DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 13, 2016

Guangzhou Bosma Technology Co Ltd.
Guoxing Dai
Quality Manager
2nd Floor, Building A5, No.11 Kaiyuan Avenue, Science Park,
Guangzhou Hi-tech Industrial Development Zone
Guangzhou City, Guangdong Province, P.R China
510530

Re: K160306
Trade/Device Name: Cloud Smart Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 3, 2016
Received: November 9, 2016

Dear Guoxing Dai:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160306

Device Name
Cloud Smart Thermometer (WT001-1)

Indications for Use *(Describe)*
The Cloud Smart Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human axillary temperature continuously via wireless signal transmission of the measuring result. Meanwhile, the device is reusable and is intended for axillary temperature monitoring for persons over two years old, and it is used for household and medical institutions.

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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# 510(k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

## (1) Applicant information:


| | |
|---|---|
| Applicant: | GUANGZHOU BOSMA TECHNOLOGY CO LTD<br>2nd Floor, Building A5, No.11, Kaiyuan Avenue, Science Park, Guangzhou Hi-tech Industrial Development Zone, Guangzhou City, Guangdong Province, P.R.China |
| Contact person: | XingguoDai |
| Phone number: | +86 1372 603 7760 |
| Fax number: | +86 020 3220 3099 |
| Email: | daixg@bosma.com.cn |
| Application date: | November 9, 2016 |


## (2) Proprietary name of the device

| | |
|---|---|
| Trade name/Model: | Cloud Smart Thermometer/WT001-1 |
| Regulation number: | 21 CFR 880.2910, Clinical electronic thermometer |
| Product code: | FLL |
| Review panel: | General Hospital |
| Regulation class: | Class II |

## (3) Predicate device:

k132761 Wireless Thermometer, cleared Jul.8, 2014

## (4) Description of device:

The Cloud Smart Thermometer (WT001-1) which is a combination device of thermometer and Bluetooth communication unit is to be worn in the axilla to monitor the axillary temperature continuously for household and medical institutions.

To start the monitoring operation, switch the thermometer on and place it on the plaster (which is a waterproof medical dressing), and then paste the plaster in the user's axilla. The thermometer will make a Bluetooth connection between the thermometer and the receiver automatically (User should setup Bluetooth properly on receiver). Then the thermometer starts to measure the body temperature by means of testing the thermistor's resistance value and calculates the body temperature every four seconds continuously and sends the temperature data to the receiver through Bluetooth connection.

The thermometer uses a CR2025 battery for operation. When the battery capacity is below 90% rated voltage, internal circuit will detect the low battery condition automatically and send

"low battery" signal through Bluetooth communication unit to receiver, then the receiver will send out a warning. Meanwhile, the thermometer is capable of monitoring the axillary temperature continuously for 24 hours and it can also save measured data in the Cloud for remote real-time monitoring.

## (5) Indications for Use:

The Cloud Smart Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human axillary temperature continuously via wireless signal transmission of the measuring result. Meanwhile, the device is reusable and is intended for axillary temperature monitoring for persons over two years old, and it is used for household and medical institutions.

## (6) Technological characteristics and substantial equivalence:

The following table compares the device to the predicate device(Wireless Thermometer, K132761, cleared Jul.08, 2014) with respect to intended use, technological characteristics, principles of operation, etc.

**Table 1 Comparison**

| Device | Targeted device | Predicate device 1 |
|---|---|---|
| Trade name | Cloud Smart Thermometer | Wireless Thermometer |
| 510(k) number | K160306 | K132761 |
| Regulation number | 21CFR 880.2910 | 21CFR 880.2910 |
| Regulation description | Clinical electronic thermometer | Clinical electronic thermometer |
| Classification name | Thermometer, Electronic, Clinical | Thermometer, Electronic, Clinical |
| Product code | FLL | FLL |
| Device class | II | II |
| Working voltage | DC3V | DC3V |
| Battery specification | MAXELL CR2025 Button battery(3.0V, 170mAh) | The button battery 3.0V, 210mAh |
| Battery life | --Continuous measurement: 120hours Note: you will get a low battery indication when the battery capacity is below 90% rated voltage --Standby time: no less than half a | 120 days at 8 hours per day Note: frequent synchronization of data may deplete power more quickly |

