March 31, 2021

Bioland Technology Ltd.
Yiqing Feng
R.A
No. A6B7 (Block G) ShangRong Industrial Zone No. 5 Baolong R
Shenzhen, Guangdong 518116
China

Re: K201879
Trade/Device Name: Digital Thermometer Model T103, T104
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 26, 2021
Received: March 1, 2021

Dear Yiqing Feng:

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,

for Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201879

Device Name
Digital Thermometer, T103 and T104

Indications for Use *(Describe)*
The digital thermometer 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K201879 510(k) Summary

A. Date of Summary Preparation: March 16, 2021

B. Applicant Information

Name: Bioland Technology Ltd.

Address: No. A6B7 (Block G) Shangrong Industrial Zone, No.5 Baolong Road, Baolong Community Longgang District, 518116 Shenzhen, Guangdong PEOPLE'S REPUBLIC OF CHINA

Tel: +86-755-36900999

Fax: +86-755-33296299

Contact person: Yiqing Feng

E-mail: regulator-a@bioland.com.cn

C. Subject Device Information

Trade name: Digital Thermometer
Model: T103, T104
Classification name: Thermometer, Electronic, Clinical
Product Code: FLL
Regulation number: 21 CFR 880.2910
Device class: II

D. Predicate Device Information

Device name: Digital Thermometer
510(k) number: K190990
Manufacturer: Xiamen Ants Bro Technology Co., Ltd.

E. Intended use / Indication for Use

The digital thermometers are 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.

F. Device Description

The digital thermometer is an electronic thermometer using a thermistor to measure human body temperature for people of all ages.

The digital thermometer are designed to be non-sterile, reusable clinical thermometers intended for the determination of human body temperature by contact the sensing probe with patient's axillary and oral. The measurement duration is less than 1 minute. The device has a storage function in which the last measured value is automatically stored after measurement is successfully completed.

This device is designed for people of all ages to use at home. There is BF applied part. No special protection against the use in the environment of ignitable gases.

G. Substantial Equivalence Table

Item	Subject Device	Predicate Device	Remark
Manufacturer	Bioland Technology Ltd	JOYTECH HEALTHCARE CO., LTD	N/A
Model	T103, T104	TM-3002	N/A
Classification	II	II	SE
Product code	FLL	FLL	SE
Classification name	Thermometer, electronic, clinical	Thermometer, electronic, clinical	SE
Regulation No.	880.2910	880.2910	SE
510(K) number	K201879	K190990	N/A
Thermometer type	Digital thermometer	Digital thermometer	SE
Intended Use/ Indication for use	The digital thermometer 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	Digital thermometer 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	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
Measurement Site	Axillary and oral	Axillary and oral	SE
Measurement range	32.0 ºC ~43.0 ºC (90.0ºF~109.4 ºF)	32 ºC ~43.0 ºC	Similar Note 1
Display resolution	0.1 ºC/ 0.1 ºF	0.1 ºC	Similar Note 1
Measuring accuracy	±0.1 ºC (37.0 ºC ~39.0 ºC) ±0.2 ºC (35.0 ºC ~ 36.9 ºC or 39.1 ºC ~ 42.0 ºC) ±0.3 ºC (under 35.0 ºC or over 42.0 ºC) ±0.2 ºF (98.0 ºF ~ 102.0 ºF) ±0.3 ºF (95.0 ºF ~ 97.9 ºF or 102.1 ºF ~ 107.6 ºF) ±0.5 ºF (under 95.0 ºF or over 107.6 ºF)	±0.1ºC, 37.0 ºC ~ 39.0 ºC ±0.2 ºC, 35.0 ºC ~36.9 ºC, 39.1 ºC ~42.0 ºC ±0.3 ºC, 32.0 ºC ~34.9 ºC, 42.1 ºC ~43.0 ºC	Similar Note 1
Measurement speed	Within 1 min	45s	Similar Note 2
Power ON/OFF	Switch the thermometer ON and OFF by press the power button, or automatic shutdown within 10 minutes.	Switch the thermometer ON and OFF by shaking it or switch the thermometer ON and OFF by press	Similar Note 3

Item	Subject Device	Predicate Device	Remark
		the power button.	
Operating Environment Condition	5 ºC ~40 ºC (41ºF~104 ºF), 15~95%RH (non-condensing) , 70-106kPa	5 ºC～40 ºC (41ºF~104 ºF) 15%~95%RH 700hPa ~ 1060hPa	SE
Voice function	There s buzzing noise occur when the device turning on and when the measurement is completed.	There s buzzing noise occur when the device turning on and when the measurement is completed.	SE
Patient contacting Materials	Enclosure and key: ABS Plastic Probe: Stainless steel	Enclosure and key: ABS Plastic Probe: Stainless steel	SE
Probe cover use?	NO	NO	SE
Service life	3 years	3 years	SE
Ingress protection rating	IP22	IP22	SE
Reprocessing	Cleaning	Cleaning	SE
Biocompatibility	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 ISO 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: Compared to the predicate device, the “Measurement range”, “Display resolution” and “Measuring accuracy” of the subject device only added the requirement of the Fahrenheit scale. The accuracy requirement of the Celsius scale is the same. The subject device measurement accuracy is in compliance with ISO 80601-2-56 and ASTM E1112 requirements. The differences of display resolution and measuring accuracy will not raise any safety or effectiveness issue.

Note 2: After placing the thermometer on the measurement site, the measured result can only be displayed when the temperature is stable. Generally, the measurement time is not fixed at a certain value, so the measurement speed of the subject device is within 1 minute. The difference of measurement speed will not raise any safety or effectiveness issue.

