November 18, 2019

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

Re: K183393
Trade/Device Name: Digital Thermometer DMT series (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-3018, DMT-4238, DMT-4338)

Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 14, 2019
Received: October 17, 2019

Dear Mr. 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/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)*
K183393

Device Name

Digital Thermometer DMT series(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-3018,DMT-4238,DMT-4338)

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. And 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.

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510(k) Summary

The assigned 510(k) number is: K183393

1. **Date Prepared:** 2019.11.18

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

Model: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-3018, DMT-4238、DMT-4338

Common Name: Digital Thermometer

Classification name: Clinical Electronic Thermometer

4. Classification Information:

Product Code: FLL

Device Class: II

Panel: 80

Regulation number:21 C.F.R.880.2910

Regulation Description: Clinical electronic thermometer

5. Predicate Device Information:

The Digital Thermometers are substantially equivalent to the following devices:

Digital Thermometers, Models: DMT series;

FDA 510(k)number: K163518;

Manufactured by JOYTECH HEALTHCARE CO., LTD.

6. Intended use / 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. And 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.

7. Device Description:

The Digital Thermometers DMT series(Except DMT-455) are used to measure the human body temperature in regular mode orally, rectally, or under the arm.The device model DMT-455 is intended to measure temperature orally.

The Digital Thermometers DMT series consists of a temperature sensor, low power consumption integrated circuit (IC), LCD display, and buzzer. The resistance of 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.Only model DMT-4726 and DMT-4735 are predictive optional thermometers.The patient contacting materials are Stainless Steel,TPE and Acrylonitrile Butadiene Styrene (ABS).

8.Model List

Features / Models	A	B	C	D	E	F	G	H	I	J	K
DMT-101	○	●	○	○	○	○	○	○	≤60 Seconds	12.3 x 1.8x 0.9	Approx. 10 g
DMT-411	○	●	○	●	○	●	○	○	≤45 Seconds	12.3 x 1.8x 0.9	Approx. 10 g
DMT-301	○	●	○	○	○	●	○	○	≤60 Seconds	12.3 x 1.8x 0.9	Approx. 10 g
DMT-102	○	●	○	○	○	○	○	○	≤60 Seconds	12.4 x 1.8x 1.1	Approx. 10 g
DMT-202	○	●	●	○	○	○	○	○	≤60 Seconds	12.4 x 1.8x 1.1	Approx. 10 g
DMT-412	○	●	●	●	○	●	○	○	≤45 Seconds	12.4 x 1.8x 1.1	Approx. 10 g
DMT-423	●	○	●	○	○	○	○	○	≤60 Seconds	12.4 x 2.4x 1.2	Approx. 12 g
DMT-433	●	○	●	●	○	●	○	○	≤45 Seconds	12.4 x 2.4x 1.2	Approx. 12 g
DMT-455	○	●	○	○	○	○	○	○	≤60 Seconds	5.8x 4.1x 4.3	Approx. 13 g
DMT-108	○	●	○	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.3x 1.2	Approx. 12 g
DMT-418	○	●	○	●	Δ	●	○	○	≤45 Seconds	13.9 x 2.3x 1.2	Approx. 12 g
DMT-106	○	●	○	○	○	○	○	○	≤60 Seconds	12.2 x 1.9x 1.1	Approx. 11 g
DMT-206	○	●	●	○	○	○	○	○	≤60 Seconds	12.2 x 1.9x 1.1	Approx. 11 g
DMT-416	○	●	●	●	○	●	○	○	≤45 Seconds	12.2 x 1.9x 1.1	Approx. 11 g
DMT-427	●	○	●	○	○	○	○	○	≤60 Seconds	12.4 x 1.9x 1.1	Approx. 11 g
DMT-437	●	○	●	●	○	●	○	○	≤45 Seconds	12.4 x 1.9x 1.1	Approx. 11 g
DMT-4218	●	○	●	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.2x 1.3	Approx. 11 g
DMT-4318	●	○	●	●	Δ	●	○	○	≤45 Seconds	13.9 x 2.2x 1.3	Approx. 11 g
DMT-3018	●	○	●	○	Δ	●	○	○	≤60 Seconds	13.9 x 2.2x 1.3	Approx. 11 g
DMT-1019	○	●	○	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.3x 1.3	Approx. 11 g
DMT-2019	○	●	●	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.3x 1.3	Approx. 12 g
DMT-4119	○	●	●	●	Δ	●	○	○	≤45 Seconds	13.9 x 2.3x 1.3	Approx. 12 g
DMT-4220	●	○	●	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.3x 1.3	Approx. 13 g
DMT-4320	●	○	●	●	Δ	●	○	○	≤45 Seconds	13.9 x 2.3x 1.3	Approx. 13 g
DMT-2021	○	●	●	○	Δ	○	○	○	≤60 Seconds	12.2 x 1.9x 1.0	Approx. 11 g
DMT-4121	○	●	●	●	Δ	●	○	○	≤45 Seconds	12.2 x 1.9x 1.0	Approx. 11 g
DMT-209	○	●	●	○	○	○	○	○	≤60 Seconds	12.8 x 2.0x 1.2	Approx. 11 g
DMT-1030	○	●	○	○	○	○	○	○	≤60 Seconds	13.2 x 2.3x 1.2	Approx. 11 g
DMT-2030	○	●	●	○	○	○	○	○	≤60 Seconds	13.2 x 2.3x 1.2	Approx. 11 g
DMT-4130	○	●	●	●	○	●	○	○	≤45 Seconds	13.2 x 2.3x 1.2	Approx. 11 g
DMT-1031	○	●	○	○	○	○	○	○	≤60 Seconds	13.0 x 1.9x 1.0	Approx. 12 g
DMT-2031	○	●	●	○	○	○	○	○	≤60 Seconds	13.0 x 1.9x 1.0	Approx. 12 g
DMT-4131	○	●	●	●	○	●	○	○	≤45 Seconds	13.0 x 1.9x 1.0	Approx. 12 g
DMT-4226	●	○	●	○	Δ	○	○	○	≤60 Seconds	13.5 x 3.4x 1.7	Approx. 22 g
DMT-4326	●	○	●	●	Δ	●	○	○	≤45 Seconds	13.5 x 3.4x 1.7	Approx. 22 g