| | | |
|---|---|---|
| | year | |
| Measuring range | 25°C ~45°C | 25℃~45℃ |
| Accuracy | ±0.1°C (at 36.0～40.0°C);<br>±0.2°C (at other temperature range); | ±0.05℃ (35℃~38.5℃)<br>±0.1℃ (25℃~34.99℃) and (38.51℃~45℃) |
| Repeatability error | ≤0.2°C | N/A |
| Temperature unit | °C or °F (settable in App) | °C or °F |
| Display unit specification | iOS or Android device display | iOS device Display |
| Signal transmission | Wireless 2.4G Bluetooth 4.0 | Wireless 2.4G Bluetooth BLE |
| Receiver (mobile terminal) | iOS7.0 or above smartphone or tablet;<br>Android 4.3 or above smartphone, tablet or television | iPhone 4S, iPhone 5, iPad ($3^{rd}$generation), iPad ($4^{th}$ generation), iPad mini, iPod touch ($5^{th}$generation) |
| Valid transmission distance | Up to 15 meters (under barrier-free environment) | Up to 5 meters |
| Response time | 10 minutes at least required for the device to obtain a steady state reading | 8 minutes at least required for the device to obtain a steady state reading |
| Measuring frequency/time | Every 4 seconds | Every 4 seconds |
| Storage time (Bluetooth sending frequency) | Three modes:<br>--Accuracy mode, data saved every 4 seconds<br>--Power mode, data saved every 60 seconds, a default mode<br>--Ultra Power Saving mode, data saved every 120 seconds | N/A |
| Operating temperature | 0°C ~+40°C | 5℃~40℃ |
| Operating humidity | 15%~85% (non-condensing) | 15~85% |

| | | |
|---|---|---|
| Indications for use/Intended use | The Cloud Smart Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human axillary temperature continuously via wireless signal transmission of the measuring result. Meanwhile, the device is reusable and is intended for axillary temperature monitoring for persons over two years old, and it is used for household and medical institutions. | The Wireless Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human armpit temperature continuously via wireless signal transmission of the measuring result. This system is reusable and intended for armpit temperature monitoring for persons over two years old. |
| Location for use | OTC | OTC |
| Thermometer type | Axilla | Armpit |
| Shelf life | 3 years | 5 years |
| Skin-contacting components | Plastic shell, temperature sensor, medical plasters | Plastic shell, temperature probe, medical patches |
| Materials of skin-contacting components | Plastic shell: ABS<br>Temperature Sensor: Stainless steel 304<br>Medical plaster: medical waterproof dressing | Plastic shell: ABS<br>Temperature probe: N/A<br>Medical patches: medical dressing |
| Materials statement | ISO 10993-1:2009<br>ISO 10993-5:2009/(R) 2014<br>ISO 10993-10:2010 | GB/T16886.1-2011<br>GB/T16886.5-2003<br>GB/T16886.10-2005 |

Discussion of feature comparison:

The Cloud Smart Thermometer, Model WT001-1 has similar indications for use and technological characteristics as the predicate device:

- WT001-1 has the same intended use as the predicate device: to measure axillary temperature.
- The same and/or similar technologies and parameters are used in WT001-1 thermometers as the predicate device.
- The identified differences in technological characteristics do not raise new or different questions of safety and effectiveness.
- Although some specifications are slightly different from the predicate device, the thermometer quality has been verified and validated as a part of performance testing and safety /EMC testing and the results are included as a part of this submission. Performance information and evidence of compliance to recognized standards demonstrate the device is

substantially equivalent to the predicate device.

- The targeted device may connect to iOS device and Android device through wireless method, but the predicate device can only connect to iOS device. Risk analysis and associated verification (include cybersecurity test, FCC test and wireless verification) have been performed that the wireless feature is acceptable.
- Both devices use similar materials for construction and have direct skin surface contact.

Based upon the same intended use, similar materials for device construction, product specification and operation, as well as performance testing, it could be concluded that the Cloud Smart Thermometer, Model WT001-1 device is substantially equivalent to the predicate device.

**(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:

- IEC 60601-1Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1-11 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 Medical Electrical Equipment -Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement
- ASTM E1112-00 (Reapproved 2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- CFR 47 FCC PART 15 Subpart C: 2014 section 15.247 under the operating frequency of 2400~2483.5MHz

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) demonstrate that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels. And Cybersecurity test is performed in accordance with "Content of Premarket Submission for Management of Cybersecurity in Medical Devices".

The body-contacting components of this device (plastic shell, temperature sensor, and medical plaster) were tested according to ISO 10993-1 for skin-contacting biocompatibility:

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

## (8) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.