Bioland Technology Ltd
Eric Tan
Regulatory Engineer
No. A6B7 (Block G) ShangRong Industrial Zone, No. 5 Baolong Road
Shenzhen, 518116 CN

Re: K213011
Trade/Device Name: Infrared Thermometer (model: E201)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 7, 2022
Received: March 7, 2022

Dear Eric Tan:

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)*
K213011

Device Name
Infrared Thermometer (model: E201)

Indications for Use *(Describe)*
The Infrared Thermometer (model: E201) is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1~5cm. The device can be used by consumers in homecare environment.

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.

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510(k) Summary - K213011

A. Applicant

Name: Bioland Technology Ltd.

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Contact person: Eric Tan

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

Date of summary prepared: 2021.12.29

B. Subject device

Trade name: Infrared Thermometer
Model: E201
Classification name: Clinical Electronic Thermometer
Review Panel: General Hospital
Product Code: FLL
Regulation number: 880.2910
Device class: Class 2
Code of Federal Regulations: 21CFR 880.2910

C. Predicate Device

Device name: Infrared Thermometer Model MD-H30
510(K) number: K191570
Manufacturer: Guangzhou Berrcom Medical Device Co., Ltd.

D. Indications for Use

The Infrared Thermometer(model: E201) is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1~5cm. The device can be used by consumers in homecare environment.

E. Device Description

The Infrared Thermometer, model E201, is a light weight, handheld and reusable infrared thermometer that measures temperatures for people of all ages by detecting infrared energy radiated from the forehead and auditory canal in the homecare environment. It uses 3.0V alkaline batteries and can be operated continuously.

To measure body temperature, the probe of the thermometer is inserted into a patient's outer ear canal or put onto the skin of a patient's forehead. In forehead mode, the thermometer must keep 1-5 cm distance with the forehead of patient, a probe cover is not needed for the forehead and ear mode. The reference body site of E201 infrared thermometer is oxter (axillary).
The device has the following features:

1) The device is intended to be used in the homecare environment;
2) The device is mainly composed of infrared sensor(Thermopile), signal receiving processor, buttons, buzzer, LCD display. It is powered by 2*1.5 AAA batteries;
3) Switching between °C and °F;
4) Multi-functional, can measure ear and forehead temperature;
5) The 32 sets measurement data can be stored, the user can view the previous measurement results;
6) Low battery indication, and auto shut-down within 30s.

F. Principle Operation

The Infrared Thermometer measures temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. All the temperature in nature above absolute zero (-273^{o}C or -459.4^{o}F) objects will radiate infrared, and the radiation of infrared energy and temperature is proportional to the relationship. Using this relationship, an object's temperature can be calculated by measuring its infrared intensity.

G. Substantial Equivalence table

Comparison items	Subject Device	Predicate Device	Remarks
Manufacturer	Bioland Technology Ltd	Guangzhou Berrcom Medical Device Co., Ltd.	N/A
Model	E201	MD-H30	N/A
Classification	II	II	Same
Product code	FLL	FLL	Same
Classification name	Thermometer, electronic, clinical	Thermometer, electronic, clinical	Same
Regulation No.	880.2910	880.2910	Same
510(K) number	K213011	K191570	N/A
Intended Use	The Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal	The infrared thermometer is intended for the intermittent measurement of body temperature from the auditory canal or central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same

Comparison items	Subject Device	Predicate Device	Remarks
Measurement Site	indirect mode use : Forehead direct mode use: Auditory canal	indirect mode use : Forehead direct mode use: Auditory canal	Same
Measurement range	32.0~43.0 ^{o}C (89.6 ^{o}F ~109.4 ^{o}F)	32.0~43.0 ^{o}C (89.6 ^{o}F ~109.4 ^{o}F)	Same
Display precision	0.1 ^{o}C / ^{o}F	0.1 ^{o}C / ^{o}F	Same
^{o}C / ^{o}F unit switchable	Yes	Yes	Same
Measuring accuracy	±0.3^{o}C(32.0^{o}C~34.9^{o}C) ±0.2^{o}C (35.0^{o}C~42.0^{o}C) ±0.3^{o}C (42.1^{o}C~43.0^{o}C)	±0.2℃ (35.0^{o}C~42.0^{o}C) ±0.3℃ for other range	Same
Power Source	AAA*2, DC 3V	AAA*2, DC 3V	Same
Low battery indication	Yes	Yes	Same
Display	LCD Display	LCD Display	Same
Operating Environment Condition	15~40^{o}C, RH≤85% (non-condense)	10~40^{o}C, RH≤95% (non-condense)	Different Note 1
Storage Environment Condition	-20~55^{o}C, RH≤93% (non-condense)	-20~55^{o}C, RH≤95% (non-condense)	Different Note 1
Contact type	Contact/non contact	Contact/non contact	Same
Sensor	Thermopile	Thermopile	Same
Reference body site	Oxter	Not applicable	
Target population	People of all ages	People of all ages	Same
Use Environment	Homecare environment	Household environment	Same
Patient Age	People of all ages	People of all ages	
Measure time	1s	1s	Same
Measurement distance (indirect mode use)	1~5cm for forehead mode	1~5cm for forehead mode	Same
Memory Set	32 sets	20 sets	Different Note 2
Reusable/non-resuable	Reusable	Reusable	Same
Use of probe cover	No	No	Same
Sensor	Thermopile	Thermopile	Same
Measurement type	indirect mode use : Forehead direct mode use: Auditory canal	indirect mode use : Forehead direct mode use: Auditory canal	Same
Display type	LCD	LCD	Same
Patient contact materials	ABS	ABS	Same