DMT-4726	●	○	●	●	Δ	●	Δ	Δ	≤45 Seconds	13.5 x 3.4x 1.7	Approx. 22 g
DMT-1027	○	●	○	○	○	○	○	○	≤60 Seconds	12.2 x1.8 x 1.1	Approx. 10 g
DMT-2027	○	●	●	○	○	○	○	○	≤60 Seconds	12.2 x1.8 x 1.1	Approx. 10 g
DMT-4127	○	●	●	●	○	●	○	○	≤45 Seconds	12.2 x 1.8 x 1.1	Approx. 10 g
DMT-1032	○	●	○	○	Δ	○	○	○	≤60 Seconds	13.8 x 2.2 x 1.2	Approx. 12 g
DMT-2032	○	●	●	○	Δ	○	○	○	≤60 Seconds	13.8 x 2.2 x 1.2	Approx. 12 g
DMT-3032	○	●	●	○	○	●	○	○	≤60 Seconds	13.8 x 2.2 x 1.2	Approx. 12 g
DMT-4132	○	●	●	●	Δ	●	○	○	≤45 Seconds	13.8 x 2.2 x 1.2	Approx. 12 g
DMT-3033	●	○	●	○	○	●	○	○	≤60 Seconds	13.9 x 2.2x 1.2	Approx. 12 g
DMT-4233	●	○	●	○	Δ	○	○	○	≤60 Seconds	13.9 x 2.2x 1.2	Approx. 12 g
DMT-4333	●	○	●	●	Δ	●	○	○	≤45 Seconds	13.9 x 2.2 x 1.2	Approx. 12 g
DMT-4235	●	○	●	○	Δ	○	○	○	≤60 Seconds	13.4 x 3.1 x 1.6	Approx. 23 g
DMT-4335	●	○	●	●	Δ	●	○	○	≤45 Seconds	13.4 x 3.1 x 1.6	Approx. 23 g
DMT-4735	●	○	●	●	Δ	●	Δ	Δ	≤45 Seconds	13.4 x 3.1x 1.6	Approx. 23 g
DMT-4236	●	○	●	○	○	○	○	○	≤60 Seconds	13.1 x 2.0x 1.2	Approx. 10 g
DMT-4336	●	○	●	●	○	●	○	○	≤45 Seconds	13.1 x 2.0x 1.2	Approx. 10 g
DMT-4343	●	○	●	●	○	●	○	○	≤45 Seconds	14.2 x 2.3x 1.3	Approx. 11 g
DMT-4238	●	○	●	○	○	●	○	○	≤60 Seconds	12.5 x 2.1x 1.2	Approx. 12.8 g
DMT-4338	●	○	●	●	○	●	○	○	≤45 Seconds	12.5 x 2.1x 1.2	Approx. 12.8 g
DMT-4139	○	●	●	●	○	●	○	○	≤60 Seconds	13.2 x 2.3x 1.3	Approx. 14.5 g
DMT-4340	●	○	●	●	○	●	○	○	≤45 Seconds	13.2 x 2.3x 1.3	Approx. 14.5 g

