttons (Setting button, Memory button, ON/OFF button, Measurement Trigger)
g) 2×1.5V AA dry batteries

The operation principle is based on Infrared Sensor technology. The sensor can turn body's temperature to analog signals, and a MCU with an AD can get the result by intelligent analyze and treat the analog signals.

3. Intended Use

The Infrared Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85) is a non-contact thermometer used to measurement forehead temperature at home or hospital. The device is indicated for use on people of all ages except for neonates/newborns.

4. Test Summary

Infrared Forehead 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
- 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 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
- 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

5. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, sensor, measurement mode, measuring range, accuracy and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	GUANGDONG GENIAL TECHNOLOGY CO., LIMITED.	Dongguan SIMZO Electronic Technology Co.Ltd.	--
510 (k) Number	K210014	K173048	--
Product Name	Infrared Forehead Thermometer	Non-contact Forehead Thermometer	--
Models	Model: T80、T81、T82、T83、T84、T85	HW-2/HW-2S/HW-3/HW-4 /HW-4S/HW-302/HW-303	--
Intended Use	The Infrared Forehead Thermometer (Model: T80、T81、T82、T83、T84、T85) is a non-contact thermometer used to measurement forehead temperature at home or hospital. The device is indicated 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	SE
Measurement Mode	Forehead measurement Mode	Forehead measurement Mode	SE
Measurement type	Non-contact type	Non-contact type	SE
Measurement method	Infrared radiation detection	Infrared radiation detection	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Measurement time	≤3S	1S	Note 2
Measurement Distance	1-5cm	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 (89.6°F ~ 109.2°F)	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 (95.9°F ~109.2°F); ±0.3°C (0.5°F),for the range 32°C - 34.9°C (89.6°F -94.8°F) and 42.1-42.9°C (107.8°F - 109.2°F)	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℉	SE
Sensor type	Thermopile	Thermopile	SE
High temperature hint	Yes	Yes	SE
Buzzer	Yes	Yes	SE
Display screen	LCD	LCD	SE
Auto power-off while no operation	Yes	Yes	SE
℃/℉ switchable	Yes	Yes	SE
Memory	32 sets	HW-2/2S:32 sets HW-3/4/4S: 1 set HW-302/303:64 Sets	Note 6
Power Supply	3.0V DC, offered by two AA batteries	2 x AAA	Note 7
Operating Conditions	Temperature: 15°C ~ 40°C (60.8°F ~ 95°F) Relative humidity: ≤85% RH	10~40°C(50°F ~104 °F) RH < 85%	Note 8
Storage Conditions	Temperature: -20°C ~55°C (-4°F ~ 131°F) Relative humidity: ≤93%RH, non-condensing	-25℃ - +55℃（-13° F-+131° F） RH≤90%	Note 8
Dimension	150(L) x 48(W) x 105(H) mm	93*153*41mm	Similar
Weight	Approximately 125 g	90-125 g	Similar
Conformance standard	EN60601-1(Safety), IEC60601-1-2(EMC) ASTME1965-98(performance)	EN60601-1(Safety), IEC60601-1-2(EMC) ASTME1965-98(performance)	SE

Note 1

Even there is minor difference subject group difference between subject device and predicate device, but the labelling had provided detail statement for applicable subject group. This difference does not affect the safety and effectiveness.

Note 2

Measurement time of the subject devices is≤3S , the predicate device's will be 1S. But both of them are complied with ASTM E 1965 and the measure time will not affect the measurement accuracy. This difference does not affect the safety and effectiveness.

Note 3

Measurement distance of the subject devices is 1-5cm, the predicate device's will be in the range of 5-8cm or 1-2cm. But the performance test result of subject device shows the accuracy meets the requirements within the distance range.

Note 4

Although there is little difference for the contact type of the subject device and predicate device, both of them are complied with ASTM E 1965 . This difference does not affect the safety and effectiveness.

Note 5

Both devices have different measurement range, but they have the same accuracy and the measurement range of subject devices meet the requirements of ASTME1965-98.

Note 6

The memory capacity of predicate devices （HW-3/4/4S,HW-302/303）are difference from subject devices ,but that does not impact the performance of subject devices.

Note 7

Although the battery size between the predicate device and subject device is different, the power requirements are similar (voltage outputs are the same), and both of them are complied with IEC 60601-1. This difference does not affect the safety and effectiveness.

Note 8

There is minor difference on operation environment and storage condition between predicate device and subject device, but both device comply with IEC60601-1-11 and ASTM E1965, so This difference does not affect the safety and effectiveness.

6. Summary of Clinical Test

Clinical tests were conducted on Model: T80、T81、T82、T83、T84、T85. 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 150 subjects which were divided into three group age ranges-Infants (less than 1 year), children (1 to 5 years old) and adult (greater than 5 years old). No less than 50 subjects in each group and 30% of them got temperature equaling or exceeding 37.5℃.

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).

7. Conclusion

The subject device Infrared Forehead Thermometer has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

8. Summary Prepared Date

28 May 2021