Note 3: Compared to the predicate device, the subject device can’t be turned ON and OFF by shaking it, but it can automatically shut down within 10 minutes. This difference is a functional difference before and after measurement, which has no influence on the accuracy of measurement. The difference in Power ON/OFF will not raise any safety or effectiveness issue.

Based on the comparison chart above, we believe that the T103 and T104 digital thermometer is

substantially equivalent to its predicate device cited above and do not raise any new safety and/or effectiveness issues.

H. Predicate Device Comparison

The subject device and the predicate device have the same intended use, intender user, target population, Measurement Site, Components, Sensor and the similar technical parameter; they both use thermistor resistance detection method to detect human body temperature. The subject device and predicate device conform to the same standards. Thus, the subject device is substantially equivalent to the predicate devices.

I. Non-clinical Test

Testing name	Referenced standard	Summary result	Verdict
Electric safety testing	IEC 60601-1: 2005/A1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance FDA Recognition number: 19-4	The subject complies with the applicable requirements set forth in the referenced electric safety standard.	Pass
EMC testing	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 FDA Recognition number: 19-8	The subject complies with the applicable requirements set forth in the referenced EMC	Pass
Electric safety for medical device used in the home healthcare environment	IEC 60601-1-11:2015 Medical electrical equipment – General requirements for basic safety and essential performance - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. FDA Recognition number: 5-89	The subject complies with the applicable requirements set forth in the referenced IEC 60601-1-11:2015	Pass
Usability	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA Recognition number: 5-89	The subject complies with the applicable requirements set forth in the referenced IEC 60601-1-6:2010+A1:2013	Pass
Performance testing	ISO 80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential	The subject complies with the applicable requirements set forth in the referenced performance	Pass

	performance of clinical thermometers for body temperature measurement. FDA Recognition number: 6-403 ASTM E1112-00 (2008) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature	standards.	
Biocompatibility testing	ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process FDA Recognition number: 2-258 ISO 10993-5: 2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity FDA Recognition number: 2-245 ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity FDA Recognition number: 2-174	The subject complies with the applicable requirements set forth in the referenced biological evaluation standards.	Pass

All necessary testing was conducted on the T103 and T104 digital thermometer to support a determination of substantial equivalence to the predicate devices.

The nonclinical, bench testing included*:*

1. Performance testing according to ISO 80601-2-56 and ASTM E1112 applicable requirements;
2. Electromagnetic compatibility testing;
3. Evaluation of relevant electrical safety, electromagnetic compatibility and electrostatic discharge requirements per IEC 60601-1 and IEC 60601-1-2.

- Performance testing is performed in accordance with ISO 80601-2-56 and ASTM E1112.The T103 and T104 digital thermometer complies applicable requirements of ISO 80601-2-56 and ASTM E1112 including displayed temperature range, laboratory accuracy, ambient conditions for operation and storage, identification, marking and documents.
- Electrical safety testing is performed in accordance with IEC 60601-1. The digital thermometer complies with to applicable IEC 60601-1 requirements including general requirements, protection against electrical hazards, protection against mechanical hazards, protection against excessive temperatures, hazardous situations and fault conditions, and constructions.

- Electromagnetic Compatibility testing is performed in accordance with IEC 60601-1-2. The digital thermometer complies with applicable IEC 60601-1-2 requirements including radiated emission test, electrostatic discharge immunity test, radiated RF electromagnetic field immunity test, and power frequency magnetic field immunity test.
- For lay person, the IEC 60601-1-11 was performed and the thermometer is accordance with applicable requirements

In addition to the above bench testing, the T103/T104 digital thermometer also underwent the following testing:

- T103 and T104 digital thermometer via axillary and oral to get temperature value within 1 min. Biocompatibility of patient-contacting materials (cap and outer shell) was performed according to ISO 10993-1/5/10, the patient contacting materials of the outer shell and stainless-steel cap have been tested in accordance with ISO 10993-1 for Cytotoxicity, Sensitization, and Irritation.
- Software verification and validation report in accordance with "Guidance for the content for premarket submissions for software contained in medical devices"
- Usability testing was completed in accordance with IEC 60601-1-6 and the digital thermometer is complied with the applicable requirements of standard.

Non-clinical performance reports were provided to document verification and validation activities which are intended to demonstrate substantial equivalence of the subject device with the noted changes, to the predicate device.

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the T103 and T104 digital thermometer meet the established specifications necessary for consistent performance during its intended use. In addition, the testing also demonstrates that the T103 and T104 digital thermometer does not raise different questions of safety or effectiveness when compared to the predicate devices.
The results demonstrate that the devices perform as intended and are substantially equivalent to the performance of the predicate in accordance with applicable standards.

J. Clinical Test

Name of clinical testing	Referenced standard	Summary of testing	Patient population (age groups, number of subjects)	Verdict
Clinical accuracy and repeatability testing	ISO 80601-2-56: 2017 Medical electrical equipment-Part 2-56: Particular requirements for basic safety and essential performance	The methods and criteria of clinical accuracy and repeatability testing	50 subjects in each age group, infants (0-1 year), children (1-5 years) and adults	Pass

	of clinical thermometers for body temperature measurement FDA Recognition number: 6-403	had been clinically assessed to meet the requirements of clinical accuracy per the referenced standards.	(>5 years) (Total 150 subjects)	

K. Conclusion

Non-clinical and clinical performance was conducted on the subject device and all tests met specified criteria. Base on the information provided in this submission, the subject device, T103 and T104 digital thermometers are substantially equivalent to the predicate device.