April 12, 2024

Zhuzhou Goldenhot Medical Technology Co.,Ltd.
℅ Meihua Cai
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
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China

Re: K240109
Trade/Device Name: Medical electronic thermometer (FC01, FC02)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 15, 2024
Received: January 16, 2024

Dear Meihua Cai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Porsche Bennett
Porsche Bennett
for David Wolloscheck, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240109

Device Name
Medical electronic thermometer (FC01, FC02)

Indications for Use *(Describe)*
The Medical Electronic Thermometer (FC01, FC02) is intended to measure the human body temperature under the arm. The devices are reusable for clinical or home use for 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.

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K240109- 510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

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III. Subject Device

510(k) Number: K240109
Trade Name: Medical electronic thermometer (FC01, FC02)
Common or Usual Name: Thermometer, electronic, clinical
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Regulation Number: 21 CFR 880.2910

IV. Predicate Device

510(k) Number: K223044
Trade Name: Digital Thermometer (Model QT001)
Common or Usual Name: Thermometer, electronic, clinical
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Regulation Number: 21 CFR 880.2910

V. Device Description

The Medical Electronic Thermometer (FC01, FC02) is a hand-held device which can measure human body temperature at the site of the armpit. The devices are reusable for clinical or home use for people of all ages. The results can be displayed on the LCD. The FC01 and FC02 have only one operating mode which is direct mode. The Medical Electronic Thermometer measures human body temperature by placing the probe tip under the armpit with a measuring time of about 300 seconds.

The Medical Electronic Thermometer consists of a temperature sensor (NTC), low power integrated circuit (IC), buzzer, and battery. The resistance of sensor changes with temperature and the integrated circuit (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.

Models FC01, FC02 of the subject device have a variety of functions, such as buzzer prompt, unit switching, low battery detection, memory, Indicator light, automatic power-off function. The difference between the two models is the color. The measuring range is 32.0 ℃ ~ 42.0 ℃, the minimum index value is 0.1 ℃, allowing the maximum error of ± 0.3 ℃, the operating environment is temperature ＋5 ℃ ~ ＋40 ℃ Humidity: ≤85% RH, and the atmospheric pressure is 70KPa ~ 106KPa. Users should avoid long-term use in environments with high temperatures, humidity, or direct sunlight.

VI. Indications for Use

The Medical Electronic Thermometer (FC01, FC02) is intended to measure the human body temperature under the arm. The devices are reusable for clinical or home use for people of all ages.

VII.Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Medical electronic thermometer (Enclosure)	ABS, PC, Stainless Steel	Surface-contacting device: Intact skin	Less than 24 hours

VIII. Comparison of Technological Characteristics With the Predicate Device

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

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
510(k) Number	K240109	K223044	/
Trade name	Medical electronic thermometer (FC01, FC02)	Digital Thermometer (Model QT001)	/
Manufacturer	Zhuzhou Goldenhot Medical Technology Co.,Ltd	Shen Zhen Rong Feng Technology Co., Ltd	/
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product code	FLL	FLL	Same
Device classification	Class II	Class II	Same
Indication for use/ Intended use	The Medical Electronic Thermometer (FC01, FC02) is intended to measure the human body temperature under the arm. The devices are reusable for clinical or home use for people of all ages.	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.	Different Note 1
Prescription or OTC	OTC	OTC	Same
Principle of Operation	The thermistor placed at the top of the measuring part is used as a temperature sensing device, when the temperature of the external measured heat source is changed, the resistance value of the thermistor will be changed accordingly, the internal microprocessor converts, processes, and corrects the change of resistance value of the thermistor in the measuring circuit, and then the measured temperature will be shown in the form of a number on the display screen, and at the same time the buzzer will beep, and the measuring process will be finished.	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.	Different Note 1

