January 28, 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: K213082
Trade/Device Name: Non-contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 14, 2021
Received: December 27, 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,

Gang Peng for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213082

Device Name
Non-contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311

Indications for Use *(Describe)*
The Non-Contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311, is a non-sterile, reusable, handheld device. It can be used by consumers in household environment and doctor in clinic as reference. It is intended for non-contact measuring of human body temperature of people of all ages (neonate, infant, pediatric, adult) by detecting infrared heat from the center of the forehead.

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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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	December 14, 2021
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:	Non-contact Infrared Thermometer
Models:	JXB-315, JXB-319, JXB-320, JXB-311
Classification Name:	Thermometer, Electronic, Clinical
Review Panel:	General Hospital
Device Class:	2
Regulation Number:	880.2910
Product Code:	FLL

3. Predicate Device

Manufacturer:	BroadMaster Biotech, Corp.
Device Name:	Advocate Non-Contact Infrared Thermometer
Model:	EF001A

4. Device Description

The Non-contact Infrared Thermometer (include models JXB-315, JXB-319, JXB-320, JXB-311) is a hand-held forehead thermometer, and it is intended for the non-contact intermittent measurement and monitoring of forehead temperature of human body which measures the body temperature based on the infrared energy emitted from the forehead. It is indicated for use by people of all ages.

The thermometer is also intended to measure the object temperature. After measurement, the temperature is directly displayed on the LED screen.

These thermometers have the following features:

1) Body temperature mode
2) Fahrenheit and Celsius temperature unit setting
3) LED display screen with automatic range selection, resolution is 0.1°C (0.1°F)
4) Memorize the latest 32 measurement data
5) LED display screen
6) Low battery indication
7) Measurement distance indication
8) Over range prompt (HI/LO)
9) Auto shutdown when the device is idle for 30 seconds
10) High temperature indication

5. Intended Use

The Non-Contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311, is a non-sterile, reusable, handheld device. It can be used by consumers in household environment and doctor in clinic as reference. It is intended for non-contact measuring of human body temperature of people of all ages (neonate, infant, pediatric, adult) by detecting infrared heat from the center of the forehead.

6. Comparison with predicate device

Items	Subject Devices (K213082)	Predicate Device (K180355)	Comments
Product Code	FLL	FLL	Same
Regulation number	880.2910	880.2910	Same
Manufacturer	Guangzhou Berrcom Medical Device Co., Ltd.	BroadMaster Biotech, Corp.	/
Indications for use	The Non-Contact Infrared Thermometer, Models JXB-315, JXB-319, JXB-320, JXB-311, is a non-sterile, reusable, handheld	Advocate Non-Contact Infrared Thermometer is a non-sterile, reusable, handheld device. It can be	Same

Items	Subject Devices (K213082)	Predicate Device (K180355)	Comments
	device. It can be used by consumers in household environment and doctor in clinic as reference. It is intended for non-contact measuring of human body temperature of people of all ages (neonate, infant, pediatric, adult) by detecting infrared heat from the center of the forehead.	used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.	
Prescription/OTC	OTC use	OTC use	Same
Intended user	Lay user and professional	Lay user and professional	Same
Intended patient population	Neonate, infant, pediatric, adult	Neonate, infant, pediatric, adult	Same
Sensor	Thermopile	Thermopile	Same
Operational principle	Infrared radiation detection	Infrared radiation detection	Same
Contact type	Non-contact use	Non-contact use	Same
Display type	LED display	LCD display	SE (Note 1)
Measurement site	Forehead	Forehead	Same
Measurement Range	32.0°C ~ 43.0°C (89.6°F ~ 109.4°F)	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(±0.6°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(±0.6°F)	34.0°C~ 34.8°C(93.2°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)	SE (Note 2)
Measurement distance	≤3cm (1.2in)	5-10 cm (2-3.94in)	SE (Note 3)
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
Memory capacity	32sets	12 sets	SE (Note 4)
Low battery	Yes	Yes	Same

Items	Subject Devices (K213082)	Predicate Device (K180355)	Comments
indication			
Degree of protection	IP22	IP20	SE (Note 5)
Auto-off time	30s	60s	SE (Note 6)
Operation Condition	Temperature: 10°C~40°C Relative Humidity: ⩽85%, Atmospheric Pressure: 70kPa~106kPa	Temperature: 10°C~40°C Relative Humidity: ⩽80% Atmospheric Pressure: 70kPa~106kPa	SE (Note 7)
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
Materials of skin-contacting components	ABS, PC	Enclosure of red &black ABS, LCD Lens of PMMA and Probe of Metals	SE (Note 8)
Biocompatibility	Comply with ISO10993-5:2009 & ISO10993-10:2010	Comply with ISO10993-5:2009 & ISO10993-10:2010	Same
Electrical safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC60601-1-2	IEC60601-1-2	Same
Performance	ASTM E1965-98 ISO80601-2-56	ASTM E1965-98 ISO80601-2-56	Same

Note 1: Display type

The subject device meets 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 2: Measurement Accuracy

The measurement accuracy of subject devices in the range of 34°C to 43°C is same with predicate device, and the measurement accuracy of subject device still compiles with the requirement of ASTM E1965-98 and ISO 80601-2-56 standard. This difference does not raise any issues on the device safety and effectiveness.

Note 3: Measurement distance

The performance of subject device within the specified measurement distance compiles with the requirement of ASTM E1965-98 and ISO 80601-2-56 standard. This difference does not raise any issues on the device safety and effectiveness.

Note 4: Memory capacity

The purpose of function of measurement data memories is intended to store and view the previous readings. This function has been verified during software verification, and the performance testing shows that the subject device complies with performance standard ISO 80601-2-56 and ASTM E1965-98. The difference does not raise any issues on the device safety and effectiveness.

Note 5: Degree of protection

The subject device complies with the requirement of IEC60601-1, ASTM E1965-98 and ISO 80601-2-56 standard. The difference does not raise any issues on the device safety and effectiveness.

Note 6: Auto-off time

Although the time of auto-off time is shorter than predicate device, but both of subject devices and predicate device are meet the basic safety requirement of IEC 60601-1, and IEC 60601-1-11. The difference does not raise any issues on the device safety and effectiveness.

Note 7: Operation Condition

The operation condition of the subject device is tested and validated to meet the requirement of ASTM E1965-98 and ISO80601-2-56. The difference does not raise any issues on the device safety and effectiveness.

Note 8: Materials of skin-contacting components

The biocompatibility tests have conducted on the final finished device to demonstrate that the subject device did not have any potential toxicity, skin sensitization and skin irritation during normal use. 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 subject devices Non-contact Infrared Thermometer (Models: JXB-315, JXB-319, JXB-320, JXB-311) is substantially equivalent to the predicate device (K180355). 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.