July 8, 2020

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

Re: K200599
Trade/Device Name: Digital Thermometer, Model DMT-4756
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 5, 2020
Received: June 8, 2020

Dear Mr. 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. 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 Payal Patel
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)*
K200599

Device Name
Digital Thermometer, Model DMT-4756

Indications for Use *(Describe)*
The Digital Thermometer DMT-4756 is intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages, including children under 8 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.

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510(k) Summary

The assigned 510(k) number is: K200599

1. **Date Prepared:** 2020.07.08

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

Model: DMT-4756

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-4756 is substantially equivalent to the following device:

510k number	model	Product code	manufacturer
K183393	DMT-4726	FLL	JOYTECH HEALTHCARE CO., LTD.

6. Intended use / Indication for Use:

The Digital Thermometer DMT-4756 is intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all age, including children under 8 with adult supervision.

7. Device Description:

The digital thermometer DMT-4756 is hand held device which can measure human body's temperature orally, axillary (under the arm), and rectally. The results can be displayed on LCD.

The flexible tip is foldable,when the flexible tip folded, DMT-4756 is used to measure human body's temperature rectally, while the flexible tip unfolded, it is used to measure temperature orally and axillary (under the arm).

The digital thermometer have several functions,such as beep alarm,unit switchable, low battery detection,memories,backlight,auto power off functions.

DMT-4756 is a predictive digital thermometer. Users only need 10 seconds for predictive quick read and 30 seconds for final temperature readings.

8. Substantial Equivalence Comparison:

SE Comparisons	Subject device K200599 DMT-4756	Predicate device K183393 (Model:DMT-4726)	Comparison Result
Intended Use /Indication for use	The Digital Thermometer DMT-4756 is intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all age, including children under 8 with adult supervision	The Digital Thermometer DMT-4726 is intended to measure the human body temperature in regular mode orally, rectally or under the arm. The device is reusable for clinical or home use on people of all ages, including children under 8 with adult supervision.	Identical (Only change in model number)
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	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	Identical
Sensor	Thermistor	Thermistor	Identical
Signal processing and display	-Internal firmware and local LCD display	-Internal firmware and local LCD display	Identical
Measurement Site	orally, rectally or under the arm	orally, rectally or under the arm	Identical
Range	32.0℃~43.9℃(89.6℉-111.0℉)	32.0℃~43.9℃(89.6℉-111.0℉)	Identical
Accuracy	±0.1℃ between 35.5℃ to 42.0℃(±0.2℉,95.9℉-107.6℉), ±0.2℃ under 35.5℃ or over 42.0℃(±0.4℉under 95.9℉or over 107.6℉)	±0.1℃ between 35.5℃ to 42.0℃(±0.2℉,95.9℉-107.6℉), ±0.2℃ under 35.5℃ or over 42.0℃(±0.4℉under 95.9℉or over 107.6℉)	Identical
Display resolution	0.1 ℃/0.1 ℉	0.1 ℃/0.1 ℉	Identical
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
Memories	10 memories	10 memories	Identical
Material	ABS,TPE,Stainless steel	ABS,TPE,Stainless steel	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

Construction	The probe is foldable into the body of the thermometer	Flexible Digital Thermometer	Different (Note1)
Measurement method & time	10s Predictive read 30s Final read.	Approximate 5 ~ 10s	Different (Note 2)
Weight	Approx. 40 grams including battery	Approx. 23 grams including battery	Different (Note3)
Thermometer Size	10.6cm*3.2cm*2.5cm(L x W x H)	13.5cm*3.4cm*1.7cm(L x W x H)	Different (Note3)
LCD Size	2.5cm*1.4cm	2.7cm*2.1cm	Different (Note3)
Color &Coding	White(R9003), Green(P564C)	White(R9003), Blue(P294C)	Different (Note3)
Predictive mode	Yes	Optional	Different (Note2)
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
Battery type	One 3.0V CR2032 battery	One 3.0V CR2032 battery	Identical
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

Analysis

From the comparison table, the subject device and predicate device(K183393) 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 subject device and predicate device(K183393) as follows and we have conducted the tests to verify that the differences do not raise new questions of safety and effectiveness,please see below::

Note 1	Add foldable construction function	Performance testing shows the subject device complies with standard ISO 80601-2-56. The difference does not raise new questions of safety and effectiveness
Note 2	Measure time changed from approximate 5~10s to “10 second predictive quick read,30	Performance test including clinical test shows the subject device complies with performance standard. The differences do not raise new questions of safety and effectiveness

	second for final temperature reading", and predictive mode changed from optional to have this function	
Note 3	Weight,Size,color changed;	Biocompatibility test and performance bench test met the requirements in the standards. The differences do not raise new questions of safety and effectiveness

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 Thermometer, DMT-4756 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
- ASTM E1112:00(Reapproved 2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

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 health care 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.

10. Discussion of Clinical Tests Performed:

The clinical tests were conducted on the DMT-4756 for each measurement site. The clinical tests evaluated 450 of subjects. The thermometer was evaluated in three groups 1) infants—newborn to one year; 2) children—greater than one to five years; and 3) adults—greater than five years old.The clinical performance test protocol and data analysis was conducted in accordance with ISO 80601-2-56. The test report showed the clinical performance of the subject device complied with the requirement of ISO 80601-2-56.

11. Conclusions:

Based on the performance testing,comparison and analysis in the submission, the subject digital thermometer DMT-4756 are substantially equivalent to the predicate thermometer DMT-4726(K183393).