April 5, 2024

Famidoc Technology Company Limited
Amos Zou
Management Representative
No.212 Yilong Road, Hexi Industrial Zone, Jinxia,
Changan Town
Dongguan, Guangdong 523853
China

Re: K233192
Trade/Device Name: Wireless Smart Thermometer (Model: FDTH3400, FDTH3401, FDTH3402, FDTH3403, FDTH3404, FDTH3405, FDTH3406, FDTH3407, FDTH3408, FDTH3409, FDTH3410, FDTH3411, FDTH-V0-13, FDTH-V0-4)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 7, 2024
Received: March 7, 2024

Dear Amos Zou:

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

Enclosure

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)*
K233192

Device Name
Wireless Smart Thermometer (Model: FDTH3400, FDTH3401, FDTH3402, FDTH3403, FDTH3404, FDTH3405, FDTH3406, FDTH3407, FDTH3408, FDTH3409, FDTH3410, FDTH3411, FDTH-V0-13, FDTH-V0-4)

Indications for Use *(Describe)*
Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).

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 -K233192

This summary of 510(K) substantial equivalence information is being submitted in accordance with the requirement 21 CFR 807.92.

1. Submitter of 510(K):

Company Name:	Famidoc Technology Company Limited
Address:	No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town Dongguan Guangdong 523853 CN
Contact person:	Amos Zou
TEL:	+86 -769-89272488
E-mail:	qa@famidoc.com
Date of Prepared:	April 4, 2024

2. Subject Device:

Device Trade Name:	Wireless Smart Thermometer (Model: FDTH3400, FDTH3401, FDTH3402, FDTH3403, FDTH3404, FDTH3405, FDTH3406, FDTH3407, FDTH3408, FDTH3409, FDTH3410, FDTH3411, FDTH-V0-13, FDTH-V0-4)
Regulation Name	Clinical electronic thermometer
Product Code:	FLL
Regulation number	21 CRF 880.2910
Device Class	II

3. Predicate Device:

510(K)	K173730
Trade Name	Kinsa QuickCare Thermometer
Manufacturer	KINSA, Inc.
Regulation Name	Clinical electronic thermometer
Product Code:	FLL
Regulation number	21 CRF 880.2910
Device Class	II

4. Description of Subject Device:

Wireless Smart Thermometer (Model: FDTH3400, FDTH3401, FDTH3402, FDTH3403, FDTH3404, FDTH3405, FDTH3406, FDTH3407, FDTH3408, FDTH3409, FDTH3410, FDTH3411, FDTH-V0-13, FDTH-V0-4) utilizes a modular design method and consists of six main modules:

- Buzzer module: Control the product buzzer to produce audible notifications;
- Display module: Display driver content through notifications, and combine to produce various display interfaces;

- Battery voltage management module: Detect the battery power of the product and output the battery power level;
- Temperature measurement module: After collecting the electrical signal of the external temperature sensor through AD, it is restored to the temperature value through various algorithms
- Button module: This module is used to identify whether the product button is active;
- Wireless function module: Transfer the measurement data to the mobile device.

5. Indications for Use

Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).

6. Technical Characteristic and Substantial Equivalence

The following table compares the technological characteristics between the subject device to the predicate device.

7. **Comparison of Technological Characteristics with Predicate Device**

Elements of Comparison	Subject Devices				Predicate Device	Comparison Result
Device Name & 510k Number	Wireless Smart Thermometer (Model: FDTH3400, FDTH3401, FDTH3402, FDTH3403, FDTH3404, FDTH3405, FDTH3406, FDTH3407, FDTH3408, FDTH3409, FDTH3410, FDTH3411, FDTH-V0-13, FDTH-V0-4)				Kinsa QuickCare Thermometer- K173730	/
Device Model	FDTH3400~FDTH3405	FDTH-V0-13	FDTH3406~FDTH3411	FDTH-V0-4	KSA-110	/
Intended Use and Indications for Use						
Intended Use	Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).	Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).	Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).	Wireless Smart Thermometer is intended to be used at home for the intermittent measurement and monitoring of human body temperature orally, rectally, and under the arm. The devices are reusable for the adult and pediatric patient population (not suitable for neonates).	The Kinsa QuickCare Thermometer is used for the intermittent measurement and monitoring of human body temperature, orally, rectally and under the arm. The device is for the adult and pediatric population.	Similar
Performance Specification						
Power supply voltage	CR1632 battery	CR1632 battery	CR1632 battery	CR1632 battery	Battery powered CR2032 (3V)	Similar
Display module	LED（No backlight）	LED（No backlight）	LCD（No backlight）	LCD（No backlight）	LCD（No backlight）	Similar Note 1
Measuring	Adjusted mode / Direct	Adjusted mode / Direct	Adjusted mode	Adjusted mode	Adjusted mode	Similar

