September 3, 2025

Dongguan E-test Technology Co., Ltd
Wan Victor
Official Correspondent
Room 201,301, Building 1, Changping Section No.1,
Dongshen Road, Changping Town
Dongguan, Guangdong 523570
China

Re: K250231
Trade/Device Name: Automatic Upper Arm Blood Pressure Monitor (BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 28, 2025
Received: August 1, 2025

Dear Wan Victor:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JENNIFER W. SHIH -S

for LCDR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250231

Device Name
Automatic Upper Arm Blood Pressure Monitor model: BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856)

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 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K250231

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

Company Name: DONGGUAN E-TEST TECHNOLOGY CO., LTD
Establishment Registration Number: 3017896172
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Contact Person (including title): Wan Victor (General Manager)
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Application Correspondent:

Contact Person: Mr. Wan Victor
DONGGUAN E-TEST TECHNOLOGY CO., LTD.
Address: Room 201,301, Building 1, Changping Section No.1, Dongshen Road, Changping Town, Dongguan City, Guangdong, China Dongguan Guangdong 523560 China
Tel: 0769-81158038
Email: regulatory@glomed-info.com

2. Subject Device Information:

Type of 510(k): Traditional
Common Name: Noninvasive blood pressure measurement system
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Trade Name: Automatic Upper Arm Blood Pressure Monitor
Model Name: BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulatory Class: II

3. Predicate Device Information

Predicate Device

Sponsor: DONGGUAN E-TEST TECHNOLOGY CO., LTD.
Trade Name: Automatic Upper Arm Blood Pressure Monitor
Model: BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X, BA-818, BA-819
Common Name: Noninvasive blood pressure measurement systems
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
510(K) Number: K193627
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulation Class: II

Reference Device

Sponsor: Dongguan E-Test Technology Co., Ltd.

Trade Name: Automatic Upper Arm Blood Pressure Monitor
Model: BA-815, BA-816
Common Name: Noninvasive blood pressure measurement systems
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
510(K) Number: K193624
Review Panel: Cardiovascular
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.

The product includes Bluetooth transmission functionality which can connect to APP and transfer data for APP, and the measuring data, including systolic diastolic pressures and pulse rate can be displayed on APP. The APP can control the device measuring when connecting device.

There are 18 models and 2 types (Arm type and tunnel type). Arm type has models BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X. They are all the same except for appearance and buttons. Tunnel type has models BA-835, BA-836, BA-839, BA-840, BA-856. They are all the same except for appearance and cuff circumference. Arm type has cuff as accessory and there are 6 sizes, you can select suitable size according to your arm circumference. The product provides 4 AA batteries or DC 6.0V adapter for power supply for power supply.

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 the cuff around the left upper arm according to the instruction in the user's guide manual.

6. Comparison to predicate devices

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Verdict
Company	DONGGUAN E-TEST TECHNOLOGY CO., LTD	DONGGUAN E-TEST TECHNOLOGY CO., LTD	DONGGUAN E-TEST TECHNOLOGY CO., LTD	--
Trade Name	Automatic Upper Arm Blood Pressure Monitor	Automatic Upper Arm Blood Pressure Monitor	Automatic Upper Arm Blood Pressure Monitor	--
Model	BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X, BA-835, BA-836, BA-839, BA-840, BA-856	BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X, BA-818, BA-819	BA-815, BA-816	--

