June 18, 2018

Ageless Health Industrial 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: K172895
Trade/Device Name: AGE Automatic Upper Arm Blood Pressure Monitor with Models BA-815, BA-816, BA-818 and BA-819
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 8, 2018
Received: May 15, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172895

Device Name
AGE Automatic Upper Arm Blood Pressure Monitor with Models BA-815, BA-816, BA-818 and BA-819

Indications for Use *(Describe)*
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.

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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Chapter 5. 510(k) Summary

510(k) Summary

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

1. Submitter's Information

510(k) Owner's Name: Ageless Health Industrial Ltd.
Establishment Registration Number: Applying
Address: 3/F, A1 Bldg, Dongshen Sima Industrial Area, No.33 Shenbei Road, Sima Village, Changping Town, Dongguan, Guangdong, China
Contact Person: Victor Wan (Vice-president)
Email: victor@agelh.com

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

Common Name: System, Measurement, Blood-Pressure, Non-Invasive
Trade Name: AGE Automatic Upper Arm Blood Pressure Monitor
Models: BA-815, BA-816, BA-818, BA-819
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 21 CFR 870.1130
Regulation Class: 2

3. Predicate Device Information

Sponsor	Ageless Health Industrial Ltd.
Device Name	AGE Automatic Upper Arm Blood Pressure Monitor
510(k) Number	K153552
Product Code	DXN
Regulation Number	21 CFR 870.1130
Regulation Class	II

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 / Indications for 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.

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
- IEC 60601-1-11, 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 [Including: Technical Corrigendum 1 (2011)]
- IEC 80601-2-30, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Noninvasive Sphygmomanometers
- 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 and conclusion

The technological characteristics, features, specifications, materials, and intended use of the device is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new issues 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	--
Model Name	BA-815, BA-816, BA-818, BA-819	BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X	--
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
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
Measuring Range	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	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	2 x 90 sets record	SE
Software Version	V01	V01	SE
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

Elements of Comparison	Subject Device	Predicate Device	Verdict
Cuff Circumference	For BA-815: 22-34 cm; For BA-816: 28-42 cm; For BA-818 and BA-819, there are 6 size: 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)	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)	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 kPa	Temperature: 5°C ~ 40°C Humidity: 15~90%RH Atmospheric Pressure:86 kPa~106 kPa	SE
COMPLIANCE STANDARDS			
Electrical, Mechanical and Thermal Evaluation	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30	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 81060-2-30	ISO 81060-2-30	SE

Comparison in Detail(s):

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.

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

8. Date of the summary prepared: September 16, 2017