Method	mode	mode				Note 2
Measuring type	Axillary / Oral / Rectal	Axillary / Oral / Rectal	Axillary / Oral / Rectal	Axillary / Oral / Rectal	Axillary / Oral / Rectal	Same
Measuring range	32.00℃ ~ 42.90℃ (89.60℉~109.22℉)	32.00℃ ~ 42.90℃ (89.60℉~109.22℉)	32.0℃ ~ 42.9℃ (89.6℉~109.2℉)	32.0℃ ~ 42.9℃ (89.6℉~109.2℉)	32℃-42.8℃ (89.6℉-109.2℉)	Similar Note 3
Measuring accuracy	±0.10℃: between 35.00℃~42.00 ℃ (±0.18℉ between 95.00℉~107.60℉) ±0.20℃(or±0.36℉): outside this ranges	±0.10℃: between 35.00℃~42.00℃ (±0.18℉ between 95.00℉~107.60℉) ±0.20℃(or±0.36℉): outside this ranges	±0.3℃: between 34.0℃~42.0℃ (±0.6℉ between 93.2℉~107.6℉) ±0.4℃(or±0.8℉): outside this ranges	±0.3℃: between 34.0℃~42.0℃ (±0.6℉ between 93.2℉~107.6℉) ±0.4℃(or±0.8℉): outside this ranges	±0.2℉(0.1℃),89.6℉-109. 2℉(32℃-42.8℃)	Differe nt Note 4
Display resolution	0.01℃(0.01℉)	0.01℃(0.01℉)	0.1℃(0.1℉)	0.1℃(0.1℉)	0.1℃(0.1℉)	Similar Note 5
Measurement time	Adjusted mode：Less than 8s (for water bath) Direct mode：Less than 50s (for water bath)	Adjusted mode：Less than 8s (for water bath) Direct mode：Less than 50s (for water bath)	Less than 8s (for water bath)	Less than 8s (for water bath)	Adjusted mode: 8 seconds nominally	Similar Note 6
High body temperature hint	≥37.60℃(99.68℉)	≥37.60℃(99.68℉)	≥37.6℃(99.7℉)	≥37.6℃(99.7℉)	≥37.8℃(100.4℉)	Different Note 7
Temperature unit	℃/℉	℃/℉	℃/℉	℃/℉	℃/℉	Same

Memory group	8 groups of memories (FDTH3401) 7 groups of memories (FDTH3402) 6 groups of memories (FDTH3403) 5 groups of memories (FDTH3404) 3 groups of memories (FDTH3405) Last time memory	Last time memory display	8 groups of memories (FDTH3406) 7 groups of memories (FDTH3407) 6 groups of memories (FDTH3408) 5 groups of memories (FDTH3409) 3 groups of memories (FDTH3410) Last time memory	Last time memory display	Full temperature history available on mobile device	Similar Note 8

