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

June 1, 2016

Ageless Health Industrial Co., Ltd
% Cecelia Ceng
Regulatory Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510663 CN

Re: K153552
Trade/Device Name: AGE Automatic Upper Arm Blood Pressure Monitor, Model: BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X (X can be A, B, C, D, E, F).
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 25, 2015
Received: December 11, 2015

Dear Cecelia 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,

Shawn W. Forrest -S
2016.06.01 22:58:44 -04'00'

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K153552

Device Name
AGE Automatic Upper Arm Blood Pressure Monitor
Model: BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X (X can be A, B, C, D, E, F).

Indications for Use *(Describe)*
AGE Automatic Upper Arm Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is six sizes.

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.

Chapter 6. 510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 870.1130.

1. **Submitter Information**

Sponsor Name: Dongguan 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
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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:	Noninvasive blood pressure measurement systems
Trade Name:	AGE Automatic Upper Arm Blood Pressure Monitor
Classification Name:	Noninvasive brood pressure measurement system
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Number:	21 CFR 870.1130
Regulation Class:	2

3. Predicate Device Information

Sponsor:	Dongguan Ageless Health Industrial Co., Ltd
Common Name:	Noninvasive blood pressure measurement systems
Trade Name:	AGE Automatic Upper Arm Blood Pressure Monitor
510(k) number:	K123882
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Number:	21 CFR 870.1130
Regulation Class:	2

4. Device Description

AGE Automatic Upper Arm Blood Pressure Monitor is a battery driven automatic non-invasive blood pressure meter. It can automatically conduct the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult at arm within its claimed range and accuracy via the Oscillometry technique. The device also has low voltage indication, which will be triggered when the battery is low.

5. Intended Use

AGE Automatic Upper Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an air cuff buckled around one's arm according to the instruction in the user's guide manual.

6. Test Summary

AGE Automatic Upper Arm Blood Pressure Monitor has been evaluated the safety and performance by lab bench testing according to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005 + A1:2012
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances - Requirements and tests, 2014
- ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, 2010
- AAMI / ANSI / ISO 81060-2 Second Edition, Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type. (Cardiovascular)

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

Elements of Comparison	Subject Device	Predicate Device	Verdict
Product Name	AGE Automatic Upper Arm Blood Pressure Monitor	AGE Automatic Upper Arm Blood Pressure Monitor	--
Intended Use and Indications for Use			
Intended Use	AGE Automatic Upper Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.	AGE Automatic Upper Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.	SE
Indications for Use	AGE Automatic Upper Arm Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is six sizes.	AGE Automatic Upper Arm Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 24~34 cm.	SE Note 1
ELECTRICAL REQUIREMENT			
Power Supply	DC 6V (4 X AA 1.5V alkline batteries)	6Vdc (4 “AA” batteries)	SE
PERFORMANCE SPECIFICATION			
Measuring Method	Oscillometry	Oscillometry	SE
Measurement range for pressure	0~280 mmHg	0~280 mmHg	SE
Operating Range for Pressure (Cuff Pressure)	0~280 mmHg	0~280 mmHg	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Cuff Display Range	0~280 mmHg	0~280 mmHg	SE
Pressure resolution	1mmHg or 0.1kPa	1mmHg or 0.1kPa	SE
Accuracy	Pressure: ±3 mmHg Pulse: ±5%	Pressure: ±3mmHg Pulse: ±5%	SE
Patient Population	Adult	Adult	SE
Measurement Site of Body	Upper Arm	Upper Arm	SE
Inflation and Deflation	Automatic	Automatic	SE
Memory Size	2 x 90 sets record（BA-822X is 90 sets）	2 x 90 sets record	SE Note 2
Software Version	V01	V1.1	SE Note 3
Indicators	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	SE
Physical Dimensions	Please refer to “Table 1 Physical Dimensions and weight for each model” of “Chapter 6”		SE Note 4
Weight			
Cuff Circumference	size A: 17cm--22cm (SMALL ADULT CUFF) size B: 22cm--30cm (ADULT CUFF-1) size C: 24cm--34cm (ADULT CUFF-2) size D: 22cm--42cm (L-LARGE ADULT CUFF) size E: 30cm--42cm (LARGE ADULT CUFF) size F: 42cm--50cm (EXTRA LARGE ADULT CUFF)	24~34 cm	SE Note 1
OPERATING & STORAGE CONDITIONS			
Storage Environment	Temperature: -20°C ~ +65°C Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa	Temperature: -20°C ~ +65°C Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa	SE
Working Environment	Temperature: 5°C ~ 40°C Humidity: 15~90%RH Atmospheric Pressure:86 kPa~106	Temperature: 5°C ~ 40°C Humidity: 10~90%RH Atmospheric Pressure:86 kPa~106 kPa	SE Note 2

