DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 6, 2017

Guangzhou Jinxinbao Electronic Co., Ltd
Ms. Elly Xu
Consultant Manager
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122, International Mayors Communication Centre
NO.55 Shizhou middle road
Nanshan District, Shenzhen, 518101
TAIWAN

Re: K163603
Trade/Device Name: Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: April 25, 2017
Received: May 08, 2017

Dear Elly Xu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163603

Device Name
Digital Thermometer

Indications for Use *(Describe)*
Digital Thermometer is intended to measure the body temperature either oral or axillaries (under arms) and to be used by consumers in a household environment. The device is intended for repeatable use by one patient. It is intended for 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K163603 510(k) Summary

This 510(K) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Administrative Information

Date of Summary prepared	May 31, 2017
Manufacturer information	Company title: Guangzhou Jinxinbao Electronic Co., Ltd. Company address: No.38 Huanzhen Xi Road, Dagang Town, Nansha Distric, Guanzhou, Guangdong,China 511470 Contact person: Mowu Zhu Phone: +86-020-34938449 Fax: +86-020-34936960 E-mail: jxb_qc_moo@jxb-htb.net
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Ms. Elly Xu; Mr. Field Fu E-Mail: elly@cefda.com; cefda13485@163.com

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Digital Thermometer
Model:	DT001, DT007, DT008
Classification name:	Clinical Electronic Thermometer
Review Panel:	General Hospital
Product Code:	FLL

Device Class:	II
Regulation Number:	880.2910

3. Predicate Device Information

Sponsor:	Fudakang Industrial Co., Ltd
Device:	Digital Thermometer
Model:	BT-A11CN, BT-A21CN, BT-A41CN
510(K) Number:	K101387

4. Device Description

The Digital Thermometer utilizes measured thermistor resistance and a microcontroller unit to determine and display human body temperature. Changes in the probe temperature due to oral or auxiliary contact correspond to changes in resistance. The probe Temperature values are digitally displayed on an LCD screen in 0.2 degrees Fahrenheit increments. The measurements do not account for a probe cover. The user contacting materials are Stainless steel and Acrylonitrile Butadiene Styrene (ABS).

The Digital Thermometer includes 3 models: DT001, DT007 and DT008. The differences of these models are in appearance and specifications. All of them have the samebasic functions:

- Precision of 0.1°C for measurements between 35°C and 39°C for measurement
- Data displayed in Celsius
- Automatic stop (energy saver)

5. Indications for Use

Digital Thermometer is intended to measure the body temperature either oral or axillaries (under arms) and to be used by consumers in a household environment. The device is intended for repeatable use by one patient. It is intended for use on people of all ages.

6. Technological characteristics of the proposed device compared to the predicate device

Items	Predicate Device (K101387), Fudakang Digital Thermometer	Subject Device	Remarks
Indication for Use	Intended for measurement and monitoring of human body temperature by doctor or consumers in the hospital or home. BT-A11CN, BT-A21CN and BT-A41CN can be used in axillary measurement, oral measurements and rectal measurement.	Digital Thermometer is intended to measure the body temperature either oral or axillaries (under arms) and to be used by consumers in a household environment. The device is intended for repeatable use by one patient. It is intended for use on people of all ages.	See explanation below
Use environment	Clinical or home	Home use	Same
Components	Sensor, buzz film, housing, stainless steel cap, LCD display, measurement control module	Sensor, buzz film, housing, stainless steel probe, LCD display, measurement control module(MCU)	Same
Sensor	Thermistor	Thermistor	Same
Power requirements	Battery	1.5V d.c	Same
Material used	Housing: ABS Probe: Stainless steel	Housing: ABS Probe: Stainless steel	Same
Measure range	32°C ~42.9°C	32°C ~42.9°C	Same
Operating mode	Direct mode	Direct mode	Same
Measuring accuracy	±0.1°C between 35.0°C to 39.0°C; The rest: ±0.2°C	±0.1°C between 36.0℃to 39.0℃; The rest: ±0.2℃	See explanation below
Response time	60s	30s	See explanation below

Items	Predicate Device (K101387), Fudakang Digital Thermometer	Subject Device	Remarks
Biocompatibility	Comply with ISO 10993-5:2009, ISO 10993-10:2010	Comply with ISO 10993-5:2009, ISO 10993-10:2010	Same
Electric safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11:2010	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11:2010	Same
Performance	ASTM E1112	ASTM E1112, ISO 80601-2-56.	Same

The predicate device and subject device indications for use are not identical in language. The predicate device provides a list of models and can be used for obtaining a rectal temperature reading and the subject device identifies the user populations. The differences in technology between the subject and the predicate device are the measuring range of subject device meet the maximum error of ±0.1°C, temperature range from 37°C to 39°C, which is stated in standard ASTM E 1112. Also, the subject device has a shorter response time in obtaining and displaying the temperature measurement on the LCD display. These minor differences in indications for use, and differences in technology do not raise different questions of safety and effectiveness.

7. Brief discussion of the nonclinical tests

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Performance tests protocols were performed in accordance with applicable standards and FDA guidance documents. The results of the tests demonstrate the compliance to applicable thermometer standards and FDA guidance documents which are list below, and demonstrate the performance of new devices is equivalent to the predicate devices.

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 - Requirements and Tests.

IEC 60601-1-11 Edition 1.0 2010-04, 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 First Edition 2009-10-01, Medical Electrical Equipment - Part 2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement.

ISO 10993-1:2009, Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing Within a Risk Management Process.

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.

FDA Guidance: Reprocessing Medical Devices in Health Care Settings – Validation Methods and Labeling.

8. Clinical tests

Substantial equivalence does not depend on the clinical test data as the subject and predicate device both have thermistors utilized in direct mode and clinical testing is not required.

9. Conclusions

Based on device comparison analysis and non-clinical performance bench testing, the proposed device is substantially equivalent to legally marketed predicate device.