November 23, 2020

Dongguan E-Test Technology Co., Ltd
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road,
Guangzhou Science Park
Guangzhou, 510000
China

Re: K193621
Trade/Device Name: Digital Thermometer (Model BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 21, 2020
Received: October 28, 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 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)*
K193621

Device Name
Digital Thermometer (Model: BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318)

Indications for Use *(Describe)*
Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.
It can be used for axillary measurement, oral measurement and rectal 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.

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510(k) Summary -K193621

This summary of 510(K) information is being submitted in accordance with the requirements of

SMDA and 21 CFR 807.92.

Date: 11/20/2020

1. Submitter's Information

510(k) Owner's Name: DONGGUAN E-TEST TECHNOLOGY CO., LTD

Establishment Registration Number: Applying

Address: Room 201,301, Building 1, Changping Section No.1, Dongshen Road, Changping Town, Dongguan City, Guangdong, China.

Tel: +86-0769-81158038

Contact Person (including title): Victor Wan (Vice-president)

E-mail: victor@agelh.com

Application Correspondent:

Contact Person: Ms. Cassie Lee

DONGGUAN E-TEST TECHNOLOGY CO., LTD

Address: Room 201,301, Building 1, Changping Section No.1, Dongshen Road, Changping Town, Dongguan City, Guangdong, China

Tel: +86-0769-81158038
Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Thermometer, electronic
Trade Name:	Digital Thermometer -(Model BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318)
Classification Name:	Thermometer, electronic, clinical
510(K) Number:	K193621
Review Panel:	General Hospital

Product Code: FLL

Regulation Number: 880.2910

Regulation Class: 2

3. Predicate Device Information

510(K) Number: K172508

Sponsor: Dongguan Ageless Health Industrial Co., Ltd.

Common Name: Thermometer, electronic

Trade Name: Ageless Health Medical Digital Thermometer

Classification Name: Thermometer, electronic, clinical

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, a buzzer for sounding effect, an ASIC for processing the target temperature digitally, and a LCD for displaying the temperature result. The design principle of thermometer is based on thermos sensor and ASIC technology. A thermistor is used as thermos sensor. 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.

5. Intended Use

Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.
It can be used for axillary measurement, oral measurement and rectal measurement.

6. Test Summary

The whole product and manufacturing used for the Digital thermometer are identical to those of the predicate device, which were demonstrated to conform with the following standards:

- IEC 60601-1 (2005/(R)2012 and A1:2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 80601-2-56 (2018) Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- IEC 60601-1-2 (2014) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 (2015) Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ASTM E1112-00 (2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- ISO 10993-5 (2009) Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 (2010) Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization

7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Company	DONGGUAN E-TEST TECHNOLOGY CO., LTD	Ageless Health Industrial Co., Ltd.	--
Name and Model	Digital Thermometer, models: BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318	Ageless Health Medical Digital Thermometer, models: BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318	--
510(k) Number	K193621	K172508	--
Thermometer Type	Digital Thermometer	Digital Thermometer	SE
Intended Use / Indication for Use	Digital Thermometers are intended for the measurement and monitoring of human body	Ageless Health Medical Digital Thermometers are intended for the measurement and monitoring	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
	temperature by doctor or consumers in the hospital or home. It can be used for axillary measurement, oral measurement and rectal measurement.	of human body temperature by doctor or consumers in the hospital or home. It can be used for axillary measurement, oral measurement and rectal measurement.	
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 Temperature Range	32.0°C ~ 42.9°C	32.0°C ~ 42.9°C	SE
Measurement Accuracy	35.0 ~ 39.0°C : +/- 0.1°C The rest: +/- 0.2°C	35.0 ~ 39.0°C : +/- 0.1°C The rest: +/- 0.2°C	SE
Ambient Temperature	10~35°C	10~35°C	SE
Response Time	60s	60s	SE
Complied Standard	IEC 60601-1, IEC 80601-2-56, IEC 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-5, ISO 10993-10	IEC 60601-1, IEC 80601-2-56, IEC 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-5, ISO 10993-10	SE

Conclusion

The subject device Digital Thermometer has all features of the predicate devices. No differences will affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device. All hardware and software of the subject device are based on that of the predicate device (K172508), since no new testing is presented in the submission.

8. Summary Prepared Date

20 November 2020