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
Sensor	Thermistor	Thermistor	Same
Signal processing and display	Internal firmware and local LCD display	Internal firmware and local LCD display	Same
Measurement Site	Armpit	armpit, orally or rectally	Different Note 1
Measuring Range	32℃～42.0℃ (89.6℉～107.6℉)	32℃～42.9 ℃ (89.6℉～109.2℉)	Different Note 2
Accuracy	Lower than35.3℃ ± 0.3 ℃ (95.5 ℉ ±0.5℉) 35.3 ℃ ～ 36.9 ℃ ± 0.2 ℃ (95.5 ℉～98.4℉ ±0.4℉) 37.0 ℃ ～ 39.0 ℃ ± 0.1 ℃ (98.6 ℉～102.2℉ ±0.2℉) 39.1 ℃ ～ 41.0 ℃ ± 0.2 ℃ (102.4 ℉～105.8℉ ±0.4℉) Higher than 41.0 ℃ ± 0.3 ℃ (105.8℉ ±0.5℉)	±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℉)	Different Note 3
Display resolution	0.1 ℃/0.1 ℉	0.1 ℃/0.1 ℉	Same
Components	Measurement module, Memory module, Business function module, Button module, Buzzer module, Display module	Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module.	Similar
Patient Contacting Materials	ABS, PC， Stainless Steel	ABS, TPE, Stainless steel	Different Note 8
Memories	12 memories (including For storing the last measured value)	For storing the last measured value	Different Note 4
Power Supply	Power adapter specification: 5V 1A	One 3.0 V CR1225 battery	Different Note 5
Operation environment condition	Temperature: 5℃-40℃ (41℉-104℉) Relative humidity:≤85%RH Atmospheric pressure:70kPa-106kPa	Temperature: 5℃-40℃ (41℉-104℉) Relative humidity:15%RH-95%RH Atmospheric pressure:70kPa-106kPa	Different Note 6

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
Storage and transportation condition	Temperature: -20℃-55℃ (-4℉-131℉) Relative humidity:10%RH-93%RH Atmospheric pressure:70kPa-106kPa	Temperature:-20℃ ~55℃（-4℉~131℉) Relative humidity:15%RH-95%RH Atmospheric pressure:50kPa-106kPa	Different Note 6
Measuring Time	Approximately 5 minutes	Approximately 3 minutes	Different Note 7
Thermometer Size	135.6 (L)*15.8 (W)*8.5 (H)mm	138mm x 25mm x 12mm (L x W x H)	Different Note 8
Weight	About 13.0g (including battery)	Approx. 10 grams including battery	Different Note 8
Shelf life	3 years	3 years	Same
Biocompatibility	Complied with ISO 10993-5 、ISO 10993-10 and ISO 10993-23	Complied with ISO 10993-5 and ISO 10993-10	Same
Electrical safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same
Performance	Complied with ISO 80601-2-56:2017/AMD 1:2018 and ASTM E1112-00(2018).	Complied with ISO 80601-2-56:2017/AMD 1:2018 and ASTM E1112-00(2018).	Same

Comparison discussion:

Note 1

There is minor difference; the subject device is only used under the arm, where the predicate device measures at additional sites. The difference does not raise any new or different safety and effectiveness questions.

Note 2

The subject device and predicate device have different measurement ranges, 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 3

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 4

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 5

The Power supply of the subject device is different from the predicate device. The electrical safety and EMC test were conducted to demonstrate the difference does not raise any new performance or safety concerns.

Note 6

Operating range, Storage, and transportation condition difference: The subject device has been tested and the test results met the requirements of IEC 60601-1 and ISO 80601-2-56. The difference does not raise any new or different safety and effectiveness questions.

Note 7

After placing the thermometer on the measurement site, the measured result can only be displayed when the temperature is stable. Generally, the measurement time is not fixed at a certain value. The difference of measurement time will not raise any safety or effectiveness issue.

Note 8

Weight, size, materials: Biocompatibility test and performance bench test met the requirements of ISO 10993-5, ISO 10993-10 and ISO 10993-23. The differences do not raise any new questions of safety and effectiveness.

IX. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Medical electronic thermometer was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices –Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- IEC 60601-1-11 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

3) Performance testing

- ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)]

- ASTM E1112-00(2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

4) Software Verification and Validation

Software documentation is consistent with ***moderate level*** of concern. System validation testing demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

X. Conclusions

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 questions of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.