June 7, 2018

Fudakang Industrial Co., Ltd
% Field Fu
Shenzhen Joyantech Consulting Co., Ltd
NO. 55 Shizhou Middle Road
Nanshan District, Shenzhen, GD755
CHINA

Re: K172121
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 28, 2018
Received: May 9, 2018

Dear Field Fu:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172121

Device Name
Digital Thermometer

Indications for Use *(Describe)*
Digital thermometers (Model: TP-100, TP-200, TP-300, TP-400, TP-500, BT-A31A-BT) is intended for the measurement and monitoring of oral or axillary for adult , pediatric and infant temperature via thermistor by doctor or consumers in the hospital or home. The result of measurement and monitoring will be transmitted via Bluetooth (BLE) to Bluetooth enabled smart mobile device (cell phone, iPad) with GuardiAngel App installed.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant Name	Fudakang Industrial Co., Ltd.
Address	No.8 Yinghe Road, Yuanjiangyuan Management Zone, Changping Town, Dongguan City, Guangdong 523560, China
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Contact person	Bob Yu
Contact person's e-mail	bobyu@fudakang.com
Date Prepared	July 4, 2017
Website	http://www.fudakang.com/

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen
Phone No.	+86-755-86069197
Contact person	Field Fu; Christy Young;
Contact person's e-mail	christy@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Digital Thermometer
Common name	Digital Thermometer
Model	TP100, TP200, TP300, TP400, TP500,BT-A31A-BT
Classification	Ⅱ
Classification name	Clinical Electronic Thermometer
Product code	FLL
Regulation No.	880.2910

3. Legally Marketed Predicate Device

Trade Name	Fudakang Bluetooth Digital Thermometer (Model: BT-A41CN-BT)
510(k) Number	K160308
Product Code	FLL
Manufacturer	Fudakang Industrial Co., Ltd.

Trade Name	Electronic Thermometer, Model WT1 and WT2
510(k) Number	K152739
Product Code	FLL

Manufacturer	Guangdong Biolight Meditech Co., Ltd

4. Device Description

The Digital Thermometer is a general purpose thermometer. The thermometer is intended for oral or axillary temperature measurements of the human body. The thermometer should be used with a smart phone or other Bluetooth smart device on which the GuadiAngel app is installed. The thermometer communicates with the user's device through a Bluetooth connection.

5. Intended Use/Indication for Use

Digital thermometers (Model: TP-100, TP-200, TP-300, TP-400, TP-500, BT-A31A-BT) is intended for the measurement and monitoring of oral or axillary for adult , pediatric and infant temperature via thermistor by doctor or consumers in the hospital or home. The result of measurement and monitoring will be transmitted via Bluetooth (BLE) to Bluetooth enabled smart mobile device (cell phone, iPad) with GuardiAngel App installed.

6. Substantial Equivalence Comparison

Item	**Proposed Device: Digital Thermometer**	**Predicate Device: Fudakang Bluetooth Digital Thermometer (Model: BT-A41CN-BT) (K160308)**	**Predicate Device: Electronic Thermometer, Model WT1 and WT2 （K152739）**
Product Code	FLL	FLL	FLL
Regulation number	21 CFR 880.2910	21 CFR 880.2910	21 CFR 880.2910
Manufacturer	Fudakang Industrial Co., Ltd	Fudakang Industrial Co., Ltd	Guangdong Biolight Meditech Co., Ltd
Intended Use	Digital thermometers (Model: TP-100, TP-200, TP-300, TP-400, TP-500, BT-A31A-BT) is intended for the measurement and monitoring of oral or axillary for adult , pediatric and infant temperature via thermistor by doctor or consumers in the hospital or home. The result of measurement and monitoring will be transmitted via Bluetooth (BLE) to	Fudakang Bluetooth Digital thermometer (Model: BT-A41CN-BT) is intended for the measurement and monitoring of oral, axillary, and rectal temperature of adults via a thermistor. The device is for use of a doctor or lay consumers in the hospital or home. The result of measurement can be transmitted to smart mobile device (cell phone, iPad) while displayed on the LCD.	Electronic Thermometer is intended for measuring and monitoring human body temperature orally and/or under arm for adult, pediatric and infant. It can be used in healthcare facility and home.

