April 22, 2020

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

Re: K190984
Trade/Device Name: Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 17, 2020
Received: March 24, 2020

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,

for Tina Kiang, Ph.D.
Director
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of Gastrorenal, OB/GYN, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190984

Device Name
Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650)

Indications for Use *(Describe)*
Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650)
is a non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode using the center of the forehead as the measurement site on people of all ages. The devices are reusable for home use only.

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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K190984

510(k) Summary

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
Address: 4th and 5th floor, No. 5 Building, Tech.&Innovation center, No. 289 Wengjiao Road, Haicang District, Xiamen China
Tel: +86-134-5902-0349
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Contact Person: Jane Xu
Email: Sales1@asxd.com.cn

Date: April 22, 2020

Application Correspondent:

Contact Person: Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650)
Common Name: Clinical electronic thermometer
Classification name: Thermometer, electronic, clinical
Review Panel: General Hospital
Product Code: FLL
Regulation Class: II
Regulation Number: 21 CFR 880.2910

3. Predicate Device Information

Sponsor: Kaz USA, Inc., a Helen of Troy Company
Trade Name: Braun BNT400 No Touch + Forehead Thermometer
Common Name: Clinical electronic thermometer
Classification Name: Thermometer, Electronic, Clinical
510(K) Number: K181242
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulation Class: II

4. Device Description

The Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650) is a hand-held, battery powered, infrared Thermometer that coverts a user's forehead temperature, using the infrared energy emitted from the area around the user's forehead, to an oral equivalent temperature when placed within 1-5 cm to the subject's forehead with no contact. It uses a thermopile sensor with integrated thermistor for ambient temperature readings.

It composed by a measuring sensor, set buttons, a start button, battery compartment, Buzzer, a LCD and a ABS plastic enclosure, and measuring without probe cover.

5. Intended Use / Indications for Use

Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650) is non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a no touch mode using the center of the forehead as the measurement site on people of all ages. The devices are reusable for home use only.

6. Test Summary

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

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-56 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- 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"
- 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
- Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement according to ASTM E1965-98 (2016): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

6.2 Discussion of Clinical Tests Performed

Clinical tests were conducted on the Model HA-610. 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 ISO80601-2-56. The test report showed the clinical performance of the subject devices complied with the requirement of ISO 80601-2-56.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Infrared Forehead Thermometer is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Remark
Company	Xiamen Ants Bro	Kaz USA, Inc., a Helen of	--

Elements of Comparison	Subject Device	Predicate Device 1	Remark
	Technology Co., Ltd.	Troy Company	
Device Name and Model	Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650)	Braun BNT400 No Touch + Forehead Thermometer	--
510(k) Number	Applying	K181242	--
Product Code	FLL	FLL	SE
Thermometer Type	Infrared Forehead Thermometer	Infrared Forehead Thermometer	SE
Intended Use & Indications for Use	Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650) is non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a no touch mode using the center of the forehead as the measurement site on people of all ages. The devices are reusable for home use only.	The Braun BNT400 No Touch + Forehead Thermometer is non-sterile, reusable, clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch mode using the center of the forehead as the measurement site on people of all ages.	SE Difference in name and included home use.
Measurement method	Infrared radiation detection	Infrared radiation detection	SE
Measurement mode	Forehead measure mode	Forehead measure mode	SE
Features	High Temperature Alarm feature and memory feature	Fever Insight temperature guidance feature and memory feature	SE Note 2
Measuring range	34.0 – 43.0°C (93.2 – 109.4°F)	34.0 – 43.0°C (93.2 – 109.4°F)	SE
Measurement Accuracy (Body)	± 0.2°C (35.0 ~ 42.0°C) / ± 0.4°F (95.0 ~ 107.6°F) ± 0.3°C (34.0 ~ 34.9°C) (42.1 ~ 43.0°C)	± 0.2°C (35.0 ~ 42.0°C) / ± 0.4°F (95.0 ~ 107.6°F) ± 0.3°C (34.0 ~ 34.9°C) (42.1 ~ 43.0°C)	SE
Display Resolution	0.1 °C/°F	0.1 °C/°F	SE
C/F switchable	Yes	Yes	SE
Display	LCD display	LCD display	SE

Elements of Comparison	Subject Device	Predicate Device 1	Remark
Battery type	1.5V AAA x 2	1.5V AAA x 2	SE
Low battery indication	Yes	Yes	SE
Materials	ABS	User contacting materials include ABS (device housing / handle, power button), TPR (temperature button & forehead touch bumper), & PMMA (LCD lens & protective scanner cap).	SE Note 3
Measurement distance	1-5 cm	0-2.5cm	Note 4
Operating condition	Temperature: 10 - 40°C (50.0 - 104.0°F) Humidity: ≤ 85%RH	Temperature: 15 - 40°C (59 - 104.0°F) Humidity: 15 ~ 95%RH	SE Note 1
Biocompatibility	ISO 10993	ISO 10993	SE
Electric Safety and EMC	IEC 60601-1, lEC 60601-1-2, IEC 60601-1-11	IEC 60601-1, lEC 60601-1-2, IEC 60601-1-11	SE
Performance	ISO 80601-2-56	ISO 80601-2-56	SE

Comparison in Detail(s):

Note 1:

The “Operating condition” of subject device is a little different from the predicate devices, but all of them are meet the safety standards IEC 60601-1 and IEC 60601-1-11, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

Although the “High Temperature Alarm feature” of subject device is a little different from the predicate devices, but both measuring temperature of subject device and predicate device are for indicate only diagnosis should be made by a professional physician, so this difference will not cause safety and effectiveness issues.

Note 3:

The subject medical device in its final finished form is identical to Digital Thermometer (K190990) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g. plasticizers, fillers, additives, cleaning agents, mold release agents).

Note 4:

Although the “Measurement distance” of subject device is a little different from the predicate devices, but both of subject device and predicate device are meet the clinical accuracy requirements of the standards ISO 80601-2-56, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Finial Conclusion:

The subject device Infrared Forehead Thermometer (Models: HA-610, HA-620, HA-630, HA-640, HA-650) have all features of the predicate devices K181242. 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.