March 12, 2021

ShenZhen ZhengKang Technology Co., Ltd.
℅ Iris Wang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town
Shenzhen, Guangdong 518000
China

Re: K203707
Trade/Device Name: Infrared Forehead Thermometer, Model JZK-601, JZK-602, JZK-603
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 8, 2020
Received: December 18, 2020

Dear Iris Wang:

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)*
K203707

Device Name
Infrared Forehead Thermometer, Model JZK601, JZK602, JZK603

Indications for Use *(Describe)*
The Infrared forehead thermometer (Models JZK-601, JZK-602, JZK-603) is a non-contact infrared thermometer intended for 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.

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

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Date Prepared	March 10, 2021
Manufacturer	ShenZhen ZhengKang Technology Co., Ltd. Address: 2&3/F, Building A, No.3 FuXing Yi Lane, HeHua Community, PingHu Street, LongGang District, ShenZhen, GuangDong, China. Contact person: Huayong Yang TEL: +86 -0755-83260864 E-Mail: 893488645@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. Iris Wang; Mr. Field Fu E-Mail: iris@cefda.com; field@cefda.com
Establishment registration number	3015697152

2. Device Information

Device Name:	Infrared Forehead Thermometer
Model:	JZK-601, JZK-602, JZK-603
Classification Name:	Thermometer, Electronic, Clinical
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer:	Shenzhen Calibeur Industries Co., Ltd.
Device Name:	Infrared Thermometer
Model:	DT-8836T, DT-8836P
510(k) Number:	K191251
Regulation Number:	880.2910
Product Code:	FLL

4. Device Description

Infrared forehead thermometers (includes model JZK-601, JZK-602, JZK-603) are intended to measure the body temperature through receiving infrared energy radiation via the forehead for people of all ages. These thermometers have the capability to measure temperature via body mode or object mode, and the temperature is directly shown on the LCD display. These thermometers have the following features:

1) The device is intended to be reusable for home use and clinical use.
2) The device is mainly composed of infrared sensor, signal receiving processor, keys, buzzer, LCD display.
3) Switching of temperature unit between °C and °F.
4) The latest 32 sets of memory for measuring human body and object; the user can view or delete the previous measurement results.
5) Buzzer on or off to set the prompt tone on or off.
6) Prompt tone function and backlights function.
7) The prompt limit setting function.
8) Low battery indication, and auto power-off.

5. Intended Use/ Indications for Use

The Infrared forehead thermometer is a non-contact infrared thermometer (Models JZK-601, JZK-602, JZK-603) intended for 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.

6. Comparison with Predicate Device

The subject device infrared forehead thermometer, Model: JZK-601, JZK-602, JZK-603 is substantially equivalent to the predicate device (K191251). This conclusion is based upon comparison on intended use, technological characteristics, materials and applicable safety standards. The difference between the subject device and predicate device do not raise any issues on the device safety and effectiveness.

Items	Subject Device (K203707) (Model: JZK-601, JZK-602, JZK-603)	Predicate Device (K191251)	Comparison
Regulation number	880.2910	880.2910	Same
Product code	FLL	FLL	Same
Intended Use/ Indications for use	The Infrared forehead thermometer (Models JZK-601, JZK-602, JZK-603) is a non-contact infrared thermometer intended for 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.	The Infrared thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	Comparable (1) See below
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	32 - 42.9°C (89.6 - 109.2°F)	32.0 - 42.5°C (89.6 - 108.5°F)	Comparable (2) See below
Accuracy	±0.3°C(0.5°F) within 32 - 34.9°C (89.6~94.8°F) ±0.2°C (0.4°F) within 35 - 42°C (95.0~107.6°F) ±0.3°C(0.5°F) within 42.1 - 42.9°C (107.8~109.2°F)	±0.2°C (0.4°F) within 35.0°C - 42.0°C (95.0°F ~ 107.6°F), ±0.3°C(0.5°F) other range	Same
Display	0.1°C /0.1°F	0.1°C(0.1°F)	Same
Measurement distance	1-5cm	≤3cm	Comparable (3) See below
Measurement place	Forehead	Forehead	Same
Response time	≤3 seconds	1s	Comparable (4) See below
Sensor type	Thermopile	Thermopile	Same
Scale Selection	°C /°F	°C /°F	Same
Memory	32 sets	60 sets	Comparable (5) See below
Buzzer	Yes	Yes	Same
Shelf Life	5 years	Not Available	Acceptable (6) See below
IP classification	IP22	Not Available	Acceptable (6) See below
Auto power-off while no operation	Yes	Yes	Same
Power supply	JZK-601 and JZK-603: DC 3V (2× AA 1.5V Alkaline batteries) JZK-602: DC 3V (2× AAA	2 * 1.5V AAA	Comparable (7) See below