A=Flexible tip

B=Rigid tip

C=Waterproof

D=Instant

E=TEMPERATURE ARROW INDICATING function

F=℃/℉ switchable

G=Backlight function

H=Predictive

I=Water Bath Response time

J=Physical dimensions（L x H x W in cm） K=Weight（

including battery in grams）

● = Yes

○ = No

Δ =Optional

9. Comparing to Predicate Device:

SE Comparisons	Subject device Present application k183393	Predicate device k163518 (Model:DMT series)	Comparison Result
Intended Use /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. including children under 8 with adult supervision. 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.	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. including children under 8 with adult supervision. 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.	Identical
Measurement Site	DMT series (except DMT-455): orally, rectally or under the arm	DMT series (except DMT-455): orally, rectally or under the arm	Identical
	DMT-455:orally	DMT-455:orally	
Range	DMT series (except DMT-30XX,DMT-47XX): 32.0℃~43.9℃(90.0℉~111.9℉)	DMT series (except DMT-30XX,DMT-47XX): 32.0℃~42.9℃(90℉~109.9℉)	Similar
	DMT-301,DMT-3032,DMT-3033, DMT-3018: 32.00℃~43.99℃(90.00℉~111.99℉)	DMT-301,DMT-3032,DMT-3033: 32.00℃~42.99℃(90.00℉~109.99℉)	Similar
	DMT-4735,DMT-4726: 32.0℃ ~43.9℃(89.6℉~111.0℉)	DMT-4735,DMT-4726: 32.0℃ ~42.9℃(89.6℉~109.2℉)	Similar
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℉) DMT-301, DMT-3032, DMT-3033, DMT-3018: ±0.10 °C between 35.5°C to 42°C ±0.20°C under 35.5°C or over 42°C	±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	DMT series(except DMT-301, DMT-3032,DMT-3033,DMT-3018): 0.1˚C/0.1 ˚F		DMT series(except DMT-301, DMT-3032,DMT-3033): 0.1˚C/0.1 ˚F		Identical
	DMT-301,DMT-3032,DMT-3033, DMT-3018:0.01℃/0.01℉		DMT-301,DMT-3032,DMT-3033: 0.01℃/0.01℉		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
Principle of operation	A change of thermistor resistance, caused by changes of temperature. The resistance is measured by microcontroller unit (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 microcontroller unit (MCU), so changes of temperature will correspond to changes of resistance		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
Patient contact material	ABS,TPE,Stainless Steel		ABS,TPE,Stainless Steel		Identical
Colour coding	ABS	9003	ABS	9003	Identical
	TPE	P351C,P288C,P374C,P284C,P2715C,P109C,P428C,P427C	TPE	P351C,P288C,P374C,P284C,P2715C,P109C,P428C,P427C	
Storage and transportation condition	Temperature: -4℉～131℉ (-20℃~55℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~		Temperature: -4℉～131℉ (-20℃~55℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~		Identical

	1060hPa	1060hPa	
Battery type	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)	Identical
	DMT-4726,DMT-4735: One 3.0V CR2032 battery	DMT-4726,DMT-4735: 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

The differences between two devices are:

1.Changed thermometer chip to extend temperature measuring range from 32.0~42.9℃ to 32.0~43.9 ℃ ,as new version of standard ISO 80601-2-56:2017 required, no other functions changed.

2.New model DMT-3018: it is a new model that have same appearance and same electrical scheme with predicate device model DMT-4318 but have only different temperature range and PCB with the predictive device.

10. 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
- 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 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.

11. Discussion of Clinical Tests Performed:

Clinical tests were conducted on the DMT-4726 and DMT-4735. The clinical tests evaluated 450 of subjects. and 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 were conducted in accordance with the requirement of ISO 80601-2-56. The test report showed the clinical performance of the subject devices complied with the requirement of ISO 80601-2-56.

12. Conclusions:

Based on the information provided in this submission,the subject digital thermometers DMT series are substantially equivalent to the predicate thermometers, model: DMT series.