July 12, 2020

Dongguan E-Test Technology Co., Ltd
℅ Cassie Lee, Manager
Dongguan E-Test Technology Co., Ltd
Room 201,301. Building 1, Changping Section No.1, Dongshen Road
Dongguan City, Guangdong, China 523588

Re: K193628
Trade/Device Name: Automatic Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: December 24, 2019
Received: December 26, 2019

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)*
K193628

Device Name
Automatic Wrist Blood Pressure Monitor

Indications for Use *(Describe)*
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.

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.

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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: Ms. 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 Wrist Blood Pressure Monitor
Model Name: BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613
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 Wrist Blood Pressure Monitor Models: BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613
510(k) Number	K151281
Product Code	DXN
Regulation Number	870.1130

Regulation Class	II

4. Device Description

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 / Indications for Use

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

6.1 The whole product and manufacturing used for the Automatic Upper Wrist 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)

6.2 Summary of new tests on subject device

- IEC 60601-1-2: 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances - Requirements and tests
- Mechanical test according to ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21 and IEC 60601-1-11:2015

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Automatic Wrist 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.

Comparison table:

Elements of Comparison		Subject Device	Predicate Device	Verdict
Company		DONGGUAN E-TEST TECHNOLOGY CO., LTD	Dongguan Ageless Health Industrial Co., Ltd	--
Product Name		Automatic Wrist Blood Pressure Monitor	AGE Automatic Wrist Blood Pressure Monitor	--
Model Name		BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613	BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613	--
Classification Name		System, Measurement, Blood-Pressure, Non-Invasive	System, Measurement, Blood-Pressure, Non-Invasive	SE
510(k) Number		Applying	K151281	--
Product Code		DXN	DXN	SE
Intended Use / Indications for Use		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.	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.	SE
Energy source		3Vdc (2 “AAA” batteries)	3Vdc (2 “AAA” batteries)	SE
Design	Software	Same version software		SE
	hardware	Same version hardware		SE
Material		ABS plastic, Nylon, Latex	ABS plastic, Nylon, Latex	SE
Measurement Site		Wrist	Wrist	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Measuring range	Pressure: 0~294 mmHg Pulse: 40~199 beats/minute	Pressure: 0~294 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
Cuff Circumference	13.5~19.5cm	13.5~19.5cm	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, 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
Software Version	V01	V01	SE
Size and Weight of model BW-601	73.5mm(L) 73.2mm(W) 30.9mm(H) 270g	73.5mm(L) 73.2mm(W) 30.9mm(H) 270g	SE
Size and Weight of model BW-602	72.69mm(L) 64.0mm(W) 28.0mm(H) 150g	73.5mm(L) 73.2mm(W) 30.9mm(H) 270g	SE
Size and Weight of model BW-603	76.0mm(L) 60.5mm(W) 27.1mm(H) 260g	87mm(L) 67.9mm(W) 31mm(H) 262g	SE
Size and Weight of model BW-605	73.5mm(L) 60.5mm(W) 30.9mm(H) 270g	87mm(L) 64mm(W) 31mm(H) 265g	SE Note 1
Size and Weight of model BW-606	75.0mm(L) 70.0mm(W) 32.6mm(H) 280g	87mm(L) 63.4mm(W) 31mm(H) 265g	SE
Size and Weight of model BW-611	75.0mm(L) 70.0mm(W) 32.6mm(H) 280g	87mm(L) 62mm(W) 30mm(H) 245g	SE Note 1

Elements of Comparison	Subject Device	Predicate Device	Verdict
Size and Weight of model BW-612	73.5mm(L) 73.2mm(W) 30.9mm(H) 270g	78mm(L) 72mm(W) 29mm(H) 255g	SE Note 1
Size and Weight of model BW-613	76.0mm(L) 60.5mm(W) 27.1mm(H) 260g	78mm(L) 72mm(W) 29.6mm(H) 260g	SE Note 1
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: 15~95%RH Atmospheric Pressure: 86 kPa~106kPa	Temperature: -20°C ~ +65°C Humidity: 15~95%RH Atmospheric Pressure: 86 kPa~106kPa	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	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

Comparison in Detail(s):

Note 1:

Although there is a little difference for “appearance”, “Physical Dimensions” and “Weight” from the predicate devices, but it will not affect the main function and the intended use of the device.

Final Conclusion:

The subject device noninvasive sphygmomanometer (Automatic Upper Wrist Blood Pressure Monitor) (Model: BW-601, BW-602, BW-603, BW-605, BW-606, BW-611, BW-612, BW-613) 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.

Except for new tests mentioned in section 6.2 above, all hardware and software of the subject device are based on that of the predicate device K151281.

8. Date of the summary prepared: July 7, 2020