Sponsor:	*Ageless Health Industrial Ltd.*
Subject Device:	*AGE Automatic Upper Arm Blood Pressure Monitor, Model: BA-801, BA-802, BA-803, BA-805, BA-806, BA-811, BA-812, BA-813*
File No.:	*510(k) submission report (V1.0), Chapter 6*

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

AUG 14 2013

Sponsor Name: Ageless Health Industrial 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: 0769-81158038
Fax: 0769-82289331
E-mail: victor@agelh.com / c.ceng@foxmail.com
Web: www.agelh.com

2. Subject Device Information

Type of 510(k) submission:	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:	Fudakang Industrial Co., Ltd.
Common Name:	Noninvasive blood pressure measurement systems
Trade Name:	Arm Automatic Blood Pressure Meter

510(k) number:	K110281
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 oscillometric 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 the cuff around the left 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, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, 2007
- 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
- ANSI/AAMI SP10, Manual, electronic or automated sphygmomanometers, 2002+A1:2003+A2:2006+(R)2008

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
Manufacturer	Ageless Health Industrial Ltd.	Fudakang Industrial Co., Ltd.	--
Product Name	AGE Automatic Upper Arm Blood Pressure Monitor	Arm Automatic Blood Pressure Meter	--
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 arm according to the instruction in the user's guide manual.	Fudakang Arm Automatic Blood Pressure Meter 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 limited to 24~34 cm.	Fudakang Arm Automatic Blood Pressure Meter 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 22cm-30cm.	SE Note 1
ELECTRICAL REQUIREMENT			
Power Supply	6Vdc (4 "AA" batteries)	6Vdc (4 "AA" batteries)	SE
PERFORMANCE SPECIFICATION			
Measuring Method	Oscillometry	Oscillometry	SE
Measuring Range	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute	Pressure: 0~300 mmHg Pulse: 30~180 beats/minute	Note 2
Accuracy	Pressure: ±3 mmHg Pulse: ±5%	Pressure: ±3mmHg Pulse: ±5%	SE
Patient Population	Adult	Adult	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Measurement Site of Body	Arm	Arm	SE
Cuff Circumference	24~34 cm	22~30 cm	SE Note 1
Inflation and Deflation	Automatic	Automatic	SE
Memory Size	2 x 90 sets record	60 or 90 sets record	SE Note 3
OPERATING & STORAGE CONDITIONS			
Storage Environment	Temperature: -20℃ ~ +65℃ Humidity: 10~95%RH	Temperature: -20℃ ~ +60 ℃ Humidity: < 95%RH	Note 3
Working Environment	Temperature: 5℃ ~ 40℃ Humidity: 10~90%RH	Temperature: 5℃ ~ 40℃ Humidity: < 90%RH	Note 3
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	AAMI SP10	AAMI SP10	SE

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. 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. 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.

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

31 March 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2013

Ageless Health Industrial
c/o Mr. Victor Wan
3F, A1 bldg, Dongshen Sima Industrial Area No. 33 Shenbai Road
Changping, Dongguan, Guangdong, China 523570

Re: K123882
Trade/Device Name: AGE Automatic Upper Arm Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 27, 2013
Received: August 2, 2013

Dear Mr. Victor Wan:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sponsor: *Ageless Health Industrial Ltd.*

Subject Device: *AGE Automatic Upper Arm Blood Pressure Monitor, Model: BA-801, BA-802, BA-803, BA-805, BA-806, BA-811, BA-812, BA-813*

File No.: *510(k) submission report (V1.0), Chapter 5*

Chapter 5. Statement of Indications for Use

Indications for Use

510(k) Number (if known): Applying

Device Name: AGE Automatic Upper Arm Blood Pressure Monitor

Model: BA-801, BA-802, BA-803, BA-805, BA-806, BA-811, BA-812, BA-813

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 limited to 24~34 cm.

Prescription Use ___ ___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ X_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number_____

Digitally signed by Owen P. Faris -S
Date: 2013.08.14 15:45:49 -04'00'

Page 1 of 1