	1.5V Alkaline batteries)		
Display screen	LCD	LCD	Same
Contact materials	ABS	ABS	Same
Backlight	JZK-601 and JZK-603: Three color backlight (green, yellow, and red) JZK-602: two color backlight (green and red)	Not Available	Acceptable (6) See below
Operation Environment	10 - 40°C (50 - 104°F) Humidity:≤95%	10 - 40°C (50 - 104 °F) RH 15 - 95%	Comparable (8) See below
Storage Environment	-20 - 60°C (-4 - 140°F) Humidity: ≤95%	-25 - 55°C (-13 - 131°F) RH:15 - 95%	Comparable (9) See below
Dimension	JZK-601 and JZK-603: 154 x 96 x 42mm JZK-602: 143 x 81 x 36mm	153.8 x 62.4 x 62.4 mm	Comparable (10) See below
Weight	JZK-601 and JZK-603: 93g JZK-602: 86g	96g	Comparable (10) See below
Conformance standard	ISO80601-2-56 (performance) IEC60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	ISO80601-2-56 (performance) IEC60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	Same
Patient contact materials	ABS	ABS	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Discussion of Comparable Items:

(1) Indications for Use

The subject device indications for use includes the models and measurement distance. Therefore, this difference does not affect the performance and accuracy

(2) Measurement Range

The measurement range of subject device is different from the predicate device. The performance testing shows that the subject device complies with the performance standard ISO 80601-2-56 and ASTM E1965-98. Therefore, this difference does not affect the performance and accuracy.

(3) Measurement distance

The measurement distance of subject device is a little different from the predicate device. The performance testing shows that the subject device complies with the performance standard ISO 80601-2-56 and ASTM E1965-98. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness of the subject device.

(4) Response time

The response time of subject device is different from the predicate device. However, the software has been validated according to FDA's software guidance. The performance testing shows that the subject device complies with performance standard during performance testing ISO 80601-2-56 and ASTM E1965-98 and clinical testing. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness of the subject device.

(5) Memory

The memory of subject device is different from predicate device. The software function of memory of subject device has been verified during software verification according to FDA's software guidance, and the performance testing shows that the subject device complies with performance standard ISO 80601-2-56 and ASTM E1965-98performance and clinical testing. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness of the subject device.

(6) Shelf Life, IP Classification, Backlight

The shelf life, ingress protection classification, and backlight of the predicate were not available. However, the device is comparable to other devices on the market. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness of the subject device.

(7) Power supply

The power supply of subject device for model: JZK-602 is the same with the predicate device, but the power supply of subject device for model: JZK-601/JZK-603 is different from the predicate device. However, the both of the subject device has been demonstrated to comply with the requirements of electrical safety IEC 60601-1 and Electromagnetic Compatibility IEC 60601-1-2. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(8) Operation Environment

The operation environment of subject device is different from the predicate device, but the measurement accuracy of subject device has been demonstrated to comply with the requirements of standards IEC 60601-1 and ISO 80601-2-56 in operation environment. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(9) Storage Environment

The operation and storage environment of subject device is different from the predicate device, but the subject device has been demonstrated to comply with the requirements of standards IEC

60601-1 and ISO 80601-2-56. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

(10) Dimension, Weight

The dimension and weight of subject device is different from the subject device. The difference is caused by their different appearance and construction, but the electrical safety, electromagnetic compatibility, performance of subject device has been evaluated to meet the requirements of the standards IECS60601-1, IEC 60601-1-2, ASTM E1965-98 and ISO 80601-2-56. Therefore, we considered that the difference does not raise any issues on the device safety and effectiveness.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has been tested in compliance with the following standards:

1) AAMI/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 device has been tested in compliance with the 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 device has been tested in compliance with the 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

The software documentation of the subject device 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.

8. Clinical Study

The clinical study is conducted as the requirement of ASTM E1965-98 (Reapproved 2016). The test report showed the clinical performance of the subject device complied with the requirement of ASTM E1965-98(Reapproved 2016).

The clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation. The clinical study evaluated 200 subjects, and the infrared forehead thermometer was evaluated in all age groups. All subjects were divided into three age groups, including (1)Infants – newborn to one year, (2)Children - greater than one to five years; (3)Adults - greater than five years old. 50 newborns 0 up to 3 months, 50 infants older than 3 months up to 1 year, 50 children older than 1 year and younger than 5 years, and 50 people older than 5 years are selected.

The clinical test report showed the clinical performance of the subject devices complied with the requirement of ASTM E1965-98(Reapproved 2016).

9. Conclusion

The subject device Infrared Forehead Thermometer (Model: JZK-601, JZK-602, JZK-603) is substantially equivalent to the predicate device (K191251). This conclusion is based upon comparison on intended use, technological characteristics and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.