January 20, 2023

Guangzhou Berrcom Medical Device Co., Ltd.
% Liz Li
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square,
Liuxian Avenue, Xili Town
Shenzhen, Guangdong 518000
China

Re: K214077
Trade/Device Name: Digital Thermometer, Model: DT007, DT008
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 14, 2022
Received: December 21, 2022

Dear Liz Li:

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,

David Wolloscheck, Ph.D.
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)*
K214077

Device Name
Digital Thermometer, Model: DT007, DT008

Indications for Use *(Describe)*
DT007 Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral temperature measurement at home, and used for axillary, oral and rectal temperature measurement in the hospital. The rectal body temperature measurement cannot be used for multi-patient use at home. The product is reusable and provided nonsterile. The device is intended for use on people of all ages.

DT008 Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral temperature measurement at home, and used for axillary, oral and rectal temperature measurement in the hospital. The rectal body temperature measurement cannot be used for multi-patient use at home. The product is reusable and provided nonsterile. The device is intended for use on 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.

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K214077 - 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

Preparation Date	Dec.20, 2021
Manufacturer	Guangzhou Berrcom Medical Device Co., Ltd. Address: No. 38 Huanzhen Xi Road, Dagang Town, Nansha, Guangzhou, China. Contact person: Zhigang Du TEL: +86-020-34938449 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: Liz Li E-Mail: **liz@cefda.com**; grace@cefda.com
Establishment registration number	3008395508

2. Device Information

Type of 510(K):	Traditional
Submission:	K214077
Device Name:	Digital Thermometer
Model:	DT007, DT008
Classification Name:	Clinical Electronic Thermometer
Review Panel:	General Hospital
Device Class:	II
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer:	Smart Technology Co., Ltd.
Device Name:	Digital Thermometer
Model:	DT100
510(k) Number:	K203731
Product Code:	FLL

4. Device Description

The basic principle of Digital Thermometer is that a change in thermistor resistance is caused by a change in temperature. The device measure body temperature by using a direct mode. The resistance is measured by a microcontroller unit, so that changes in temperature will correspond to

changes in resistance. And the temperature value is displayed on the LCD screen.
The device can be used for axillary, oral in the home, and used for axillary, oral and rectal temperature measurement in the hospital. The device is reusable and provided non-sterile. The device is intended for use on people of all ages. The probe cover is required when measuring the oral or rectal temperature, but not when measuring the axillary temperature.
The Digital Thermometer includes two models: DT007 and DT008. The differences of these two models are in appearance, PCB layout, external dimension and weight. All of them have the same function and they have the following basic functions:

- Data displayed on LCD
- Automatic stop (energy saver)
- Small, convenient, easy to use

5. Intended Use/ Indications for Use

DT007 Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral temperature measurement at home, and used for axillary, oral and rectal temperature measurement in the hospital. The rectal body temperature measurement cannot be used for multi-patient use at home. The product is reusable and provided nonsterile. The device is intended for use on people of all ages.
DT008 Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral temperature measurement at home, and used for axillary, oral and rectal temperature measurement in the hospital. The rectal body temperature measurement cannot be used for multi-patient use at home. The product is reusable and provided nonsterile. The device is intended for use on people of all ages.

6. Comparison with Predicate Device

Items	Subject Device (K214077)	Predicate Device (K203731)	Comparison
Device name and model	Digital thermometer, (Model: DT007, DT008)	DT100 Digital Thermometer	/
Product code	FLL	FLL	Identical
Intended Use / Indications for Use	Digital Thermometer is intended for the measurement of human body temperature by doctors or customers in the hospital or at home. It can be used for axillary, oral temperature measurement at home, and used for axillary, oral and rectal temperature measurement in the hospital. The rectal body temperature measurement cannot be used for multi-patient use at home. The product is reusable and provided nonsterile. The device is intended for use on people of all ages.	DT100 Digital thermometer is intended for the measurement of human body temperature by doctor or consumers in the hospital or home. It can be used for axillary, oral and rectal measurement. The product is reusable and provided nonsterile. The device is for people of all ages.	Similar#1
Principle of operation	Thermistor resistance technology.	Thermistor resistance technology.	Identical
Measurement site	axillary, oral and rectal	axillary, oral and rectal	Identical
Where used	Hospital or home	Hospital or home	Identical
Operation environment condition	Ambient temperature: 5℃～40℃ (41℉～104℉) Relative humidity: ≦85% Pressure altitude: 700hPa to 1060hPa	16 to 40℃(60.8 to 104℉) and 15 to 95% humidity noncondensing;	Different#2
Storage condition	Storage temperature: -20℃～55℃ (-4℉～131℉) Storage humidity: ≦95% Pressure altitude: 700hPa ~ 1060hPa	-20 to 50℃ (-4 to 120℉) and 15 to 95% humidity noncondensing	

