January 15, 2021

Zhongshan Jinli Electronic Weighing Equipment Co., Ltd.
℅ Ms. Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town
Shenzhen, Guangdong 518000
China

Re: K201582
Trade/Device Name: Non-contact Electronic Forehead Infrared Thermometer, Model: FT3010
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 10, 2020
Received: December 18, 2020

Dear Ms. Yoyo Chen:

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,

CAPT Alan Stevens
Acting 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)*
K201582

Device Name
Non-contact Electronic Forehead Infrared Thermometer, Model: FT3010

Indications for Use *(Describe)*
The Non-contact Electronic Forehead Infrared Thermometer, Model FT3010 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

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

K201582

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

Submission Date	May 27, 2020
Manufacturer information	Zhongshan Jinli Electronic Weighing Equipment Co., Ltd. Address: 283rd South Min'an Road, Xiaolan Town, Zhongshan City, Guangdong Province, 528416, P.R.China Contact person: Mr. Jerry Liang TEL: +86(0760) 28133793; +86 13928121219 FAX: +86(0760) 28133793 E-Mail: jerry@kinleehealth.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. Yoyo Chen E-Mail: yoyo@cefda.com; field@cefda.com

卓远天成

2. Device Information

Device Name:	Non-contact Electronic Forehead Infrared Thermometer
Model:	FT3010
Classification Name:	Clinical Electronic Thermometer
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer	Microlife Intellectual Property GmbH
Device name	Microlife Non-Contact Infrared Forehead Thermometer
Model	FR1DG1 (NC200)
510(K) Number:	K191829
Product Code	FLL

4. Device Description

Non-contact Electronic Forehead Infrared Thermometer, Model FT3010 is a hand-held, battery powered IR thermometer. It is intended to measure the temperature of human body from forehead without contact to human body. It is indicated for use by people of all ages in the home.

The work principle of Non-contact Electronic Forehead Infrared Thermometer, Model FT3010, is by using the infrared sensor converts the radiated power into an electrical signal, electrical signal is processed by the ambient temperature compensation circuit and an internal MCU circuit. The electrical signal is displayed in degrees Celsius (or Fahrenheit) on LCD.

The Non-contact Electronic Forehead Infrared Thermometer has the following features:

- Measure the forehead temperature;
- Provide the prompt tone for high or low body temperature alert;
- Equip with 32 sets of measurement memories;
- LCD digital displayer with backlight;
- Display unit of Fahrenheit or Celsius;
- Automatic shutdown feature to save energy;
- Low battery detection;

5. Indications for Use

The Non-contact Electronic Forehead Infrared Thermometer, Model FT3010 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.

6. Comparison with predicate device

The subject device Non-contact Electronic Forehead Infrared Thermometer, Model FT3010 is substantially equivalent to the predicate device (K191829). The comparison of technological characteristics between the subject device and predicate device is listed as follows:

Items	Subject Device (K201582)	Predicate Device (K191829)	Comparison
Intended use	The Non-contact Electronic Forehead Infrared Thermometer, Model FT3010 is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.	Same
Thermometer type	Infrared thermometer Non-contact	Infrared thermometer Non-contact	Same
Device Measurement Technology	Infrared radiation detection	Infrared radiation detection	Same
Measurement location	Forehead	Forehead	Same
Measurement Range	Body temperature: 22.0~43.0°C (71.6~109.4°F);	Body mode: 34.0°C -43.0 °C (93.2-109.4 °F);	Different Note (1)
Measurement accuracy	Body temperature: 22.0°C ~43.0 °C: ±0.2 °C 71.6°F ~109.4°F: ±0.4°F	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 34°C ~ 34.9°C, 42.1°C ~43°C, ±0.4 °F: 95.0 ~ 107.6 °F, ±0.5 °F: 93.2 ~94.8 °F， 107.8~109.4 °F	Different Note (1)
Temperature Measurement distance	30mm~50mm	Appropriate within 5 cm	Similar
Display Type	LCD Display	LCD Display	Same
Display resolution	0.1°C (0.1°F)	0.1°C (0.1°F)	Same
Power supply	DC 3V (2 x AA LR6 batteries)	DC 3V (2x 1.5V AAA batteries)	Different Note (2)
Measurement time	≤ 1second	≤ 3 second	Different Note (3)
Measurement data memories	32 sets memories	30 sets memories	Different Note (4)

