July 7, 2021

Shenzhen Combei 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: K202741
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: May 24, 2021
Received: June 7, 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,

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)*
K202741

Device Name
Infrared Forehead Thermometer, Model:FR200

Indications for Use *(Describe)*
Infrared Forehead Thermometer is intended for the intermittent measurement and monitoring of forehead 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.

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510K 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

The date the summary was prepared	May 24, 2021
Manufacturer information	Shenzhen Combei Technology Co., Ltd. Address: Floor 3, Bldg. B, Jinxiongda Technology Park, No.105, Huanguan South Road, Dahe Community, Guanlan, Long Hua District, Shenzhen, Guangdong, China, 518110 Contact person: Kevin Fong TEL: 086-755-29588956 E-Mail: kevin.fong@combei.cn
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 Tel: +86(755)86069197 E-Mail: yoyo@cefda.com; field@cefda.com
Establishment registration number	3013561145

2. Device Information

Device Name:	Infrared Forehead Thermometer
Model:	FR200
Common name:	Clinical Electronic Thermometer (Infrared Thermometer)
Classification Name:	Thermometer, Electronic, Clinical
Review Panel:	General Hospital
Device Class:	Class II
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
Regulation Number:	880.2910
Device Class:	Class II
Product Code	FLL

4. Device Description

The Infrared Forehead Thermometer, model FR200 is a hand-held forehead thermometer and it is intended for the non-contact intermittent measurement and monitoring of forehead temperature which is based on the infrared energy emitted from the forehead. It is indicated for use by people of all ages in the home.

After measurement, the temperature is directly shown on the LCD display so that the users can quickly get measurement results after properly scanning the forehead. The features of the thermometer are as follow:

1) This device can be used for measuring the body temperature and object temperature
2) Measurement in a matter of seconds;
3) Switching between °C and °F;
4) Automatic range selection; resolution is 0.1°C (0.1 °F);
5) Body mode and object mode switching
6) Low battery indication, and auto shut-down;
7) With a high and low temperature alarm function (color and sound indication);
8) Multiple reading recall (30 sets data could be stored and recalled);
9) Two color backlight display:
10) Ambient detection

5. Indication for Use

Infrared Forehead Thermometer is intended for the intermittent measurement and monitoring of forehead temperature. The device is indicated for use by people of all ages in the home.

6. Comparison with Predicate Device

The subject devices are 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 (K202741)	Predicate Device (K191829)	Comparison
Product code	FLL	FLL	Same
Regulation number	880.2910	880.2910	Same

Items	Subject Device (K202741)	Predicate Device (K191829)	Comparison
Device class	2	2	Same
Intended use	Infrared Forehead Thermometer is intended for the intermittent measurement and monitoring of forehead 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	34.0°C~43.0°C (93.2°F ~ 109.4° F);	34.0°C -43.0 °C (93.2-109.4 °F);	Same
Measurement accuracy	±0.2°C (±0.4°F): 34.0°C ~ 43.0°C (93.2°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)
Temperature Measurement distance	3cm~5cm	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	d.c.3.0V (2pcs AAA batteries)	d.c.3.0V (2pcs AAA batteries)	Same
Measurement data memories	30 sets memories	30 sets memories	Same
Backlight	Green and red backlight according to the measured temperature;	Green and red backlight according to the measured temperature;	Same
Auto-off time	Approx. 1 minute after last measurement has been taken	Approx. 1 minute after last measurement has been taken	Same
Operation Condition	Temperature: 16-40.0 °C (60.8-104.0 °F) Humidity: 15-95%RH, non-condensing	Ambient Temperature: 15°C~40°C（59°F~104°F）; Relative humidity: 15%~95%RH	Different (Note 2)

Items	Subject Device (K202741)	Predicate Device (K191829)	Comparison
Storage and transportation condition	Temperature: -20 °C to +50 °C (-4 °F to 122 °F) Humidity:15-95 % relative maximum humidity(non-condensing)	Ambient Temperature: -25°C~55°C（-13°F～131°F）; Relative humidity: 15%~95%RH	Different (Note 2)
Protection against electric shock	Internally power supply, Type BF	Internally power supply, Type BF	Same
IP Class	IP22	IP22	Same
High temperature alarm	Yes	Yes	Same
Auto measurement	No	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	Different (Note 3)
Sensor type	Thermopile	Thermopile	Same
Housing material	ABS/ PA-757	ABS/PA 707	Different (Note 4)
Patient-contact button material	ABS/ PA-757	PMMA	Different (Note 4)
Display case	PMMA/CM-203	unknown	Different (Note 4)
Physical Dimensions	145 x 36 x 33 mm	156.7*43*47 mm	Similar
Weight	62g (without battery)	68.5 g (Battery excluded)	Similar
Expected Service Life	5 year	5 year	Same
Safety & Performance	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; ISO 80601-2-56; ASTM E1965-98.	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; ISO 80601-2-56; 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 Accuracy Support	Yes	Yes	Same

Note 1 Measurement accuracy

The measurement accuracy for the subject device is different with the predicate device. 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 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 3 Auto measurement

The predicate device can take a measurement automatically when the device detects the distance is appropriate within 5 cm. The purpose of auto measurement is to obtain the body temperature. However, for the subject device, the user can read the body temperature by aim the probe at the center of the forehead and keep distance of no more than 3~5cm and press measurement button. The measurement function has been verified during software verification and validation. Otherwise, a clinical study was carried out on 160 subjects for all ages of population, it is demonstrating the subject device clinically safe and effective with all age groups. The difference does not raise new issues on the device safety and effectiveness.

Note 4 Housing material, Patient-contact button material and Display case

Although the patient contact materials 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.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject devices have 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 devices have 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 devices have passed performance testing in according to following standard.

1) 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
2) ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

7.4. Software verification and 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

Clinical accuracy testing was conducted in according to ASTM E1965-98(Reapproved 2016) and ISO 80601-2-56:2017. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consisting of 180 subjects, of which 60 subjects are infants, 60 subjects are children and the rest 60 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

The Infrared Forehead Thermometer (Model FR200) is substantially equivalent to the predicate device (K191829). 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.