	display(FDTH3400)		display(FDTH3411)			
Sensor type	Thermistor	Thermistor	Thermistor	Thermistor	Thermistor	Same
Wireless interface	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same
Materials	TPE, ABS, Stainless Steel	TPE, ABS, Stainless Steel	TPE, ABS, Stainless Steel	TPE, ABS, Stainless Steel	Biocompatible metals and resins	Similar Note 9
OPERATING & STORAGE CONDITIONS						
Operation condition	Temperature:5℃~40℃ (41°F~104°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:5℃~40℃ (41°F~104°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:5℃~40℃ (41°F~104°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:5℃~40℃ (41°F~104°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	59°F-95°F(15°C-35°C)15 %to 85% R.H non-condensing	Similar Note 10
Transportation and storage condition	Temperature:-25℃~55℃ (-13°F~131°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:-25℃~55℃ (-13°F~131°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:-25℃~55℃ (-13°F~131°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	Temperature:-25℃~55℃ (-13°F~131°F) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa	-13°Fto +95°F(-25°Cto +35°C)at R.H.up to 90%non-condensingand 95°F to 158°F(35°C to 70°C) at a water vapor pressure up to 50 hPa	Similar Note 11
Shelf life	5 years	5 years	5 years	5 years	Unknown	Different Note 12
COMPLIANCE STANDARDS						
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Same
Home Use	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	Same
Performance	ISO 80601-2-56	ISO 80601-2-56	ISO 80601-2-56	ISO 80601-2-56	ISO 80601-2-56	Same

Biocompatibility	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	Same

Note 1

The display module of the subject device and predicate device is different; however, the subject device performance testing demonstrates that the difference does not raise different questions of safety and effectiveness.

Note 2

The measuring method of models FDTH3400 and FDTH-V0-13 of the subject device are different than the predicate device. The subject device models FDTH3400 and FDTH-V0-13 measure in direct mode. The direct mode measurement time is longer than the adjustment mode measurement time; however, device accuracy was tested in accordance with the ISO 80601-2-56 Standard. Therefore, the difference does not raise different questions of safety and effectiveness.

Note 3 and 4

The Measuring Range and Accuracy of the subject device and predicate device are different; however, the measuring range and accuracy of subject device are both in compliance with IEC 60601-1 and ISO 80601-2-56. Therefore, this difference does not raise different questions of safety and effectiveness.

Note 5

The display resolution of the subject device and predicate device are different as the subject device models FDTH3400 and FDTH-V0-13 have a higher display accuracy, However, this difference does not raise any different questions of safety and effectiveness.

Note 6

The measurement time of subject device and predicate device is different as the subject device models, FDTH3400 and FDTH-V0-13 measure in direct mode and therefore the measurement time is longer. Performance testing was adequately conducted in accordance with IEC 60601-1 and ISO 80601-2-56 and demonstrate that the differences do not raise different questions of safety and effectiveness.

Note 7

The high body temperature alert is different between the subject and predicate device. However, performance testing demonstrates that the difference does not raise new questions of safety and effectiveness.

Note 8

The Memory group of the subject device and predicate device are different. The memory measurement storage is indicated in the user manual and outer carton, The difference does not raise different questions of safety and effectiveness.

Note 9

The materials between the subject and predicate device are different; however, biocompatibility testing demonstrates the difference does not raise different questions of safety and effectiveness.

Note 10 and Note 11

The Temperature, Relative Humidity and Atmospheric pressure of Operation as well as the storage environment of subject devices is different between the subject and predicate device;

however, they are both in compliance with IEC 60601-1-11 and therefore, the differences do not raise different questions of safety and effectiveness.

Note 12

The subject device performance was tested over the shelf life to applicable standards as identified below. Therefore, the difference does not raise different questions of safety and effectiveness.Performance Testing:
Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

7.1 Non-Clinical Data:
The following performance data were provided in support of the substantial equivalence determination.

7.2 Biocompatibility testing
The biocompatibility evaluation for the FDTH series Upper arm Blood Pressure Monitor and the NIBP CUFF were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

7.3 Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the FDTH series Upper arm Blood Pressure Monitor, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety and the 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 standard for EMC.

7.4 Bench Testing
Bench testing was conducted on the FDTH series Upper arm Blood Pressure Monitor, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 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 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

7.5 Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

7.6 Clinical data:

Clinical testing is conducted per 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.

Based on the same product principle, and the clinical validation data on the FDTH3400 can cover all the models included in this submission.

In this clinical study, 105 patients participated in the clinical study. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any adverse events. The results showed the accuracy of the subject device is within acceptable scope specified in ISO 80601-2-56.

8. Conclusions:

The subject device has the same intended use and similar technological characteristics as the predicate device, Kinsa QuickCare Thermometer cleared under K173730. Clinical and non-clinical testing demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.