July 10, 2020

Dongguan E-Test Technology Co., Ltd
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District, Guangzhou, 510000
CHINA

Re: K193624
Trade/Device Name: 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: March 25, 2020
Received: April 13, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193624

Device Name
Automatic Upper Arm Blood Pressure Monitor

Indications for Use *(Describe)*
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.

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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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: DONGGUAN E-TEST TECHNOLOGY CO., LTD

Establishment Registration Number: Applying

Address: Room 201,301, Building 1, Changping Section No.1, Dongshen Road, Changping Town, Dongguan City, Guangdong, China.

Tel: +86-0769-81158038

Contact Person (including title): Victor Wan (Vice-president)

E-mail: victor@agelh.com

Application Correspondent:

Contact Person: Cassie Lee

DONGGUAN E-TEST TECHNOLOGY CO., LTD

Address: Room 201,301, Building 1, Changping Section No.1, Dongshen Road, Changping Town, Dongguan City, Guangdong, China.

Tel: +86-0769-81158038

Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k): Traditional

Common Name: Noninvasive blood pressure measurement systems

Classification Name: System, Measurement, Blood-Pressure, Non-Invasive

Trade Name: Automatic Upper Arm Blood Pressure Monitor

Model Name: BA-815, BA-816

Review Panel: Cardiovascular

Product Code: DXN

Regulation Number: 870.1130

Regulatory Class: 2

3. Predicate Device Information

Sponsor	Dongguan Ageless Health Industrial Co., Ltd
Device Name and Model	AGE Automatic Upper Arm Blood Pressure Monitor Models: BA-815, BA-816, BA-818, BA-819
510(k) Number	K172895
Product Code	DXN
Regulation Number	870.1130
Regulation Class	II

4. Device Description

Automatic Upper Arm Blood Pressure Monitor is designed to measure the systolic, diastolic and pulse rate of an individual by using a non-invasive technique which an inflatable cuff is wrapped around upper arm. Our method to define systolic and diastolic pressures is similar to the auscultatory method but using an electronic capacitive pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well-known technique in the market so called “oscillometric method”. The device also has low voltage indication, which will be triggered when the battery is low.

5. Intended Use / Indications for Use

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

The whole product and manufacturing used for the Automatic Upper Arm Blood Pressure Monitor are identical to those of the predicate device, which were demonstrated to conform with 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, mode of operation, and intended use of Automatic Upper Arm Blood Pressure Monitor 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
Company		DONGGUAN E-TEST TECHNOLOGY CO., LTD	Dongguan Ageless Health Industrial Co., Ltd	--
Product Name		Automatic Upper Arm Blood Pressure Monitor	AGE Automatic Upper Arm Blood Pressure Monitor	--
Model Name		BA-815, BA-816	BA-815, BA-816, BA-818, BA-819	--
Classification Name		System, Measurement, Blood-Pressure, Non-Invasive	System, Measurement, Blood-Pressure, Non-Invasive	SE
510(k) Number		Applying	K172895	--
Product Code		DXN	DXN	SE
Intended Use / Indications for Use		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.	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.	SE
Energy source		DC 6V (4 X AA 1.5V alkaline batteries)	DC 6V (4 X AA 1.5V alkaline batteries)	SE
Design	Software	Same version software		SE
	hardware	Same version hardware		
Material		ABS plastic, Nylon, Latex	ABS plastic, Nylon, Latex	SE
Measurement Site		Upper Arm	Upper Arm	SE
Measuring range		Pressure: 0~280 mmHg Pulse: 40~199 beats/minute	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute	SE
Pressure resolution		1 mmHg or 0.1kPa	1 mmHg or 0.1kPa	SE
Measuring accuracy		Pressure: ± 3mmHg Pulse: ±5%	Pressure: ± 3mmHg Pulse: ±5%	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-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)	SE
Size and Weight of model BA-815	About 1150g (not include battery) (L) 235mm X (D)182mm X (H)210mm	About 1150g (not include battery) (L) 235mm X (D)182mm X (H)210mm	SE
Size and Weight of model BA-816	About 1150g (not include battery) (L) 255mm X (D)201mm X (H)228mm	About 1150g (not include battery) (L) 255mm X (D)201mm X (H)228mm	SE
Inflation and Deflation	Automatic	Automatic	SE
Measuring Method	Oscillometry	Oscillometry	SE
Patient Population	Adult	Adult	SE
Display	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon,	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
	Heart Icon, Memory Record Number		
Software Version	V01	V01	SE
Operation condition	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
Transport/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
Safety	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Biocompatibility	ISO 10993 series	ISO 10993 series	SE

Comparison in Detail(s):

Final Conclusion:

The subject device noninvasive sphygmomanometer (Automatic Upper Arm Blood Pressure Monitor) (Model: BA-815, BA-816) 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.

All hardware and software of the subject device are based on that of the predicate device (K172895), since no new testing is presented in the submission.

8. Date of the summary prepared: July 8, 2020