September 26, 2021

Smart Technology Co., Ltd.
℅ Yulan Gao
Overseas Registration Assistant Specialist
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street, Panyu District
Guangzhou, Guangdong 510006
China

Re: K203731
Trade/Device Name: DT100 Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: August 20, 2021
Received: August 24, 2021

Dear Yulan Gao:

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,

Payal Patel
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)*
K203731

Device Name
DT100 Digital Thermometer

Indications for Use *(Describe)*
DT100 Digital thermometer is intended for the measurement of human body temperature by doctor or consumers in the hospital or home. It can be used for axillary, oral and rectal measurement. The product is reusable and provided non-sterile. The device is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K203731 - 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER INFORMATION

Smart Technology Co., Ltd.

No. 8 Xingcheng East Road, Fuwan Industrial Area, Gaoming District, Foshan,

Guangdong Province, China

Phone: +86-0757-88818786

Primary Contact Person:	Mag Mei General manager Smart Technology Co., Ltd. Tel: +86-0757-88818786
Consultant:	Olivia Meng Regulatory Affairs Manager OSMUNDA Medical Device Consulting Co., Ltd Tel: (+86)-20-6231 6262 Fax: (+86) -20-8633 0253
Date Prepared:	September 24, 2021

II. SUBJECT DEVICE

Name of Device:	DT100 Digital Thermometer
Model:	DT100
Common/Usual Name:	Clinical electronic thermometer
Classification Names:	Thermometer, Electronic, Clinical
Regulation Number:	21 CFR 880.2910
Device Class:	II
Product Code:	FLL

III. PREDICATE DEVICE

Sponsor: Fudakang Industrial Co., Ltd
Device Name: Fudakang Digital thermometer; Model: BTA41-CN
510(k) Number: K101387

IV. DEVICE DESCRIPTION

DT100 digital thermometer is a fast, highly accurate, and easy to use clinical instrument for measuring patient temperatures by oral, axillary or rectal means. The digital thermometer is a hand-held, reusable, multi-user, battery operated device. It has one model DT100.

V. INDICATION FOR USE

DT100 Digital thermometer is intended for the measurement of human body temperature by doctor or customers in the hospital or home. It can be used for axillary, oral and rectal measurement. The product is reusable and provided non-sterile. The device is for people of all ages.

VI.

DT100 Digital thermometer is intended for the measurement of human body temperature by doctor or consumers in the hospital or home. It can be used for axillary, oral and rectal measurement. The product is reusable and provided non-sterile. The device is for people of all ages.

VII. SUBSTANTIAL EQUIVELENCE

Specification	Proposed Device	Predicate Device	Discussion of Differences
Device name	DT100 Digital Thermometer	Fudakang Digital thermometer (BTA41-CN)	
K number	K203731	K101387	

Indications for Use	DT100 Digital thermometer is intended for the measurement of human body temperature by doctor or customers in the hospital or home. It can be used for axillary, oral and rectal measurement. The product is reusable and provided non-sterile. The device is for people of all ages.	Fudakang Digital thermometer are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.	Similar
Measurement site	axillary, oral and rectal measurement.	axillary, oral and rectal measurement.	Same
Use of probe cover	Measure oral or rectal position: Use probe cover Measure axillary position: no require of probe cover	Measure oral or rectal position: Use probe cover Measure axillary position: no require of probe cover	Same
Temperature Measurement Technology	NTC thermistor resistance technology	NTC thermistor resistance technology	Same
Power source	1.55V, LR41 alkaline or SR41 silver oxide type	1.5V button battery	Similar
composition	Main part, display screen, control button, probe tip	Main part, display screen, control button, probe tip	Same
Display resolution	0.1	0.1	Same
Material	Enclosure: Acrylonitrile Butadiene Styrene probe: stainless steel button: silicone	Enclosure and button: Acrylonitrile Butadiene Styrene probe: stainless steel	Same
Measurement Range	32°C (89.6°F)- 42.9°C(109.2°F)	32°C (89.6°F)- 42.9°C(109.2°F)	Same
Accuracy	32°C (89.6°F)- 42.9°C(109.2°F) : +/- 0.1 °C (+/-0.2°F)	35°C (95.0°F)- 39.0°C (102.0°F): +/-0.1 °C (+/-0.2°F)	Same
Response time	60 seconds	60 seconds	Same
Low battery indicator	Yes	Yes	Same
Memory function	Yes	Yes	Same
Memory capacity	Last one measurement record	Last one measurement record	Same
Reusable device	Yes	Yes	Same
Temperature Measurement Technology	NTC thermistor resistance technology	NTC thermistor resistance technology	Same
Key temperature sensor	NTC thermistor	NTC thermistor	Same

Power requirement	LR41 button cell	LR41 button cell	Same
Scale	Switchable	Switchable	Same
Biocompatibility	Comply with ISO 10993-1 ISO10993-5 ISO10993-10	Comply with ISO 10993-1 ISO10993-5 ISO10993-10	Same
Voluntary Standards for clinical Electronic Thermometer	ASTM E1112	ASTEM E1112	Same
Medical Electrical Safety and EMC	IEC 60601-1 IEC60601-1-2	IEC 60601-1 IEC60601-1-2	Same
Operating and storage condition	Operation: 16 to 40° C(60.8 to 104° F) and 15 to 95% humidity noncondensing; Storage: -20 to 50° C (-4 to 120° F) and 15 to 95% humidity noncondensing	Operation: 16 to 40° C(60.8 to 104° F) and 15 to 95% humidity noncondensing; Storage: -20 to 50° C (-4 to 120° F) and 15 to 95% humidity noncondensing	Same

Substantial equivalence conclusion:

Technical parameters are the same/similar between the proposed and predicate device. We believe that the Digital thermometer is as safe and effective, and performs in a substantially equivalent manner to the predicate device.

VIII. NON-CLINICAL PERFORMANCE DATA

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

Biocompatibility:

The thermometer has been evaluated according to ISO 10993-5 and ISO 10993-10, and has been demonstrated as biocompatible safety.

Electrical Safety and EMC:

The device was tested in accordance with:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

- 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

- 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

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.

- ASTM E1112 Standard specification for electronic thermometer for intermittent determination of patient temperature

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Smart Technology has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol were developed to test each requirement. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

IX. CLINICAL TESTING DATA

No clinical testing data is included in this submission.

X. CONCLUSION

The DT100 digital thermometer is substantially equivalent to the Fudakang Digital thermometer with respect to the technological characteristics, Indications for use, non-clinical and performance testing.