May 10, 2023

Shen Zhen Rong Feng Technology Co., Ltd
Jett Lee
Regulation Manager
3/F R Building ShaSi Industrial Park, Shajing Town
BaoAn District
Shenzhen, Guangdong
China

Re: K223044
Trade/Device Name: Digital Thermometer (Model QT001)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 9, 2023
Received: April 10, 2023

Dear Jett Lee:

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,

David Wolloscheck

David Wolloscheck, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223044

Device Name
Digital Thermometer (Model: QT001)

Indications for Use *(Describe)*
The Digital Thermometer QT001 is intended to measure the human body temperature in armpit, orally or rectally, and the device is 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.

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510(k) Summary

K223044

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Summary Prepared Date: 25 April 2023

1. Submitter Information

Sponsor Company Name: SHEN ZHEN RONG FENG TECHNOLOGY CO.,LTD

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Contact Person (including title): Hong Xiao Lan (Engineer)

E-mail: 844352259@qq.com

Application Correspondent: SHEN ZHEN RONG FENG TECHNOLOGY CO.,LTD

Address: 3/F R building ShaSi Industrial Park,Shajing Town,BaoAn district,ShenZhen city,GuangDong Province,China

- **Contact Person:** Iris Fung
- **Tile:** Regulation Manager
- **Tel: +86-13211147965**
- **Email: jianda-lee@foxmail.com;** mdc-fs@foxmail.com;

2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Clinical Electronic Thermometer

Trade Name: Digital thermometer (Model: QT001)

Classification Name: Clinical electronic thermometer

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 21 CFR 880.2910

Regulation Class: II

3. Predicate Device Information

Sponsor: JOYTECH HEALTHCARE CO., LTD.

Trade Name: Digital Thermometer

510(k) number: K200599
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Regulation Class: II

4. Device Description

The digital thermometer QT001 is hand held device which can measure human body's temperature at the site of armpit, orally or rectally, the device is reusable for clinical or home use on people of all ages. The results can be displayed on LCD. The QT001 has only one operating mode: direct mode.

The digital thermometer measures temperatures of human body by placing the probe tip into the armpit, oral, rectum directly with the measuring time about 3 minutes.

The digital thermometer 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.

The thermistor sensor(Type:503F) reacts to temperature. In different temperature, the thermistor has a different resistance value. The essence of temperature measurement is actually measuring the resistance of the sensor, usually is to change the resistance into voltage or current and other analog signals, and digital signals, and then the processor converts the signals to the corresponding temperatures.

QT001 has several functions, such as beep alarm, unit switchable, low battery detection, memories, backlight, auto power off functions.

5. Indication for use

The Digital Thermometer QT001 is intended to measure the human body temperature in armpit, orally or rectally, and the device is reusable for clinical or home use on people of all ages.

6. Comparison to Predicate Device

A comparison of key technological characteristics between the subject devices and predicate device was listed as below:

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	SHEN ZHEN RONG FENG TECHNOLOGY CO.,LTD	Joytech Healthcare Co., Ltd	--

Elements of Comparison	Subject Device	Predicate Device	Verdict
510 (k) Number	K223044	K200599	--
Product Name	Digital Thermometer	Digital Thermometer	--
Models	QT001	DMT-4756	--
Intended Use	The Digital Thermometer QT001 is intended to measure the human body temperature in armpit, orally or rectally, and the device is reusable for clinical or home use on people of all ages.	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.	Similar There is minor difference, but the user manual have been indicated in the instructions that children should not be allowed to perform the test unsupervised It will not affect safety and effectiveness.
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	armpit, orally or rectally	orally, rectally or under the arm	Identical
Measuring Range	32.0∽42.9 ℃(89.6℉∽109.2℉)	32.0℃~43.9℃ (89.6℉~111.0℉)	Different(Note 1)
Accuracy	±0.1℃,34.0℃-42.0℃（±0.2℉，93.2℉-107.6℉） ± 0.2 ℃ under34.0 ℃ or over 42.0℃ （±0.4℉ under 93.2℉ 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℉)	Different(Note 2)
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
Sensor type	Thermopile	Thermopile	Identical
Material	ABS, TPE, Stainless steel	ABS, TPE, Stainless steel	Identical

