DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 31, 2015

Dongguan Ageless Health Industrial Co., Ltd
c/o Ms. Cecilia Ceng
Regulatory Manager
Guangzhou Glomed Biological Technology Co., Ltd
Suit 306, Kecheng Mansion. No.121 Science Road,
Guangzhou Science Park
Guangzhou, 510663
CHINA

Re: K152508
Trade/Device Name: Ageless Health Medical Digital Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 17, 2015
Received: November 23, 2015

Dear Ms. Ceng:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K152508

Device Name
Device Name: Ageless Health Medical Digital Thermometer

Indications for Use *(Describe)*
Ageless Health Medical Digital Thermometers are intended for use in measuring human body temperature (Armpit or Oral).

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

K152508

This summary of 510(K) information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

1. Submitter Information

Sponsor Name: Dongguan Ageless Health Industrial Co.,Ltd.

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Application Correspondent:

Contact Person: Ms. Cecilia Ceng / Mr. Tim Wong

Guangzhou GLOMED Biological Technology Co., Ltd.

Tel: +86-20-61099984

Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k):	Traditional
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

3. Predicate Device Information

Sponsor: SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.

Classification Name: Thermometer, electronic, clinical

Trade Name: Electronic thermometer

510(k) number: K131210

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 880.2910

Regulation Class: 2

4. Device Description

Ageless Health Medical 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 thermosensor and ASIC technology. A thermistor is used as thermosensor. 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

Ageless Health Medical Digital Thermometers are intended for use in measuring human body temperature (Armpit or Oral).

6. Test Summary

Ageless Health Medical Digital Thermometer has been evaluated the performance by lab bench testing according to the following standards:

- IEC 60601-1 (2005 + CORR.1:2006 + CORR.2:2007 + AM1:2012) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 80601-2-56 (2009) 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 (2007) Medical Electrical Equipment - Part 1-2: Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1-11 (2010), 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
- ASTM E1112-00 (2006) 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

The same tests on Ageless Health Medical Digital Thermometer and the predicate device demonstrate the substantial equivalence of the two.

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	Conclusion
Company	Ageless Health Industrial Ltd.	SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.	--
Name and Model	Ageless Health Medical Digital Thermometer, models: BT-301,	Electronic thermometer, models: TF3100, TF3101, TF3102	--

Elements of Comparison	Subject Device	Predicate Device	Conclusion
	BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318		
510(k) Number	Applying	K131210	--
Thermometer Type	Digital Thermometer	Digital Clinical Thermometer	SE
Intended Use	Ageless Health Medical Digital Thermometers are intended for use in measuring human body temperature (Armpit or Oral).	It is intended for use in measuring temperature in human body (Armpit or Oral).	SE
Indication for Use	Ageless Health Medical Digital Thermometers are intended for use in measuring human body temperature (Armpit or Oral).	It is intended for use in measuring temperature in human body (Armpit or Oral).	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 Requirements	1.5V button battery	1.5V button battery	SE
Measurement Temperature Range	32.0°C ~ 42.9°C	32.0°C ~ 42.0°C	SE Note 1
Accuracy	35.0 ~ 39.0°C : +/- 0.1°C The rest: +/- 0.2°C	0.05°C (35.30 ~ 39.00°C) 0.1°C (< 35.30°C or > 39.0°C)	SE Note 1
Ambient temperature	10~35°C	5~40°C	SE Note 1
Response Time	60s	5min	SE Note 1
Protection Degree against Ingress of Water and Particulate Matter	IP22	IP22	SE
Patient Contacting	ABS plastic and stainless steel	ABS plastic and stainless steel	SE

Elements of Comparison	Subject Device	Predicate Device	Conclusion
Material			
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 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-5, ISO 10993-10	SE

Note 1

Although some specifications of Measurement Temperature Range, Accuracy, and Response Time are different for subject device and predicate device, they are both complied with related performance standards.

Conclusion

The subject device Ageless Health Medical Digital Thermometer has all features of the predicate device,only with few differences(accuracy, Ambient temperature, Response Time). The technological principle is also the same with the predicate device's.Thus, the subject device is substantially equivalent to the predicate device.

8. Summary Prepared Date

30 December 2015