Elements of Comparison	Subject Device	Predicate Device	Verdict
	kPa		
COMPLIANCE STANDARDS			
Electrical, Mechanical and Thermal Evaluation	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	SE
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	SE
Performance	ISO 81060-2	AAMI SP10	SE Note 5

Note 1

Although there is difference for measurement cuff circumference of subject device and predicate device, both of them are complied with ISO 81060-2. This difference does not affect the safety and effectiveness.

Note 2

Although some specifications of operating & storage conditions, memory size are different for subject device and predicate device, they are both complied with IEC 60601-1. The differences do not affect the safety and effectiveness. The storage and operating pressure ranges of subject device and predicate device are same, and the storage and operating pressure ranges of predicate device was provided by the manufacturer.

Note 3

The software version of subject device is updated based on the predicate device, there is no different in PWB control circuit and software among models. The software is same as K123882.

Note 4

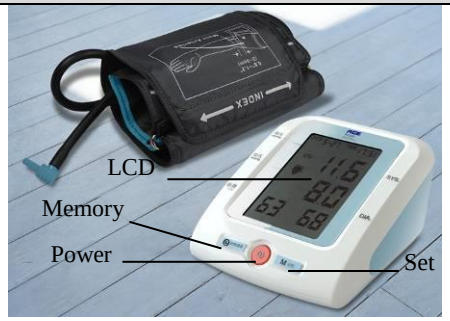
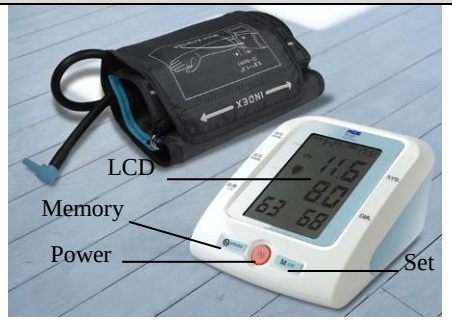
These differences of physical dimensions and weight have been verified and validated to demonstrate that it does not affect the safety and effectiveness of subject device.

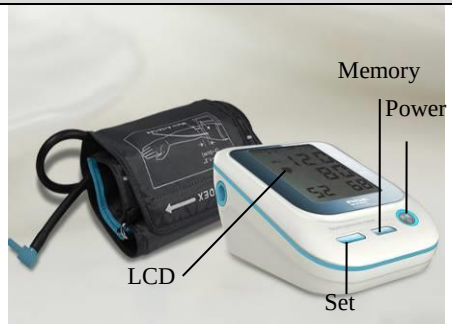
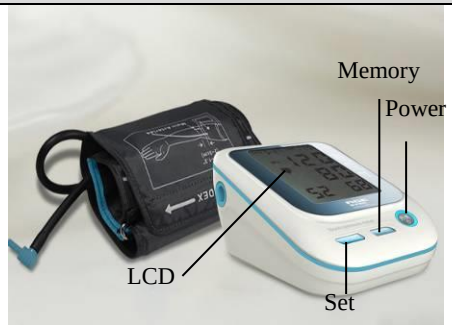
Note 5

Although the standards of performance have updated and substituted from AAMI SP10 to ISO 81060-2, all of the requirements in these three standards are intended for blood pressure monitor. Therefore,

