February 10, 2021

Hangzhou Qingyuan Medical Equipment Technology Co., Ltd.
℅ Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue
Xili Town
Shenzhen, Guangdong 518000
China

Re: K201536
Trade/Device Name: Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 28, 2020
Received: January 4, 2021

Dear 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,

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)*
K201536

Device Name
Infrared Forehead Thermometer, Model QY-EWQ-02

Indications for Use *(Describe)*
The infrared forehead thermometer is non-sterile, reusable, non-contact and handheld device for the intermittent measurement and monitoring of human body temperature from the center of the forehead from a measurement distance of 3-5 cm. It can be used by consumers in homecare environment and doctors in clinic. It is intended for measuring human body temperature of people of all ages.

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."

K201536 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

Submission Date	February 10, 2021
Manufacturer information	Hangzhou Qingyuan Medical Equipment Technology Co., Ltd. Address: No.688 Dong'an 1st Road, Xintang Street, Xiaoshan District, Hangzhou,China 311200 Contact person: Jenny TEL: +86(0571) 82623931 E-Mail: Jenny@aodicharger.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. 518000 Contact person: Ms. Yoyo Chen TEL:+86(755) 86069197 E-Mail: yoyo@cefda.com; field@cefda.com
Establishment registration number	3016658659

2. Device Information

Device Name:	Infrared Forehead Thermometer
Model:	QY-EWQ-02
Classification Name:	Clinical Electronic Thermometer (Infrared Thermometer)
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	21 CFR 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

The infrared forehead thermometer, Model of QY-EWQ-02 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 infrared forehead thermometer has the following features:

1) This device can be used for measuring the forehead temperature;
2) Body and object temperature switching
3) Two temperature unit conversion, °C or °F;
4) LCD display with backlight;
5) Automatic range selection; resolution is 0.1°C (0.1°F)
6) The latest 20 measurement data can be memorized and stored;
7) Three color backlight display (Red, Orange, Green);
8) Low battery detection;
9) Turn on/off the prompt tone;
10) High temperature alarm limit setting;
11) Ambient temperature detection;
12) Malfunction indication;
13) Low and high temperature alarm

5. Indication for Use

The infrared forehead thermometer is non-sterile, reusable, non-contact and handheld device for the intermittent measurement and monitoring of human body temperature from the center of the forehead from a measurement distance of 3-5 cm. It can be used by consumers in homecare environment and doctors in clinic. It is intended for measuring human body temperature of people of all ages.

6. Comparison with predicate device

The subject device Infrared Forehead Thermometer (Model QY-EWQ-02) 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 (K201536)	Predicate Device (K191829)	Comparison
Intended use	The infrared forehead thermometer 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	32.0°C ~43.0°C (89.6°F～109.4°F);	32.0°C ~43.0°C (89.6°F～109.4°F);	Same
Measurement accuracy	±0.2 °C: 32.0°C ~ 43.0 °C ±0.4 °F: 89.6°F～109.4°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)
Clinical Repeatability	≤0.2 °C (0.4 °F)	unknown	Different (Note 1)
Temperature Measurement distance	3 to 5 cm	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(2x 1.5V AAA batteries)	DC 3V (2x 1.5V AAA batteries)	Same
Measurement time	≤ 1second	≤ 3 second	Different (Note 2)
Measurement data memories	20 sets memories	30 sets memories	Different (Note 3)

Items	Subject Device (K201536)	Predicate Device (K191829)	Comparison
Beeper setting	Yes	Yes	Same
Date and time setting	No	Yes	Different (Note 4)
Backlight	Green, yellow and red backlight according to the measured temperature;	Green and red backlight according to the measured temperature;	Different (Note 5)
Auto-off time	Approx. 13 seconds after last measurement has been taken	Approx. 1 minute after last measurement has been taken	Different (Note 6)
Operation Condition	Ambient Temperature: 15°C～40°C（59°F～104°F）; Relative humidity: 15%~95%RH	Ambient Temperature: 15°C～40°C（59°F～104°F）; Relative humidity: 15%~95%RH	Same
Storage and transportation condition	Ambient Temperature: -25°C～55°C（-13°F～131°F）; Relative humidity: 15%~95%RH	Ambient Temperature: -25°C～55°C（-13°F～131°F）; Relative humidity: 15%~95%RH	Same
IP Class	IP22	IP22	Same
Error	Display Err when system has malfunction	Display Er0 or Er6 when system has malfunction	Different (Note 7)
High temperature alarm	5 short beeps and a red LCD backlight alerts that the temperature 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 8)
Auto measurement	None	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	Different (Note 9)
Sensor type	SGXV02-100-000-100	TPS336	Different (Note 10)
Housing material	ABS/PA-757	ABS/PA 707	Different (Note 11)
Button material	ABS/PA-757	PMMA	Different (Note 11)
IC (Integrated Circuitry)	STM8l101	HY11P14	Different (Note 10)
Physical Dimensions	155*87.7*44mm	156.7*43*47 mm	Different (Note 12)

Items	Subject Device (K201536)	Predicate Device (K191829)	Comparison
Safety & Performance	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2018; ASTM E1965-98.	IEC 60601-1:2005+AMD 1: 2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015; ISO 80601-2-56: 2018; 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 accuracy, Clinical Repeatability

Compare with predicate device, the measurement accuracy and clinical repeatability is different. But 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 different will not arise new safety and effectiveness issue.

Note 2: 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 3: 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 4: 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 5: 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 6: 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 7: Error
Although the icons are different, but the purpose means are the same. It does not affect device's performance, safety and effectiveness.

Note 8: High temperature alarm
Even though the beeping time is different, but the purpose means are the same. It does not affect device's performance, safety and effectiveness.

Note 9: 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 10: 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 11: Housing material, Button material
Although the housing material and button material for 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 12: 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.

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 passed performance testing in according to following standard.

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 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 Accuracy Validation 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, 50 subjects are children and the rest 50 subjects are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five 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, Microlife Non-Contact Infrared Forehead Thermometer cleared under K191829.