Items	Subject Device (K201582)	Predicate Device (K191829)	Comparison
Beeper setting	Yes	Yes	Same
Date and time setting	No	Yes	Different Note (5)
Backlight	White backlight	Green and red backlight according to the measured temperature;	Different Note (6)
Auto-off time	Approx. 10 second after last measurement has been taken	Approx. 1 minute after last measurement has been taken	Different Note (7)
Operation Condition	Ambient Temperature: 16°C~40°C (60.8°F~104°F) Relative humidity: 15%~95%RH (non-condense) Atmospheric pressure: 860-1060hPa	Ambient Temperature: 15°C~40°C (59°F~104°F); Relative humidity: 15%~95%RH	Different Note (8)
Storage and transportation condition	Ambient Temperature: -20°C~50°C (-4°F~122°F) Relative humidity: 15%~95%RH (non-condense) Atmospheric pressure: 860-1060hPa	Ambient Temperature: -25°C~55°C(-13°F～131°F); Relative humidity: 15%~95%RH	Different Note (8)
IP Class	IP22	IP22	Same
Error	Display Err when system has malfunction	Display Er0 or Er6 when system has malfunction	Different Note (9)
High temperature alarm	3 short beeps and LCD display " H ı " while equal to or higher than 37.5°C	10 short beeps and a red LCD backlight alerts that the temperature equal to or higher than 37.5°C	Different Note (10)
Auto measurement	No	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	Different Note (11)
Sensor type	STP583F55	TPS336	Different Note (12)
Housing material	ABS/PA-757	ABS/PA 707	Different Note (13)
Button material	ABS/PA-757	PMMA	Different

Items	Subject Device (K201582)	Predicate Device (K191829)	Comparison
			Note (13)
IC (Integrated Circuitry)	HY11P13	HY11P14	Different Note (12)
Physical Dimensions	90*43*148mm	156.7*43*47 mm	Different Note (15)
Safety & Performance	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2017; ASTM E1965-98.	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2017; ASTM E1965-98.	Same
Biocompatibility	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	Same
Clinical Study Support	Yes	Yes	Same

Note 1: Measurement Range and Accuracy
Compare with the predicate device, the subject device has a wider body temperature measurement range, and the accuracy in the temperature range is different. The difference does not affect the performance and accuracy which was evaluated in the performance testing of ISO 80601-2-56 and ASTM E1965-98. The difference does not raise new safety and effectiveness questions.

Note 2: Power supply
The electrical safety of the subject device complies with standard IEC 60601-1. The difference does not raise new issues on the device safety and effectiveness

Note 3: Measurement time
The measurement time of subject device is much quicker than predicate device, the accuracy of measurement has been validated during performance testing. The difference does not raise new issues on the device safety and effectiveness.

Note 4: Measurement data memories
This function has been verified during software verification. The difference does not raise new issues on the device safety and effectiveness.

Note 5: Date and time setting
Although there is no date and time setting functions for subject device, but both subject device and predicate device are meet the basic safety requirement of IEC 60601-1, ASTM E1965-98, and ISO 80601-2-56. The difference does not raise new issues on the device

safety and effectiveness.

Note 6: Backlight
The subject device and predicate device are all tested in according to ISO 80601-2-56 and ASTM E1965-98. The difference does not raise new issues on the device safety and effectiveness.

Note 7: Auto-off time
Both subject device and predicate device are met the basic safety requirement of ISO 80601-2-56 and ASTM E1965-98. The difference does not raise new issues on the device safety and effectiveness.

Note 8: Operation Condition, Storage and transportation condition
The subject device has been demonstrated to comply with the requirements of electrical safety IEC 60601-1, IEC60601-1-11, and ASTM E1965-98 standard. The difference does not raise new issues on the device safety and effectiveness.

Note 9: Error
Although the icons are different, but the purpose means are the same. It does not affect device's performance, safety and effectiveness.

Note 10: High temperature alarm
Even though the beeping time is different, but the purpose of the alarm is the same. It does not affect device's performance, safety and effectiveness.

Note 11: Auto measurement
The purpose of body temperature measurement can be achieved for subject device and predicate device. The subject device performance complies with ISO 80601-2-56 and ASTM E1965-98. The difference does not raise new issues on the device safety and effectiveness.

Note 12: Sensor type, IC
The subject device was tested to conform with same safety and performance standard IEC 60601-1, ASTM E1965-98, and ISO 80601-2-56. A clinical study was carried out on the subject device in accordance with ASTM E1965-98. The different will not arise new safety and effectiveness issues.

Note 13: Housing material, button material
Although the housing material and button material of the subject device and predicate device are different, but they are all compliance with the biocompatibility standards ISO 10993-5 and ISO 10993-10. The difference does not raise new issues on the device safety and effectiveness.

Note 15: Physical Dimensions
The appearance of the subject device and predicate device is different. The subject device has been tested and confirmed according to IEC 60601-1-2, IEC 60601-1, and ISO 80601-2-56 standards. The difference does not raise new issues on the device safety and effectiveness.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety testing in according to following standards.

1) 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 passed biocompatibility tests in according to following standards.

4) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
5) 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 passed performance testing in according to following standard.

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

7.4. Software Validation

Software documentation consistent with moderate level of concern was submitted in this 510(k) in according to FDA guidance - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005.

8. Clinical Study

Clinical study was conducted in according to ASTM E1965-98(Reapproved 2016). This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consisting of 150 subjects, of which 50 subjects are infants (newborn to 1 year), 50 subjects are children (1 - 5 years old) and 50 subjects are > 5 years old. The clinical test report demonstrated that the clinical data, represented by clinical bias and clinical repeatability met the acceptance criteria of the clinical study protocol.

9. Conclusion

Based on the performance testing, technological characteristics and analysis, the subject device is substantially equivalent to the predicate device.