	Bluetooth enabled smart mobile device (cell phone, iPad) with GuardiAngel App installed.		
Thermometer type	Digital thermometer	Digital thermometer	Digital thermometer
Sensor	Thermistor	Thermistor	Thermistor
Power requirements	1x3V Lithium battery	1.5V button battery	Button cell
Battery life	Approx.100 hours for continuous operation or approx.18 months while used 10 minutes per day.	Approx.100 hours for continuous operation.	Not available
Signal processing and display	Internal software and display on smart phone	Internal software and display on smart phone as well as LCD	Display in mobile application, no display on device
Signal transmission	Bluetooth 4.0	Bluetooth 4.1	Bluetooth 4.0
Receiver (mobile terminal)	iOS or Android mobile device	iOS or Android mobile device	iOS Mobile Device
Valid transmission distance	10 meters	10 meters	Not available
Measuring range	32.0-42.9℃(89.6-109.2℉)	32.0-42.9℃(89.6-109.2℉)	25.00℃～45.00℃
Accuracy	±0.1℃ 35.0-39.0℃ (±0.2℉ 95.0-102.2℉) ±0.2℃ the rest	±0.1℃ 35.0-39.0℃ (±0.2℉ 95.0-102.2℉) ±0.2℃ the rest	±0.1℃ 25.00℃～34.99℃ ±0.05℃ 35.00℃～38.50℃ ±0.1℃ 38.51℃～45.00℃
Temperature unit	°C or °F	°C or °F	°C or °F
Operation environment	5~40°C; 15% to 85%RH	5~40°C; 15% to 85%RH	Not available
Storage environment	-20~55°C; ≤85%RH	-20~55°C; ≤85%RH	Not available
Skin-contacting components	Housing, probe, tapes, holders and silicone patches	Housing, probe	Housing, probe, tapes
Materials of	Housing: ABS, liquid	Housing: ABS, silicone rubber	Stainless Steel, S216

skin-contacting components	silicone rubber Probe: Stainless steel 304 Medical Tape: Polyethylene Silicone patch: Silicone rubber mixture Holder: ABS	Probe: stainless steel 304	Polycarbonate (PC), 2458 Silicone, TPE Non-Woven Cloth Medical Melt Adhesive

Discussion of the differences:

The Digital Thermometer (Model: TP-100, TP-200, TP-300, TP-400, TP-500, BT-A31A-BT) has similar indications for use and technological characteristics as the predicate device:

Digital Thermometer has the same intended use as the predicate device（K152739）: to measure human body temperature orally and/or under arm for adult, pediatric and infant.

The same and/or similar technologies and parameters are used in digital thermometers as the predicate device. The identified differences in technological characteristics do not raise new or different questions of safety and effectiveness. Although some specifications are slightly different from the predicate device, the thermometer quality has been verified and validated as a part of performance testing and safety /EMC testing and the results are included as a part of this submission. Performance information and evidence of compliance to recognized standards demonstrate the device is substantially equivalent to the predicate device.

The targeted device may connect to iOS device and Android device through wireless method, but the predicate device can only connect to iOS device. Risk analysis and associated verification (include cybersecurity test, FCC test and wireless verification) have been performed that the wireless feature is acceptable.

Both devices use similar materials for construction and have direct skin surface contact. The biocompatibility test reports for the different materials have been provided to determine the biocompatibility of the subject device. Based upon the same intended use, similar materials for device construction, product specification and operation, as well as performance testing, it could be concluded that the Digital Thermometer (Model: TP-100, TP-200, TP-300, TP-400, TP-500, BT-A31A-BT) is substantially equivalent to the predicate device.

7. Non-clinical studies and tests performed

Non-clinical tests were conducted to verify that the targeted device meet all design specifications in order to demonstrate that it is Substantially Equivalent to the predicate device.

The test results demonstrate that the targeted device complies with the following standards:

IEC 60601-1Medical 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 compatibility

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
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
CFR 47 FCC PART 15 Subpart C section 15.247 under the operating frequency of 2402~2480MHz
ETSI EN301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-17 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmitting Systems
ETSI EN 300 328 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

Software verification and validation:
Software documentation consistent with moderate level of concern is submitted in this 510(k). System validation testing presented in this 510(k) demonstrates that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Bio-compatibility test:
The body-contacting components of this device were tested according to:
ISO 10993-5 Biological Evaluation of Medical Devices—Tests for In Vitro Cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices- Tests for Irritation and Skin Sensitization

8. Clinical study

Not applicable.

9. Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.