November 13, 2019

Guangzhou Berrcom Medical Device Co., Ltd.
% Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
NO. 55 Shizhou middle road, Nanshan District
Shenzhen, 518000
China

Re: K191570
Trade/Device Name: Infrared Thermometer Model MD-H30
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 31, 2019
Received: June 13, 2019

Dear Christy Young:

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 Geeta Pamidimukkala
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191570

Device Name
Infrared Thermometer Model MD-H30

Indications for Use *(Describe)*
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.

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.***

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*"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."*

# K191570 510(k) Summary

## 1. Contact Details

1.1 Applicant information

| | |
|---|---|
| **Applicant Name** | Guangzhou Berrcom Medical Device Co., Ltd. |
| **Address** | No.38 Huanzhen Xi Road, Dagang Town, Nansha, Guangzhou, Guangdong 511470, China |
| **Phone No.** | +86(20)34938449 |
| **Fax No.** | +86(20)34936960 |
| **Contact person** | Zhigang Du |
| **Date Prepared** | November 12 2019 |

1.2 Submission Correspondent

| | |
|---|---|
| 卓远天成 | Shenzhen Joyantech Consulting Co., Ltd<br>Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen |
| **Phone No.** | +86-755-86069197 |
| **Contact person** | Christy Young; Field Fu; |
| **Contact person's e-mail** | christy@cefda.com; cefda@foxmail.com |
| **Website** | http://www.cefda.com |

## 2. Device information

| | |
|---|---|
| **Trade name** | Infrared Thermometer Model MD-H30 |
| **Common name** | Infrared Thermometer |
| **Model** | MD-H30 |
| **Classification** | Ⅱ |
| **Classification name** | Clinical Electronic Thermometer |
| **Product code** | FLL |
| **Regulation No.** | 880.2910 |

## 3. Legally Marketed Predicate Device

| | |
|---|---|
| **Trade Name** | RII Multi-function Infrared Thermometer, Model TH52Z |
| **510(k) Number** | K162083 |
| **Product Code** | FLL |
| **Manufacturer** | Radiant Innovation Inc |

## 4. Device Description

The Infrared Thermometer, Model MD-H30 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal or central forehead. Its operation is based on measuring the natural thermal radiation from the tympanic membrane or central forehead.

To measure body temperature, the probe of the thermometer is inserted into a patient's outer ear canal or put onto the skin of a patient's central forehead. Pressing the activation button (for ear or forehead) to start the measurement of target's infrared radiation. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The final measured temperature will be appeared on a LCD display.

**5. Intended Use/Indication for Use**

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.

**6. Substantial Equivalence Comparison**

| **Item** | **Proposed Device: Infrared Thermometer** | **Predicate Device: RII Multi-function Infrared Thermometer** | **Comments** |
|---|---|---|---|
| Product Code | FLL | FLL | Same |
| Regulation number | 21 CFR 880.2910 | 21 CFR 880.2910 | Same |
| Manufacturer | Guangzhou Berrcom Medical Device Co., Ltd. | Radiant Innovation Inc. | / |
| Indications for Use | 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. | The RII Multi-function Infrared Thermometer, Model TH52Z is intended for the intermittent measurement of human body temperatures. The device is intended for the use at home by people of all ages and it can be selected Ear mode or Forehead mode. | Same |
| Thermometer type | Digital thermometer | Digital thermometer | Same |
| Sensor | Thermopile | Thermopile | Same |
| Measurement Method | Infrared radiation detection | Infrared radiation detection | Same |
| Display Type | LCD | LCD | Same |
| Measuring range | 32.0-43℃ (89.6-109.4℉) | 34~42.2℃ (93.2~108℉) | Similar (note 1) |
| Accuracy | ±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range. | ±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range. | Same |
| | | | |

| | | | |
|---|---|---|---|
| Temperature unit | °C or °F | °C or °F | Same |
| Power requirements | 2X1.5V AAA battery | 1.5V button battery | Different (note 2) |
| Operation environment | 10℃～40℃; ≤95% RH | Not available | / |
| Storage environment | -20~55°C; ≤95%RH | Not available | / |
| Materials of skin-contacting components | ABS | ABS | Same |

Issue:

Note 1: The measurement range of subject devices meet the requirements of ISO80601-2-56 and ASTM E1965-98. The difference does not raise different safety and effectiveness issues

Note 2: The batteries of proposed device are different from that of predicate device. However, the proposed device has been demonstrated to comply with the requirements of electrical safety identified in the standards. The difference does not raise different safety and effectiveness issues.

**7. Non-clinical studies and tests performed**

Non-clinical tests were conducted to verify that the targeted device meet all design specifications in order to demonstrate that it is Substantially Equivalent to the predicate device.

The test results demonstrate that the targeted device complies with the following standards:

ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility

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

ISO 80601-2-56: 2009 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

Software verification and validation:

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

Biocompatibility test:

The biocompatibility of the device was tested according to:

ISO 10993-5 Biological Evaluation of Medical Devices—Tests For In Vitro Cytotoxicity

ISO 10993-10 Biological Evaluation of Medical Devices- Tests for Irritation and Skin Sensitization

Reprocessing: Cleaning and Disinfection

The subject device is a non-sterile device. The cleaning validation was performed according to the Instructions for Use.

**8. Clinical accuracy validation**

The clinical investigation report and data analysis met the requirements of the ASTM E 1965-98. The test report shows the three group's temperature readings difference between digital thermometer and the subject device, MD-H30 are within acceptable range. It can conclude that the Infrared Thermometer, Model MD-H30 is acceptable to measure human body's temperature.

**9. Conclusion**

Basing on the comparison and analysis above, the proposed device, Infrared Thermometer Model MD-H30 is determined to be Substantially Equivalent (SE) to the predicate device.