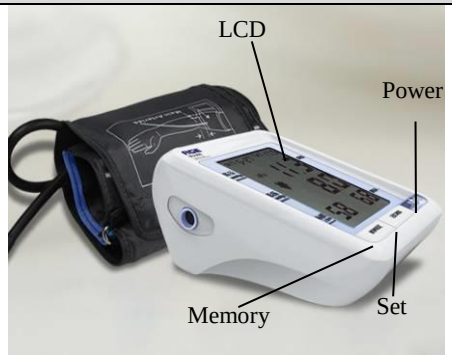
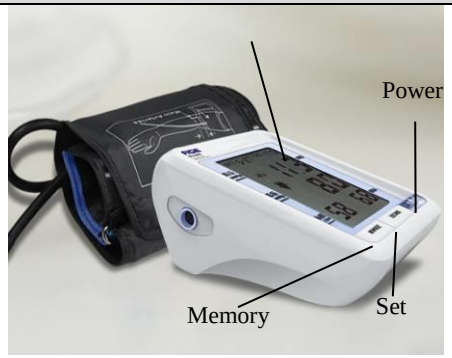
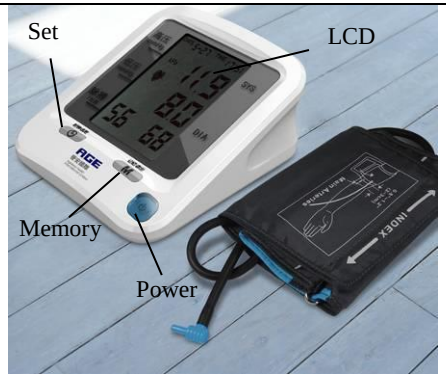
both of them met the requirements. The differences do not affect the safety and effectiveness.

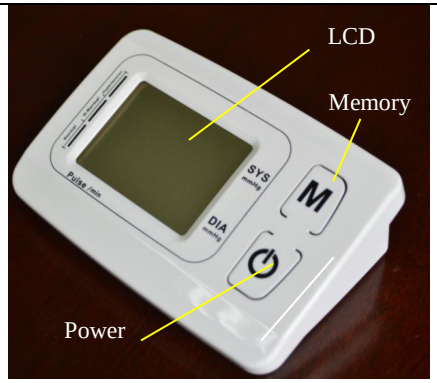
Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-801X		115mm (L) 103mm (W) 67.5mm (H) 460g	BA-801		115mm (L) 103mm (W) 67.5mm (H) 460g
BA-802X		115mm (L) 103mm (W) 67.5mm (H) 460g	BA-802		115mm (L) 103mm (W) 67.5mm (H) 460g

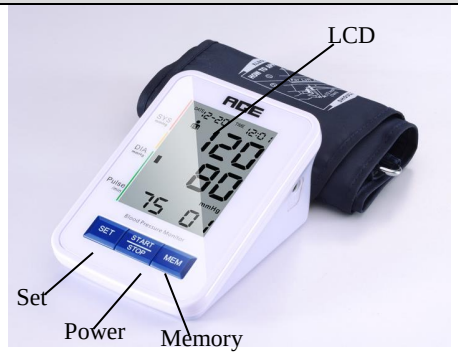
Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-803X		119mm (L) 100mm (W) 63.2mm (H) 456g	BA-803		119mm (L) 100mm (W) 63.2mm (H) 456g
BA-805X		118.3mm (L) 100mm (W) 62.9mm (H) 465g	BA-805		118.3mm (L) 100mm (W) 62.9mm (H) 465g

Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-806X		144mm (L) 112mm (W) 70mm (H) 472g	BA-806		144mm (L) 112mm (W) 70mm (H) 472g
BA-811X		144mm (L) 112mm (W) 67mm (H) 468g	BA-811		144mm (L) 112mm (W) 67mm (H) 468g

LCD

Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-812X		113.5mm (L) 92mm (W) 48mm (H) 418g	BA-812		113.5mm (L) 92mm (W) 48mm (H) 418g
BA-813X		115.3mm (L) 92mm (W) 48mm (H) 412g	BA-813		115.3mm (L) 92mm (W) 48mm (H) 412g

Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-821X		150mm (L) 100mm(W) 70mm (H) 610g			
BA-822X		153mm (L) 90mm(W) 58mm (H) 380g			

Subject Device			Predicate Device		
Model Name	**Appearance Picture**	**Size and Weight**	**Model Name**	**Appearance Picture**	**Size and Weight**
BA-823X		140mm (L) 95mm(W) 70mm (H) 420g			
BA-826X		140mm (L) 115mm(W) 60mm (H) 500g			

8. Conclusion

The subject device AGE Automatic Upper Arm Blood Pressure Monitor has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

9. Summary Prepared Date

26 April 2016