DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 19, 2017

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

Re: K163518
Trade/Device Name: Digital Thermometer, DMT Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 10, 2017
Received: August 21, 2017

Dear Yunhua Ren:

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,

Michael J. Ryan -S

for Tina Kiang, PhD
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)*
K163518

Device Name
Digital Thermometer DMT series

Indications for Use *(Describe)*

The Digital Thermometers DMT series(Except DMT-455) are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home use on people of all ages, including children under 8 with adult supervision.

The device model DMT-455 is intended to measure temperature orally, and the device is reusable for clinical or home use for children less than 4 years old with adult supervision.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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(21 CFR §807.92)

The assigned 510(k) number is: K163518

1. Date Prepared: September 06, 2017

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

Phone: +86-571-81957767

Fax: +86-571-81957750

Email: RENYH@SEJOY.COM

3. Name of the Device:

Trade Name: Digital Thermometer, DMT series

Models:DMT-101、DMT-411、DMT-301、DMT-102、DMT-202、DMT-412、DMT-423、DMT-433、DMT-455、DMT-108、DMT-418、DMT-106、DMT-206、DMT-416、DMT-427、DMT-437、DMT-4218、DMT-4318、DMT-1019、DMT-2019、DMT-4119、DMT-4220、DMT-4320、DMT-4340、DMT-4343、DMT-4139、DMT-2021、DMT-4121、DMT-209、DMT-1030、DMT-2030、DMT-4130、DMT-1031、DMT-2031、DMT-4131、DMT-4226、DMT-4326、DMT-4726、DMT-1027、DMT-2027、DMT-4127、DMT-1032、DMT-2032、DMT-3032、DMT-4132、DMT-3033、DMT-4233、 DMT-4333、DMT-4235、DMT-4335、DMT-4735、DMT-4236、DMT-4336、DMT-4737、DMT-4238、DMT-4338

Common Name: Digital Thermometer

Regulation number: 21 CFR §880.2910

Classification name: Clinical Electronic Thermometer

Regulation Class: II

Product Code: FLL

4. Predicate Device Information:

The Digital Thermometers are substantially equivalent to the following devices:

Trade Name:Digital Thermometer, DMT series

510(k) Reference:K153149

Common Name:Digital Thermometer

Regulation Number:21 CFR §880.2910

Regulation Name: Clinical Electronic Thermometer

Regulatory Class:II

Product Code: FLL

Classification Panel: General Hospital

5. Indication for Use:

The Digital Thermometers DMT series(Except DMT-455) are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home use on people of all ages, including children under 8 with adult supervision.

The device model DMT-455 is intended to measure temperature orally, and the device is reusable for clinical or home use for children less than 4 years old with adult supervision.

6. Device Description:

The Digital Thermometers DMT series are used to measure the human body temperature in regular mode orally, rectally, or under the arm. They have the same test principles, performance specifications and intended use as the Predicate device. The Digital Thermometers DMT series consists of a temperature sensor, low power consumption integrated circuit (IC), LCD display, and buzzer. The resistance of the sensor changes with temperature and the IC converts the resistance to frequency and calculates the temperature according to the relation of resistance and frequency. The

calculated temperature is displayed on the LCD. The products have similar structural designs and the patient contacting materials are the same as the Predicate devices (Stainless Steel, TPE and Acrylonitrile Butadiene Styrene (ABS)).

7. Comparing to Predicate Device:

The subject devices and predicate devices have no characteristic differences which raise new questions of safety and effectiveness. All differences are verified as substantially equivalent through applicable standardized testing. For details please see the following table:

SE Comparisons	Subject device	Predicate device K153149 (Model:MT-4132、MT-4726)	Comparison Result
Indication for use	DMT series(except DMT-455) are 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. DMT-455 is intended to measure temperature orally, and the device is reusable for clinical or home use for children less than 4 years old.	Measuring 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
Measurement Site	DMT series (except DMT-455): orally, rectally or under the arm	orally, rectally or under the arm	Similar
	DMT-455:orally		
Range	DMT series (except DMT-47XX): 32℃~42.9℃(90℉~109.9℉)	MT-4132: 32℃~42.9℃(90℉~109.9℉)	Identical
	DMT-4735,DMT-4726: 32℃~42.9℃(89.6℉~109.2℉)	MT-4726: 32℃~42.9℃(89.6℉~109.2℉)	Identical
	DMT-4737:35.5℃~42.0℃	MT-4132:	Different

	(96.0℉-109.0℉)	32℃~42.9℃(90℉~109.9℉)	
Accuracy	±0.1℃ between 35.5℃ to 42.0℃ (±0.2°F ,95.9°F-107.6°F), ±0.2℃ under 35.5℃ or over 42.0℃ (±0.4°Funder 95.9°For over 107.6 ℉	±0.1°C between 35.5°C to 42.0°C (±0.2°F,95.9°F -107.6°F), ±0.2°C under 35.5°C or over 42.0°C (±0.4°F under 95.9°F or over 107.6°F)	Identical
Display resolution	DMT series(except DMT-301, DMT-3032,DMT-3033,DMT-4737): 0.1 C/0.1 F	0.1 C/0.1 F	Identical
	DMT-301,DMT-3032,DMT-3033: 0.01℃/0.01℉	0.1 C/0.1 F	Different
	DMT-4737:Analog Display	0.1 C/0.1 F	Different
Components	Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module.	Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module.	Identical
Operating Range	Temperature: 41℉～104℉(5℃～40℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa	Temperature: 41℉～104℉(5℃～40℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa	Identical
Storage and Transportation Condition	Temperature:-4℉～131℉ (-20℃ ~55℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa	Temperature:-4℉～131℉ (-20℃ ~55℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa	Identical
	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)	MT-4132:One 1.5 V DC. button battery (size LR41or SR41, UCC 392)	Identical

Battery Type	DMT-4726,DMT-4735: One 3.0V CR2032 battery	MT-4726:One 3.0V CR2032 battery	Identical
	DMT-4737: One 3.0V CR1225 battery	MT-4726:One 3.0V CR2032 battery	Different
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-5 and ISO 10993-10	Identical
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Identical
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Identical

8. Performance data

The performance data listed below is provided in support of the substantial equivalence determination.
Performance testing was conducted to verify and validate 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 80601-2-56:2009 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

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.

9. Discussion of Clinical Tests Performed:

The clinical performance test protocol and data analysis followed the requirements of ISO 80601-2-56.

10. Conclusions:

Based on the performance testing and bench data the submit digital thermometers DMT series are substantially equivalent to the predicate thermometers, model: MT-4132 and MT-4726.