



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

June 30, 2015

Dongguan Ageless Health Industrial Co., Ltd  
c/o Ms. Cecilia Ceng  
Regulatory Manager  
Suite 306, Kecheng Mansion, No.121 Science Road,  
Guahgzhou Science Park  
Guangzhou, 510663 CN

Re: K151281  
Trade/Device Name: AGE Automatic Wrist Blood Pressure Monitor, Models BW-601,  
BW-602, BW- 603, BW-605, BW-606, BW-611, BW-612, BW-  
613  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Non-Invasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: April 20, 2015  
Received: May 14, 2015

Dear Ms. Cecilia 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

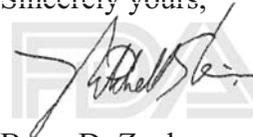
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**510(k) Number (if known):**  K151281

**Device Name:**  AGE Automatic Wrist Blood Pressure Monitor, Models BW -601, BW -602, BW -603, BW -605, BW -606, BW -611, BW -612, and BW -613

**Indications For Use:** AGE Automatic Wrist 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 wrist. The cuff circumference is limited to 13.5cm~19.5cm.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use**         
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use**  X

## 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.

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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](mailto:regulatory@glomed-info.com)

### 2. Subject Device Information

Type of 510(k): Traditional

Common Name: Noninvasive blood pressure measurement systems

Trade Name: AGE Automatic Wrist Blood Pressure Monitor, Models BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613

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: Health & Life Co.,Ltd.  
Common Name: Noninvasive blood pressure measurement systems  
Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL158LA  
510(k) number: K130564  
Review Panel: Cardiovascular  
Product Code: DXN  
Regulation Number: 21 CFR 870.1130  
Regulation Class: 2

### **4. Device Description**

AGE Automatic Wrist 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 wrist 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 Wrist 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 wrist. The cuff circumference is limited to 13.5 cm~19.5 cm.

### **6. Test Summary**

AGE Automatic Wrist 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 Wrist Blood Pressure Monitor	Full Automatic (NIBP) Blood Pressure Monitor, Model HL158LA	--
<b>Intended Use and Indications for Use</b>			
Intended Use	AGE Automatic Wrist 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 wrist	HL158LA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of	SE Note 1

Elements of Comparison	Subject Device	Predicate Device	Verdict
	according to the instruction in the user's guide manual.	this over-the-counter device is for use by people over the age of 18 with wrist circumference ranging from approx. 5.3 to 7.7 inches(13.5 cm to 19.5 cm) and for home use.	
Indications for Use	AGE Automatic Wrist 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 wrist. The cuff circumference is limited to 13.5cm~19.5cm.	HL158LA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for use by people over the age of 18 with wrist circumference ranging from approx. 5.3 to 7.7 inches(13.5 cm to 19.5 cm) and for home use.	SE Note 1
<b>ELECTRICAL REQUIREMENT</b>			
Power Supply	3Vdc (2 "AAA" batteries)	3Vdc (2 "AAA" batteries)	SE
<b>PERFORMANCE SPECIFICATION</b>			
Measuring Method	Oscillometry	Oscillometry	SE
Measuring Range	Pressure: 0~294 mmHg Pulse: 40~199 beats/minute	Pressure: 0~300 mmHg Pulse: 40~199 beats/minute	SE Note 2
Accuracy	Pressure: $\pm 3$ mmHg Pulse: $\pm 5\%$	Pressure: $\pm 3$ mmHg Pulse: $\pm 5\%$	SE
Patient Population	Adult	Adult	SE
Measurement Site of Body	Wrist	Wrist	SE
Cuff Circumference	13.5 ~ 19.5 cm	13.5 ~ 19.5 cm	SE
Inflation and Deflation	Automatic	Automatic	SE
Memory Size	2 x 90 sets record	3 $\times$ 40 sets record	SE Note 3
<b>OPERATING &amp; STORAGE CONDITIONS</b>			
Storage Environment	Temperature: -20°C ~ +65°C Humidity: 15~95%RH Atmospheric Pressure:86 kPa~106	Temperature: -25°C ~ +70 °C Humidity: $\leq$ 93%RH	SE Note 3

Elements of Comparison	Subject Device	Predicate Device	Verdict
	kPa		
Working Environment	Temperature: 5°C ~ 40°C Humidity: 15~90%RH Atmospheric Pressure:86 kPa~106 kPa	Temperature: 5°C ~ 40°C Humidity: 15~93%RH	SE Note 3
<b>COMPLIANCE STANDARDS</b>			
Electrical, Mechanical and Thermal Evaluation	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-11	SE Note 4
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 -1, 5, -10.	SE Note 5
Performance	ISO 81060-2	AAMI SP10	SE Note 6

**Note 1**

Although there is little difference for measurement cuff circumference of subject device and predicate device, both of them are complied with AAMI SP10 or ISO 81060-2. This difference does not affect the safety and effectiveness.

**Note 2**

Although the measuring range of pressure and pulse of subject device and predicate device are different, both of them are complied with AAMI SP10 or ISO 81060-2. The difference of their measuring range does not affect the safety and effectiveness.

**Note 3**

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.

**Note 4**

Although the electrical, mechanical and thermal evaluation of subject device and predicate device are different, they are both complied with IEC 60601-1 and IEC 60601-1-2. The differences do not affect the safety and effectiveness.

**Note 5**

Although the biocompatibility evaluation of subject device and predicate device are different, they are both complied with ISO 10993-5 and ISO 10993-10. The differences do not affect the safety and effectiveness.

**Note 6**

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.

**8. Conclusion**

The subject device AGE Automatic Wrist 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**

**29 June 2015**