October 2, 2020

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

Re: K201161
Trade/Device Name: Infrared Thermometer (E127)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 25, 2020
Received: September 28, 2020

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201161

Device Name
Infrared Thermometer, E127

Indications for Use *(Describe)*
Infrared thermometer is a non-sterile, reusable, handheld and non-contact device. It can be used by consumers in home care environment and doctors in clinic as reference. It is intended for measuring human body temperature of one month of age and above by detecting infrared heat from the forehead.

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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K201161
510(k) Summary

A. 10/2/2020

B. Applicant

Name: Bioland Technology Ltd.
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Tel: +86 755 3690 0999
Fax: +86 755 3329 6299
Contact person: Yiqing Feng
E-mail: regulator-a@bioland.com.cn

C. Subject device

Trade name: Infrared Thermometer
Model: E127
Classification name: Clinical Electronic Thermometer
Regulation Medical Specialty: General Hospital
Product Code: FLL
Regulation number: 880.2910
Device class: Class 2
Code of Federal Regulations: 21CFR 880.2910

D. Predicate Device

Device name: Advocate Non-Contact Infrared Thermometer
510K number: K191004
Manufacturer: BroadMaster Biotech, Corp.

E. Indication for use

The Infrared Thermometer is a non-sterile, reusable, handheld and non-contact device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people one month of age and above by detecting infrared heat from the forehead.

F. Device Description

The Infrared Thermometer, Model E127, is a light weight, handhold and non-contact Infrared Thermometer that measures temperatures of people ages 1 month and above by detecting the infrared energy radiated directly from the forehead without physical contact from a measurement distance of 1-5cm. . It uses 3.0V alkaline batteries. The device can measure temperature in direct and adjusted mode.

F. Principle Operation

The Infrared Thermometer measures temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. The reference body site is the oxter (axillary). All the temperature in nature above absolute zero (-273°C or -459.4°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.

Comparison items	**Subject Device**	**Predicate Device**	**Remarks**
Manufacturer	Bioland Technology Ltd	BroadMaster Biotech, Corp	N/A
Model	E127	EF001S	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	K201161	K191004	N/A
Intended Use	Infrared Thermometer is a non-sterile, reusable, handheld and non-contact device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of one month of age and above by detecting infrared heat from the forehead.	Advocate Non-Contact Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.	Similar Note 1
Intended users	Lay user and professional	Lay user and professional	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Target population	One month of age and above	All ranges of people	Similar Note 1
Measurement Site	Forehead	Forehead	Same
Measurement range	32.0~43.0 °C (89.6 °F ~109.4 °F)	32.0~43.0 °C (89.6 °F ~109.4 °F)	Same
Display resolution	0.1 °C / °F	0.1 °C / °F	Same

°C / °F unit switchable	Yes	Yes	Same
Measuring accuracy	±0.3 °C (32.0 °C -34.9 °C) ±0.2 °C (35-42.0 °C) ±0.3 °C (42.1 °C -43.0 °C)	±0.3 °C (32.0 °C -34.9 °C) ±0.2 °C (35-42.0 °C) ±0.3 °C (42.1 °C -43.0 °C)	Same
Measurement distance	1-5cm	5-10cm	Different Note 2
Memory	20	12	Different Note 3
Power Source	AAA*2, DC 3V	Two 1.5V AAA alkaline batteries	Same
Low battery indication	Yes	Yes	Same
Display	LCD Display	LCD Display	Same
Operating Environment Condition	15~40°C, RH≤85% (non-condense)	10 °C~40 °C, RH≤80%	Similar Note 4
Storage Environment Condition	-20~55°C, RH≤93% (non-condense)	-20~55°C, RH≤95%	Similar Note 4
Degree of protection	IP22	IP20	Different Note 5
PCB	FR4 PCB	FR4 PCB	Same
Cleaning method	The thermometer outer shell and probe can be cleaned and disinfected by 70% alcohol	The thermometer enclosure and probe can be cleaned and disinfected by70% alcohol	Same
Patient contact materials	ABS	ABS	Same
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: 2017 ASTM E 1965-98: 2016 (clinical accuracy)	ASTM E 1965-98: 2016 ISO 80601-2-56: 2017	Similar Note 6

Note 1: Target population of subject device is one month of age and above, target population of predicate device is all ranges of people; Compared to the predicate device, the target population of subject device is a little narrower, but this difference has no effect on safety and effectiveness of product.

Note 2: Due to the difference in software algorithm and temperature sensor, so the measurement distance between subject product and predicate product; But the measurement distance of subject product has been effectively verified by the clinical repeatability and accuracy, therefore, the difference of measurement distance has no influence on safety and effectiveness of product.

Note 3: Memory function is only used to store data and is not product-critical, so it has no effect on product safety and effectiveness.

Note 4: Compared to the predicate device, the operating temperature of subject device is narrower, the operating humidity of subject device is wider, and the Storage humidity of subject device is narrower, but the operating and storage condition of subject device has passed ISO 80601-2-56 and IEC 60601-1-11 testing. Therefore, the difference of operating and storage condition has no influence on safety and effectiveness of product.

Note 5: The subject device has passed IEC 60601-1 and IEC 60601-1-11 safety test. Therefore, the difference of degree of protection has no influence on safety and effectiveness of product.

Note 6: ISO 80601-2-56: 2017 is an international standard, the subject device and the predicate device have has passed ISO 80601-2-56: 2017 performance test. The subject device was tested per the requirements in ASTM E1965-98: 2016 for clinical accuracy. Therefore, the difference of declared performance standards has no influence on safety and effectiveness of product.

H. Predicate Device Comparison

The subject device and the predicate device have the same intended use and the similar technical parameters, they both use infrared radiation detection method to detect human body forehead temperature. They have same measuring range and measuring accuracy. 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.	The subject complies with the applicable requirements set forth in the referenced IEC 60601-1-11:2015	Pass
Performance testing	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. FDA Recognition number: 6-403	The subject complies with the applicable requirements set forth in the referenced performance 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 complies with the applicable requirements set forth in the referenced biological evaluation standard.	Pass

J. Clinical Testing

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 of clinical thermometers for body temperature measurement. FDA Recognition number: 6-403 ASTM E1965-98: 2016, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature FDA Recognition number: 6-125	The methods and criteria of clinical accuracy and repeatability testing had been clinically assessed to meet the requirements of clinical accuracy per the referenced standards.	50 subjects in each age group, infants (0-1 year), children (1-5years) and adults (>5 years) (Total 150 subjects)	Pass

K. Conclusion

Non-clinical performance and clinical tests were conducted on the subject device and all tests met specified criteria. Base on the information provided in this submission the subject device, E127 infrared thermometer is substantially equivalent to the predicate device, EF001S.