December 31, 2019

Xiamen Ants Bro Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, 510000
China

Re: K190990
Trade/Device Name: Digital Thermometer (Models: TM-2011, TM-3002, TM-3102)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 26, 2019
Received: December 2, 2019

Dear Cassie Lee:

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,

Geeta Pamidimukkala
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190990

Device Name
Digital Thermometer (Models: TM-2011, TM-3002, TM-3102)

Indications for Use *(Describe)*
Digital Thermometer (models TM-2011, TM-3002, TM-3102) intended for the measurement and monitoring of human body temperature by users for home use. It can be used for axillary measurement and oral measurement.

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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510(k) Summary K190990

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

1. Submitter's Information

510(k) Owner's Name: Xiamen Ants Bro Technology Co., Ltd.
Establishment Registration Number: Applying
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Application Correspondent:
Contact Person: Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k): Traditional
Common Name: Clinical electronic thermometer
Classification Name: Thermometer, electronic, clinical
Trade Name: Digital Thermometer
Model Name: TM-2011, TM-3002, TM-3102
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulatory Class: 2

3. Predicate Device Information

Sponsor: Fudakang Industrial Co., Ltd.
Trade Name: Digital Thermometer
Common Name: Clinical electronic thermometer
Classification Name: Thermometer, Electronic, Clinical
510(K) Number: K101387
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulation Class: 2

4. Device Description

Digital Thermometers comprises a thermistor for getting temperature signal, a reference resistor for comparing the resistance of the thermistor, an ASIC for processing the target temperature digitally, and a LCD for displaying the temperature. The design principle of thermometer is based on thermosensor and ASIC technology. A thermistor is used as thermosensor. The ASIC gets the sensor's signal from human body, then processes the signal and calculates the result, after that displays the temperature result by a LCD. There is buzzing noise occurs when the device turns on and when the measurement is completed (for model TM-3002 and TM-3102 only.

5. Intended Use / Indications for Use

Digital Thermometer (models TM-2011, TM-3002, TM-3102) intended for the measurement and monitoring of human body temperature by users for home use. It can be used for axillary measurement and oral measurement.

6. Test Summary

6.1 Digital Thermometer has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993-1, ISO 10993-5 and ISO 10993-10 standards
- Usability test according to IEC 62366 standard
- Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement according to ASTM E1112-00 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- 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.
- Software verification and validation test according to the requirements of the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

6.2 Discussion of Clinical Tests Performed

Clinical tests were conducted on the Model TM-3102. The clinical tests evaluated 240 of subjects. and the thermometer was evaluated in four groups A1 - 0 up to three month, A2 - three months to one year; B1 - older than one years and younger than five years; and C - older than five years old. The clinical performance test protocol and data analysis were conducted in accordance with the requirement of ISO 80601-2-56. The test report showed the clinical performance of the subject devices complied with the requirement of ISO 80601-2-56.

6.3 Discussion of Cleaning Validation

Cleaning verification was performed on TM-2011, TM-3002, TM-3102. Each model took 15 samples and 45 samples each. The test report showed the cleaning instructions are appropriate for cleaning and reuse.

7. Comparison to predicate device and conclusion

The subject device Digital Thermometers (Model : TM-2011, TM-3002, TM-3102) have all features of the predicate devices K101387. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate devices.

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	Xiamen Ants Bro Technology Co., Ltd.	Fudakang Industrial Co., Ltd.	--
Name and Model	Digital Thermometer, models: TM-2011, TM-3002, TM-3102	Digital Thermometer, Model: BT-A11CN, BT-A21CN, BT-A41 CN	--
510(k) Number	K190990	K101387	--
Product Code	FLL	FLL	SE
Thermometer Type	Digital Thermometer	Digital Thermometer	SE
Intended Use / Indication for Use	Digital Thermometer (models TM-2011, TM-3002, TM-3102) intended for the measurement and monitoring of human body temperature by users for home use. It can be used for axillary measurement and oral measurement.	Fudakang Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home. BT-A11CN, BT-A21CN, BT-A41CN can be used for axillary measurement, oral measurement and rectal measurement.	SE
Sensor	Thermistor	Thermistor	SE
Signal Processing and Display	Using the resistance change of thermal resistor to detect body temperature and displayed through the LCD.	Using the resistance change of thermal resistor to detect body temperature and displayed through the LCD.	SE
Power Requirement	1.5V button battery	1.5V button battery	SE
Battery type	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)	One 1.5 V DC. button battery (size LR41or SR41, UCC 392) DMT-4726,DMT-4735: One 3.0V CR2032 battery	SE
Measurement Temperature Range	32.0°C ~ 43°C	32.0°C ~ 43°C	SE
Voice function	For model TM-3002, TM-3102: Yes; (There is buzzing noise occur when the device turning on and when the measurement is completed.) For model TM-2011: None	Yes	SE Note 1
Patient contact material	Enclosure and Key: ABS plastic Probe: Stainless steel	Enclosure and Key: ABS plastic Probe: Stainless steel	SE
Measurement Accuracy	±0.1°C, 37.0°C ~ 39.0°C ±0.2°C ,35.0°C ~ 36.9°C, 39.1°C ~ 42.0°C ±0.3°C, 32.0°C ~ 34.9°C, 42.1°C ~ 43.0°C At Standard room temperature of 25°C (77.0°F)	35.0°C ~ 39.0°C: ±0.1°C 95.0 ~ 102.0 °F: ±0.1°F the rest: ±0.2°C At Standard room temperature of 25°C (77.0°F)	SE Note 2
Measurement Speed	45s	60s	SE Note 2

Elements of Comparison	Subject Device	Predicate Device	Remark
Measurement site	Orally, axillary	DMT series (except DMT-455): orally, rectally or under the arm DMT-455:orally	SE Note 1
Power ON/OFF	Switch the thermometer ON and OFF by shaking it or Switch the thermometer ON and OFF by press the power button	Switch the thermometer ON and OFF by press the power button	SE Note 1
Describe and compare features	For model TM-3002 and TM-3102: Voice feature For model TM-2011: No voice feature Other functions are the same	--	SE Note 1
Probe cover use?	No	For rectal measurement only	SE
Complied Standard	IEC 60601-1, ISO 80601-2-56, IEC 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-1, ISO 10993-5, ISO 10993-10	IEC 60601-1, IEC 80601-2-56, IEC 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-1, ISO 10993-5, ISO 10993-10	SE

Note 1:
Although the “Voice function”, “Measurement site” , “Describe and compare features” and “Power ON/OFF” of subject device is a little different with predicate device, but they are just for indication and operation only, and the whole product are all compliance with safety standard and performance standards, these differences will not raise any safety or effectiveness issue.

Note 2:
Although there is a little difference between the “measurement accuracy” and “Measurement Speed”, the subject device accuracy is compliance with ISO 80601-2-56 and ASTM E 1112 requirements. So, the difference of accuracy will not raise any safety of effectiveness issue.

Final Conclusion：
The subject device Digital Thermometers (Model: TM-2011, TM-3002, TM-3102) have all features of the predicate devices K101387. Thus, the subject device is substantially equivalent to the predicate devices

8. Date of the summary prepared: December 31, 2019