February 18, 2022

Guangzhou Berrcom Medical Device Co., Ltd.
% Yoyo Chen
Senior Consultant
Shenzhen Joyantech Consulting Co.,Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K213079
Trade/Device Name: Ear Thermometer, Model ET001
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 12, 2022
Received: January 18, 2022

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
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)*
K213079

Device Name
Ear Thermometer, Model: ET001

Indications for Use *(Describe)*
The Ear Thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It is a non-contact measurement method for forehead measurement, the recommended measurement distance is 0cm to 3cm. The Ear Thermometer can be used by consumers in the household environment and by healthcare providers.

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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510(k) Summary - K213079

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	January 12, 2022
Manufacturer information	Guangzhou Berrcom Medical Device Co., Ltd. Address: No.38 Huanzhen Xi Road, Dagang Town, Nansha, 511470, Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA Contact person: Zhigang Du TEL: +86(20)34938449 E-Mail: dube888@berrcom.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
Establishment registration number	3008395508

2. Device Information

Type of 510(k) Submission:	Traditional
Device Name:	Ear Thermometer
Model:	ET001
Classification Name:	Clinical Electronic Thermometer (Infrared Thermometer)
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer:	Guangzhou Berrcom Medical Device Co., Ltd.
Device Name:	Infrared Thermometer Model MD-H30
Model:	MD-H30

4. Device Description

The Ear Thermometer, model of ET001 is a hand-held, battery powered infrared thermometer. It is intended to measure the temperature of human body from ear or forehead. The infrared sensor contained in the device can monitor the energy radiated from the human ear tympanum and forehead. The device can analyze and processes the signal transmitted by the infrared sensor, and finally displays it on the screen in digital form to achieve the measurement of human body temperature. People of all ages in household environment and doctors in clinic as reference are suitable for using the device.

It has the following features:

1) Forehead and ear temperature measurement.
2) Fahrenheit and Celsius temperature unit setting.
3) Display resolution is 0.1°C (0.1°F);
4) Memorize the latest 10 measurement data;
5) Three color backlight display (red, orange, green)
6) Low battery indication.
7) Prompt for Measurement completion.
8) Buzzer feature setting (mute or unmute)
9) Turn off automatically after 75 seconds of inactivity.

5. Intended Use/Indications for Use

The Ear Thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It is a non-contact measurement method for forehead measurement, the recommended measurement distance is 0cm to 3cm. The Ear Thermometer can be used by consumers in the household environment and by healthcare providers.

6. Comparison with predicate device

Items	Subject Devices (K213079)	Predicate Device (K191570)	Comments
Product Code	FLL	FLL	Same
Regulation number	880.2910	880.2910	Same
Manufacturer	Guangzhou Berrcom Medical Device Co., Ltd.	Guangzhou Berrcom Medical Device Co., Ltd.	Same
Indications for use	The Ear Thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It is a non-contact measurement method for forehead measurement, the recommended measurement distance is 0cm to 3cm. The Ear Thermometer can be used by consumers in the household environment and by healthcare providers.	The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.	Same
Thermometer type	Digital thermometer	Digital thermometer	Same
Sensor	Thermopile	Thermopile	Same
Operational principle	Infrared radiation detection	Infrared radiation detection	Same
Measurement mode	Adjusted mode	Adjusted mode	Same
Measurement reference body site	Axilla	Axilla	Same
Measurement method	Non-contact Type	Non-contact Type	Same
Measurement distance of forehead measurement	0cm to 3cm	0cm to 3cm	Same
Patient population	People of all ages	People of all ages	Same
RX/OTC Use	OTC	OTC	Same
Display type	LCD	LCD	Same
Measurement site	Forehead and ear	Forehead and ear	Same
Measurement Range	Ear & Forehead: 32.0°C ~ 43.0°C (89.6°F ~ 109.4°F)	Ear & Forehead: 32.0°C~43°C (89.6°F~109.4°F)	Same
Measurement accuracy	32.0°C~ 34.9°C(89.6°F~94.8°F) : ±0.3°C(±0.5°F) 35.0°C~ 42.0°C(95°F~107.6°F): ±0.2°C(±0.4°F); 42.1°C~ 43.0°C(107.8°F~109.4°F): ±0.3°C(±0.5°F)	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	Same

Items	Subject Devices (K213079)	Predicate Device (K191570)	Comments
Display resolution	0.1°C (0.1°F)	0.1°C (0.1°F)	Same
Power supply	DC 3V (2pcs AAA batteries)	DC 3V (2pcs AAA batteries)	Same
Measurement time	1 second	1 second	Same
Measurement data memories	10sets	20 sets	SE (Note 1)
Beeper setting	Yes	Yes	Same
Backlight	Yes	Yes	Same
Auto-off time	75s	30s	SE (Note 2)
Audible alert	Yes	Yes	Same
Use of probe covers	No	No	Same
Operation Condition	Temperature: 10°C~40°C Relative Humidity: ≤85%, Atmospheric Pressure: 70kPa~106kPa	Temperature: 10°C~40°C Relative Humidity: ≤85% Atmospheric Pressure: 70kPa~106kPa	Same
Storage and transportation condition	Temperature: -20°C~55°C Relative Humidity: ≤95%RH, noncondensing Atmospheric Pressure: 70kpa~106kpa	Temperature: -20°C~55°C Relative Humidity: ≤95%RH, Atmospheric Pressure: 70kpa~106kpa	Same
IP Class	IP22	IP22	Same
Materials of skin-contacting components	ABS, PC	ABS	SE (Note 3)
Physical Dimensions	126×35×45mm (L x W x H)	156mm*46mm*48mm(L x W x H)	SE (Note 3)
Weight	66g	77g	SE (Note 3)

Note 1: Measurement data memories

The subject device meets the basic safety requirement of IEC 60601-1:2005+AMD 1: 2012, IEC 60601-1-11, IEC 80601-2-56 and ASTM E1965-98. The difference does not raise any issues on the device safety and effectiveness.

Note 2：Auto-off time

Although the time of auto-off time will longer than predicate device, but both of subject devices and predicate device are meet the basic safety requirement of IEC 60601-1:2005+AMD 1: 2012, and IEC 60601-1-11. The difference does not raise any issues on the device safety and effectiveness.

Note 3: Materials of skin-contacting components, Physical Dimensions, and weight

The biocompatibility tests have conducted on the subject device to demonstrate that the subject device did not have any potential toxicity, skin sensitization and skin irritation during

normal use. Otherwise, the subject device has passed the electrical safety tests in according to IEC 60601-1-2, IEC 60601-1, and IEC 60601-1-11 to demonstration that the subject device could be as safe as the predicate device in the intended use environment, and the performance testing shows that the subject device complies with performance standard ISO80601-2-56 and ASTM E1965-98. 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 meets the following standards:

1) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)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 tests in according to 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 and Validation

Software documentation consistent with ***moderate level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

8. Clinical Accuracy Validation

Clinical accuracy validation was conducted in according to ISO 80601-2-56:2017+AMD2018. 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 validation results demonstrated that the clinical data, represented by clinical bias and clinical repeatability met the acceptance criteria of the clinical validation protocol.

9. Conclusion

The Ear Thermometer (Model: ET001) is substantially equivalent to the Infrared Thermometer Model MD-H30 cleared under K191570. This conclusion is based upon comparison on intended use, technological characteristics and applicable safety standards. Any difference in the technological characteristics do not raise any new issues or concerns of safety or effectiveness.