Elements of Comparison	Subject Device	Predicate Device	Verdict
Memories	For storing the last measured value	10 memories	Different(Note 3)
Power Supply	One 3.0 V CR1225 battery	One 3.0V CR2032 battery	Identical
Operating range	Temperature: 5℃-40℃ (41℉-104℉) Relative humidity:15%RH-95%RH Atmospheric pressure:70kPa-106kPa	Temperature: 41℉～104℉(5℃～40℃) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa	Different(Note4)
Construction	Flexible tip	The probe is foldable into the body of the thermometer	Different(Note5)
Measurement method & time	Approximate 3 minutes	10s Predictive read 30s Final read.	Different(Note6)
Thermometer Size	138mm x 25mm x 12mm (L x W x H)	10.6cm*3.2cm*2.5cm(L x W x H)	Different(Note7)
Weight	Approx. 10 grams including battery	Approx. 40 grams including battery	Different(Note7)
LCD Size	2.0cm*0.7cm	2.5cm*1.4cm	Different(Note7)
Color &Coding	White(R9003),Green(P294C)	White(R9003), Green(P564C)	Different(Note7)
Predictive mode	NO	Yes	Different(Note6)
Storage and transportation condition	Temperature:-20℃ ~55℃ (-4℉~131℉) Relative humidity:15%RH-95%RH Atmospheric pressure:50kPa-106kPa	Temperature: -4℉～131℉(-20℃~55℃) Relative humidity: 15%~95%RH Atmospheric Pressure: 700hPa ~ 1060hPa	Different(Note4)
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
Biocompatibility	Complied with ISO 10993-5 and ISO 10993-10	Complied with ISO 10993-5 and ISO 10993-10	Identical
Performance	Complied with ISO 80601-2-56:2017/AMD 1:2018 and ASTM E1112:00(2018).	Complied with ISO 80601-2-56:2017	Different(Note8)
Backlight warning function	1.When measured temperature is 35.9℃ , the LCD without backlight 2.When measured temperature ≥36℃ and ≤37.1℃,, the LCD shows green backlight 3.When measured temperature ≥37.2℃ and ≤37.4℃, the LCD shows yellow backlight. 4.When measured temperature ≥37.5℃and ≤42.9℃, the LCD	/	Different(Note9)

Elements of Comparison	Subject Device	Predicate Device	Verdict
	shows red backlight. The laboratory accuracy error no greater than 0.3 °C		

Comparison discussion:

Note 1

The subject device and predicate device have different measurement range, but the measurement range of subject device meets the requirements of ASTM E1112:00 and ISO 80601-2-56. The difference does not raise any new or different safety and effectiveness questions. .

Note 2

The subject device and predicate device have different accuracy, but the accuracy of the subject device meets the requirements of ASTM E1112:00 and ISO 80601-2-56. The difference does not raise any new or different safety and effectiveness questions.

Note 3

The memory function difference: The software verification and validation were conducted to demonstrate the performance of the function as intended. The memory function does not affect accuracy of measurement; so such difference does not impact the performance of subject device.

Note 4

Operating range, Storage and transportation condition difference: The subject device has been tested and the test results met the requirements of IEC60601-1 and ISO 80601-2-56. The difference does not raise any new or different safety and effectiveness questions.

Note 5

Construction difference: Performance testing shows the subject device complies with standard ISO 80601-2-56. The difference does not raise any new questions of safety and effectiveness.

Note 6

Measurement time, predictive mode difference: Performance test was conducted in accordance with ISO 80601-2-56. The test results demonstrated the subject device complies with performance standard. The differences do not raise any new questions of safety and effectiveness.

Note 7

Weight, size, color difference: Biocompatibility test and performance bench test met the requirements of ISO 10993-5 and ISO 10993-10. The differences do not raise any new questions of safety and effectiveness.

Note 8

Performance testing shows the subject device complies with standard ISO 80601-2-56:2017/AMD 1:2018 and ASTM E1112-00 (2018). The difference does not raise any new questions of safety and effectiveness.

Note 9

Backlight warning function does not affect accuracy of measurement; the software verification and validation were conducted to demonstrate the performance of the function as intended. So such difference does not raise any new safety and effectiveness questions.

7. Test Summary

Non-clinical test:

Digital Thermometer conforms to applicable standards that include:

- ASTM E1112-00(2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
- ISO 10993-5:2009, 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
- IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes
- IEC60601-1-11:2015 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 80601-2-56:2017/AMD 1:2018 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

8. Conclusion

Based on comparison of the intended use, technological characteristics, applicable safety standards, verification and validation testing, the differences between subject device and the predicate device do not raise new issues of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.