510(k) Summary

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

1. Submitter's Information

Sponsor Name: Ageless Health Industrial Co., Ltd.

Address: 3/F, A1 Bldg, Dongshen Sima Industrial Area, No.33 Shenbei Road, Sima Village, Changping Town, Dongguan City, Guangdong Province, China

Contact Person: Victor Wan (Vice-president)

Phone: +86-769-81158038

Fax: +86-769-82289331

E-mail: victor@agelh.com

Application Correspondent:

Application Correspondent:

Contact Person: Ms. Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China

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 (models: BT-301, BT-302, BT-303, BT-305, BT-306, BT-308, BT-311, BT-318)
Classification Name:	Thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Regulation Number:	880.2910
Regulation Class:	II

3. Predicate Device Information

Predicate Device 1

510(K) Number: K152508

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: II

Predicate Device 2

510(K) Number: K101387

Sponsor: Fudakang Industrial Co., Ltd

Classification Name: Thermometer, electronic, clinical

Trade Name: Digital Thermometer

Review Panel: General Hospital

Product Code: FLL

Regulation Number: 880.2910

Regulation Class: II

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 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

Ageless Health Medical 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

Ageless Health Medical Digital Thermometer has been evaluated the safety and 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

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 1	Predicate Device 2	Remark
Company	Ageless Health Industrial Co., Ltd.	Ageless Health Industrial Co., Ltd.	Fudakang Industrial Co., Ltd.	--
Name and Model	Ageless Health Medical 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	Digital Thermometer Model: BT-A11CN, BT-A21CN, BT-A41 CN	--
510(k) Number	K172508	K152508	K101387	--
Thermometer Type	Digital Thermometer	Digital Thermometer	Digital Thermometer	SE
Intended Use / Indication for Use	Ageless Health Medical Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or home.	Ageless Health Medical Digital Thermometers are intended for use in measuring human body temperature (Armpit or Oral).	Fudakang Digital Thermometers are intended for the measurement and monitoring of human body temperature by doctor or consumers in the hospital or	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	It can be used for axillary measurement, oral measurement and rectal measurement.		home. BT-A11CN, BT-A21CN, BT-A41CN can be used for axillary measurement, oral measurement and rectal measurement.	
Sensor	Thermistor	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.	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	1.5V button battery	SE
Measurement Temperature Range	32.0°C ~ 42.9°C	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	35.0 ~ 39.0°C: +/- 0.1°C The rest: +/- 0.2°C	SE
Ambient Temperature	10~35°C	10~35°C	0~40°C	SE
Response Time	60s	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	IEC 60601-1, IEC 80601-2-56, IEC 60601-1-2, IEC 60601-1-11, ASTM E1112, ISO 10993-5, ISO 10993-10	SE

Note 1

The subject device is exactly the same as predicate device K152508, which is also our company cleared device. The only difference for subject device is added rectal measurement function in Indications for Use.

So, we add predicate device K101387 which included rectal measurement function as additional predicate device. As the parameters of subject device are also very similar to additional predicate device K101387, and their Indications for Use are the same, so differences between them do not raise different questions of safety and effectiveness for the subject device.

Conclusion

The subject device Ageless Health Medical Digital Thermometer has all features of the predicate devices. The few differences amongst the predicates and the subject do not raise different questions of safety and effectiveness.

8. Summary Prepared Date

15 August 2017