February 28, 2019

Joytech Healthcare Co., Ltd.
Ren Yunhua
General manager
No.365, Wuzhou Road, Yuhang Economic Development Zone
Hangzhou City
Hangzhou, 311100
China

Re: K182629
Trade/Device Name: Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 26, 2019
Received: January 30, 2019

Dear Ren Yunhua:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

510(k) Number *(if known)*

Device Name
Digital Thermometer DMT-4735b

Indications for Use *(Describe)*
The Digital Thermometer is intended to measure the human body temperature in regular mode orally, rectally or under the arm. And the devices are reusable for clinical or home 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.**

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."*

# 510(k) Summary

The assigned 510(k) number is:

1. **Date Prepared:** 2019.01.26

**2. Submitter's Identification:**

Name: JOYTECH HEALTHCARE CO., LTD.

Add.:No.365, Wuzhou Road, Yuhang Economic Development Zone,

Hangzhou city, 311100 Zhejiang,China

Contact Person: Yunhua Ren

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Fax: +86-571-81957750

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**3. Name of the Device:**

Trade Name: Digital Thermometer

Model: DMT-4735b

Common Name: Digital Thermometer

Classification name: Clinical Electronic Thermometer

4. **Classification Information:**

Product Code: FLL- Clinical Electronic Thermometer

Device Class: II

Panel: 80

Regulation number:880-2910

## 5. Predicate Device Information:

The Digital Thermometer DMT-4735b is substantially equivalent to the following devices:

| 510k number | model | Product code | manufacturer |
|---|---|---|---|
| K163518 | DMT-4735 | FLL | JOYTECH HEALTHCARE CO., LTD. |

## 6. Intended use / Indication for Use:

The Digital Thermometer is intended to measure the human body temperature in regular mode orally, rectally or under the arm. And the devices are reusable for clinical or home use on people of all ages.

## 7. Device Description:

The digital thermometer DMT-4735b is hand held instruments which can measure human body's temperature orally, axillary (under the arm), and rectally The results can be displayed on LCD. And, the results measured by DMT-4735b can be transmitted to mobile device (i.e. iPhone) with Bluetooth and the application APP installed on a mobile device using the iOS system or the Android system. The thermometer is reusable for clinical or home use on people of all ages with adult supervision. The device can be used with as a stand-alone device or in conjunction with the App on a compatible BLE enabled smartphone.

## 8. Substantial Equivalence Comparison:

| Comparisons | Subject device Present application | Predicate device 1 K163518 (Model:DMT-4735) | Comparison Result |
|---|---|---|---|
| Intended Use /Indication for use | Intended to measure the human body temperature in regular mode orally, rectally or under the arm. And the devices are reusable for clinical or home use on people of all ages. | Intended to measure the human body temperature in regular mode orally, rectally or under the arm. And the devices are reusable for clinical or home use on people of all ages. | Similar |
| Fundamental technology &Operating principle | A change of thermistor resistance, caused by changes of temperature. The resistance is measured by MCU, so changes of temperature will correspond to changes of resistance.<br>Then display the measured temperature on the LCD or APP through BLE. | A change of thermistor resistance, caused by changes of temperature. The resistance is measured by MCU, so changes of temperature will correspond to changes of resistance. | Similar |
| Operation | Handheld device containing user facing button, sensor head, microcontroller, display | Handheld device containing user facing button, sensor head, microcontroller, display | Same |
| Sensor | Thermistor | Thermistor | Same |
| Signal processing and display | -Internal firmware and local LCD display<br>-Also able to transfer transmit data to an auxiliary device for secondary display | Internal firmware and local LCD display | Different (Note 2) |
| Wireless Interface | Bluetooth Low Energy (BLE) | None | Different (Note 2) |
| Power requirements | Battery powered CR2032 (3V) | Battery powered CR2032 (3V) | Same |
| Material | Biocompatible Stainless Steel and ABS | Biocompatible Stainless Steel and ABS | Same |
| Scale | Switchable | Switchable | Same |
| Measurement locations | Oral, Axillary and Rectal | Oral, Axillary and Rectal | Same |
| Measurement Range | 32.00℃－43.99℃ (89.60℉-111.18℉) | 32.0℃－42.9℃ (89.6℉-109.2℉) | Different (Note 1) |
| Operating Environment | Temperature: 5℃～40℃ (41℉～104℉) | Temperature: 5℃～40℃ (41℉～104℉) | Same |

| | | | |
|---|---|---|---|
| | Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa | Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa | |
| Accuracy | ± 0.05 ℃ ( ± 0.1 ℉ ) during 35.00 ℃ ~38.00 ℃ (95.00 ℉ ~100.40℉) ± 0.1 ℃ ( ± 0.2 ℉ ) during T<35.00℃( 95.00℉) or T>38.00℃(100.40℉) | ±0.2℉(±0.1℃) during 95.9℉ ~107.6 ℉ (35.5 ℃ ~42.0 ℃ ) at 64.4 ℉ ~82.4 ℉ (18 ℃ ~28 ℃ ) ambient operating range ± 0.4 ℉ ( ± 0.2 ℃ ) for other measuring and ambient operating range | Different (Note 1) |
| Response Time | ≤60s | ≤45s | Different (Note 1) |
| Resolution of Display | 0.01 ℃ / 0.01℉ | 0.1 ℃ / 0.1℉ | Different (Note 1) |
| Low power indication | Yes | Yes | Same |
| Memory | Last memory | Last memory | Same |
| Reuse | Yes | Yes | Same |
| Display unit specification | IOS or Android device display | / | Different (Note 2) |
| Signal transmission | Bluetooth 4.0 | / | Different (Note 2) |
| Receiver (mobile terminal) | iOS8.0 or above smartphone or tablet; Android 4.3 or above smartphone or tablet | / | Different (Note 2) |
| Biocompatibility | Comply with ISO 10993-5 and ISO 10993-10 | | Same |
| Electrical Safety | Complied with IEC 60601-1 | | Same |
| EMC | Complied with IEC 60601-1-2 | | Same |

**Analysis**

From the comparison table, the subject devices and predicate devices have the similar Intended use & Indications for Use, Measurement place, Scale selection, Display screen, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices and predicate devices as follows.

| | |
|---|---|
| Note1 | The measurement range and accuracy of subject devices meet the requirements of ISO80601-2-56. |
| Note2 | FCC, EN301489-1, EN301489-17, EN 300328 and wireless coexistence test passed. |

## 9. Performance data

The following performance data were provided in support of the substantial equivalence determination:
Performance testing was conducted to validate and verify that Digital Thermometers, DMT series met all requirements of related international standards, including electrical safety, EMC, biocompatibility, software validation and product specifications. Results of these tests demonstrate compliance to the requirements of the below consensus standards.

Electrical Safety and performance requirements:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 Medical Electrical Equipment
- ISO 80601-2-56:2017 Medical electrical equipment Part 2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2015 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

Electromagnetic compatibility requirements:

- 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
- EN300328:Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;
- ETSI EN 301489-1: Electromagnetic compatibilityand Radio spectrum Matters(ERM); ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1:Common technical requirements;
- ETSI EN 301489-17: Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions or Broadband Data Transmission Systems;

Biocompatibility Evaluation for patient contacting components:

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Guidance Document:

● Guidance on the content of Premarket Notifications [510(k)] Submissions for clinical electronic thermometers

The software/firmware verification and validation was provided in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

## 10. Discussion of Clinical Tests Performed:

Clinical testing was not required to establish equivalency of the device.

## 11. Conclusions:

Based on the information provided in this submission, the submit Digital thermometer DMT-4735b is substantially equivalent to the predicate Thermometers