Components	Main part, display screen, control button, probe tip	Main part, display screen, control button, probe tip	Identical
Sensor name	Thermistor	Thermistor	Identical
Power Requirements	1.5V d.c	1.55V	Similar
Material used	Housing (including button): ABS Probe: Stainless steel	Enclosure: Acrylonitrile Butadiene Styrene probe: stainless steel button: silicone	Different#3
Measure temperature range	32°C ~ 42.9°C (89.6°F~109.2°F)	32°C ~42.9°C (89.6°F ~109.2°F)	Identical
Operating mode	Direct mode	Direct mode	Identical
Measuring accuracy	32.0°C ~35.9°C ±0.2°C 36.0°C ~39.0°C ±0.1°C 39.1°C ~42.9°C ±0.2°C	32°C- 42.9°C: +/-0.1°C	Different#4
Display resolution	0.1°C (0.1°F)	0.1°C/0.1°F	Identical
Response time	30s	60s	Different#5
Auto-off Time	10 mins	unknown	Different#6
Probe cover	Measure oral or rectal position: Use probe cover Measure axillary position: no require of probe cover	Measure oral or rectal position: Use probe cover Measure axillary position: no require of probe cover	Identical
Types of Tips	SUS304 stainless steel	unknown	Different#7
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10,	Comply with ISO 10993-5, ISO 10993-10,	Identical
Electric Safety and EMC	lEC 60601-1, lEC 60601-1-2, IEC 60601-1-11	lEC 60601-1, lEC 60601-1-2, IEC 60601-1-11	Identical
Performance	ASTM E1112, ISO 80601-2-56	ASTM E1112, ISO 80601-2-56	Identical
Device size	DT007: 128*18*10mm DT008: 125*19*11mm	unknown	Different#8
LCD size	23*11.3*9.15mm (L*W*H)	unknown	

Similar#1

The intended use of the subject device is described in more detail. The rectal measurement should be used in hospital because the high-level disinfection may only be done in hospital by health professionals. This is also specified in 【Warnings and precautions】in the user manual. This difference does not raise safety and effectiveness issues.

Similar#2

Although the “Operating environment condition” and “Storage condition” of subject device is different to the predicate device, the subject device has passed the performance test according to ASTM E1112 and ISO 80601-2-56. Additionally, the subject device was conformed to IEC 60601-1 and IEC 60601-1-11. Therefore, this difference would not raise adversely impact on safety and effectiveness.

Different#3

The materials used in the subject device is the same as the cleared device (K163603) from the same manufacturer. And the safety of the material has been demonstrated in the submission of K163603. Therefore, this difference would not raise adversely impact on safety and effectiveness.

Different#4

The measuring accuracy of subject device can meet the requirements of ASTM E1112 and ISO 80601-2-56. Therefore, this difference would not raise adversely impact on safety and effectiveness.

Different#5

The subject device has passed the performance test according to ASTM E1112 and ISO 80601-2-56. Therefore, this difference in the response time would not raise adversely impact on safety and effectiveness.

Different#6

Although the auto-off time of the predicate device is unknown, the 10-minute auto-off time of the subject device is sufficient for the intended user to obtain temperature data. Therefore, this difference would not raise adversely impact on safety and effectiveness.

Different#7

Although the information about the tips of the predicate device is unknown, the material of subject device is the same as that of the cleared device (K163603) from the same manufacturer. Additionally, the subject device has passed the performance test according to ASTM E1112 and ISO 80601-2-56. Therefore, this difference would not raise adversely impact on safety and effectiveness.

Different#8

Although the information about the size of the predicate device is unknown, the subject device has passed the performance test according to ASTM E1112 and ISO 80601-2-56. Therefore, this difference would not raise adversely impact on 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) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 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 and the cleared device (K163603) of the same manufacturer use the same human body contacting material, and has the same nature of body contact and contact duration. The safety of the material has been demonstrated in the submission of K163603, complying with the requirements of ISO 10993-1, ISO 10993-5 and ISO 10993-10.

7.3. Performance Test-Bench

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

1) ISO 80601-2-56: 2017+ A1:2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

2) ASTM E1112-00 (Reapproved 2011) Standard Specification for Electronic Thermometer 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.

7.5. Clinical Test Summary

No clinical testing was performed.

8. Conclusion

The subject device digital thermometer (Model: DT007, DT008) is substantially equivalent to the predicate device (K203731). This conclusion is based upon comparison on intended use, technological characteristics and performance testing.