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Verdict
510(k) Number	K250231	K193627	K193624	--
Medical Specialty	Cardiovascular	Cardiovascular	Cardiovascular	Same
Regulation	21 CFR 870.1130	21 CFR 870.1130	21 CFR 870.1130	Same
Product Code	DXN	DXN	DXN	Same
Regulation Class	II	II	II	Same
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 the cuff around the left upper arm according to the instruction in the user's guide manual.	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.	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.	Same
Type for use	OTC	OTC	OTC	Same
Power Source	DC 6V (4 X AA 1.5V alkaline batteries) For arm type adapter: Output DC 6V/1A For tunnel type adapter: Output DC 6V/1.5A	DC 6V (4 X AA 1.5V alkaline batteries)	DC 6V (4 X AA 1.5V alkaline batteries)	Similar Note 3
Measurement Site	Upper Arm	Upper Arm	Upper Arm	Same
Measuring Range	Pressure: 0~294mmHg Pulse: 40~199 beats/minute	Pressure: 0~280 mmHg Pulse: 40-199 beats/minute	Pressure: 0~280 mmHg Pulse: 40-199 beats/minute	Similar Note 1
Measuring Accuracy	Pressure: ±3 mmHg Pulse: ±5%	Pressure: ±3 mmHg Pulse: ±5%	Pressure: ±3 mmHg Pulse: ±5%	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Verdict
Resolution	1 mmHg	1 mmHg or 0.1kPa	1 mmHg or 0.1kPa	Same
Cuff Circumference	Arm type: 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) Tunnel type: BA-835, BA-839, BA-840: 22-34cm BA-836, BA-856: 28-42cm	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)	For BA-815: 22-34 cm; For BA-816: 28-42 cm;	Same
Inflation and Deflation	Automatic	Automatic	Automatic	Same
Measuring Method	Oscillometry	Oscillometry	Oscillometry	Same
Patient Population	Adult	Adult	Adult	Same
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	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Same
Operation condition	Temperature: 5°C ~ 40°C Humidity: 10~90%RH Atmospheric Pressure:86 kPa~106 kPa	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	Similar Note 2
Transport/storage	Temperature: -20°C ~ +65°C	Temperature: -20°C ~ +65°C	Temperature: -20°C ~ +65°C	Same

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Verdict
environment	Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa	Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa	Humidity: 10~95%RH Atmospheric Pressure:86 kPa~106 kPa	
Safety and EMC	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	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30	Same
Biocompatibility	ISO 10993 series	ISO 10993 series	ISO 10993 series	Same

Comparison in Detail(s):

Note 1:

The Pressure Measuring Range is slightly different. The IEC 80601-2-30 can demonstrate that the subject device can maintain the safety and performance within the measurement range. Thus, the difference does not raise different questions of safety and effectiveness

Note 2:

Compared with the predicate device, the subject device requires less strict operation environment. The IEC 60601-1-11 test report can demonstrate that the subject device can maintain the safety and performance within the operation and storage environment. Thus, this difference does not raise different questions of safety and effectiveness.

Note 3:

The Power Source is slightly different. The subject device meets the requirements of IEC60601-1 Thus, the difference does not raise different questions of safety and effectiveness

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Electrical safety and EMC testing were conducted on the proposed device. The device was shown to comply with IEC 60601-1-2:2020 and IEC TR 60601-4-2:2016 for electromagnetic compatibility, IEC 60601-1:2020, IEC 60601-1-11:2020, ISO 80601-2-30:2018 and ISO 81060-1:2007 for electrical safety.

2) Biocompatibility Test

We declare that the cuff in the Automatic Upper Arm Blood Pressure Monitor (Model: BA-831X, BA-832X, BA-833X, BA-837X, BA-838X, BA-842X, BA-843X, BA-845X, BA-847X, BA-849X, BA-851X, BA-852X, BA-855X) is identical to those used in the Automatic Upper Arm Blood Pressure Monitor K193627, in formulation, processing, and cleaning, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

And We declare that the cuff cover in the Automatic Upper Arm Blood Pressure Monitor (model: BA-835, BA-836, BA-839, BA-840, BA-856) is identical to those used in the Automatic Upper Arm Blood Pressure Monitor K193624 in formulation, processing, and cleaning, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

3) Software verification and validation

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket

Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Cybersecurity

Cybersecurity software documentation was created for subject device according to FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices "issued on October 18.2018.

7.2 Summary of Clinical Performance

The principles, software, algorithms, sensors, etc. of the blood pressure measurement part of the subject device and the predicate device are the same, so the clinical data of the predicate device, K193627, and reference device, K193624, can represent the subject device, and the predicate device, K193627, and reference device, K193624, have been tested according to the ISO 81060-2 standard and used for the subject device submitted this time.

8. Date of the summary prepared: September 1, 2025

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K193627, and reference device, K193624.