Comparison items	Subject Device	Predicate Device	Remarks
Biocompatibility	ISO 10993-5: 2009 ISO 10993-10: 2010	ISO 10993-5: 2009 ISO 10993-10: 2010	Same
EMC	IEC 60601-1-2: 2014	IEC 60601-1-2: 2014	Same
Electrical Safety	IEC 60601-1: 2005/A1; 2012	IEC 60601-1: 2005/A1; 2012	Same
Performance	ISO 80601-2-56 ASTM E1965-98	ISO 80601-2-56 ASTM E 1965-98	Same

Note 1: The operating and storage environment condition is a little different between the subject device and predicate device, the subject device has passed the testing according to standard ASTM E1965-98 and ISO 80601-2-56, and the predicate device also conforms to the requirement of standard ISO 80601-2-56 and ASTM E1965-98. At the same time, we indicate the operating and storage environment condition on the user manual and gift-box. Therefore, the difference of declared standards has no influence on safety and effectiveness of product.

Note 2: The purpose of memory function is intended to store and view the previous measurement data. The function has been verified during software verification. The difference does not raise any issues on the device safety and effectiveness.

H. Predicate Device Comparison

The subject device and the predicate device both have same intended use, measuring range, measuring accuracy and contact materials, they both use infrared radiation detection method to detect human forehead temperature and some technical parameters are the same. Thus, it can be concluded that 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 device 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 device complies with the applicable requirements set forth in the referenced standard.	Pass
Electric safety for medical device used in the home	IEC 60601-1-11:2015 Medical electrical equipment – General requirements for basic safety and essential performance - Part 1-11:	The subject device complies with the applicable requirements set forth in the referenced	Pass

Testing name	Referenced standard	Summary result	Verdict
healthcare environment	Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. FDA Recognition number: 19-14	standard.	
Performance testing	ISO 80601-2-56:2017 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. FDA Recognition number: 6-421	The subject device complies with the applicable requirements set forth in the referenced performance standard.	Pass
	ASTM E1965-98:2016 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature FDA Recognition number: 6-125	The subject device complies with the applicable requirements set forth in the referenced standard.	Pass
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 device complies with the applicable requirements set forth in the referenced biological evaluation standard.	Pass

Software verification and validation

Software documentation consistent with moderate level of concern is submitted in this 510(k). All software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels. The software verification and validation were conducted in accordance with the *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005*. The test results demonstrated the software function met the requirements.

J. Clinical Accuracy Testing

The clinical accuracy study for the E201 infrared thermometer was performed to determine the clinical accuracy. The study includes 150 subjects, the three groups of subjects being tested were: 1) 0~1 year old, 2) children between 1~5 years old, and 3) over 5 years old. For each age group, the ratio of febrile subjects was more than 30% and less than 50%. The reference body site of infrared thermometer is oxter. The study excluded subjects with medical conditions such as inflammation at the measuring sites and subjects using medications known to affect body temperature. The clinical accuracy test results showed that the accuracy of the E201 infrared thermometer is within acceptable scope specified in standard ISO 81061-2-56.

The clinical accuracy test information of subject device E201 as following:

Name of clinical testing	**Referenced standard**	**Summary of testing**	**Reference body site**	**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 of clinical thermometers for body temperature measurement. FDA Recognition number: 6-421	The methods and criteria of clinical accuracy and repeatability testing had been clinically assessed to meet the requirements per the referenced standards.	Oxter	50 subjects in each age group: 0-1 year, 1-5 years and older than 5 years (Total 150 subjects)	Pass

K. Conclusion

Non-clinical performance and clinical accuracy tests were conducted on the subject device and all tests met specified criteria. Base on the information provided in this submission, the subject device E201 infrared thermometer is substantially equivalent to the predicate device.