March 26, 2026

Shenzhen Urion Technology Co., Ltd.
Vivian Wang
Regulation Specialist
Flr 4-6th Of Bldg. D, Jiale Science & Tech Indust Zone,#3
Chuang Wei Rd., Heshuikou Comm, Matian St.,Guangming New Dist
Shenzhen, Guangdong 518106
China

Re: K260273
Trade/Device Name: Automatic Electronic Blood Pressure Monitor (U90B series models including (U90B, U90B Pro, U90B Plus, U90B Ultra, U90C, U90C Pro, U90C Plus, U90C Ultra).)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 24, 2026
Received: January 29, 2026

Dear Vivian Wang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

STEPHEN C. BROWNING -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

Automatic Electronic Blood Pressure Monitor (U90B series models including (U90B,U90B Pro,U90B Plus,U90B Ultra,U90C,U90C Pro,U90C Plus,U90C Ultra).)

Please provide your Indications for Use below.

This automatic blood pressure Is intended tomeasure systolic pressure, diastolic pressure and pulse rate through upper arm.Are expected to use in the home orin the hospital, intended for people over 12 years old. The Subject device is not intended to be diagnostic device.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	Jan. 24th, 2026
Manufacturer information	Submitter's Name: Shenzhen Urion Technology Co.,Ltd Address: Floor 4-6th of Building D, Jiale Science & Technology Industrial Zone, No.3, ChuangWei Road, Heshuikou Community, MaTian Street, GuangMing New District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA Contact person: Joanna Guo TEL: (+86) -755-29231308 FAX: (+86) -755-29231308 E-Mail: Joanna@urionsz.com
Submission Correspondent	Contact person: Miss Wang. E-Mail: fagui007@urionsz.com

2 Device Information

Common name of the device	System, Measurement, Blood-Pressure, Non-Invasive
Trade name of the device	Automatic Electronic Blood Pressure Monitor
Type/Model of the device	U90B series (models including U90B ,U90B Pro,U90B Plus,U90B Ultra,U90C,U90C Pro,U90C Plus,U90C Ultra)
Classification information	Classification panel: Cardiovascular Classification name: System, Measurement, Blood-Pressure, Non-Invasive Regulation Number: 870.1130 Device Class: II Product Code: DXN
type of 510(k) submission	Traditional

3 Predicate Device Information

Sponsor:	Shenzhen Urion Technology Co.,LTD
Device:	Upper Arm Electronic Blood Pressure Monitor
510(K) Number:	K243115

4 Device Descriptions

The device has four series : U90B series (models including U90B ,U90B Pro,U90B Plus,U90B Ultra,U90C,U90C Pro,U90C Plus,U90C Ultra).

All of them have same Indications for use and similar technological characteristics. All the models in the same series have the same electrical circuit design, PCB layout, critical components and internal wiring. The differences between the four series are the appearance design, circuit diagram and the PCB layout. All of them have the same working principles, software design and the similar technical specification.

Urion Blood Pressure Monitor are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual (at least 12 or above) by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Blood Pressure Monitor are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 400 mm, includes the inflatable bladder and nylon shell. All models of the arm blood pressure monitor use a single size of cuff.

5 Intended Use/ Indications for Use

This automatic blood pressure is intended tomeasure systolc pressure, diastollc pressure and pulse rate through upper arm.Are expected to use in the home or inthe hospital,intended for people over 12 years old.
The Subject device is not intended to be a diagnostic device.

6.Contraindications

（1）This product can't be used in patients who is with severe heart failure insufficiency to avoid suffocation and death.

（2）It is not necessary to use this product if you have coronary atherosclerotic heart disease to avoid narrowing or blockage of the blood vessel lumen,which may cause is chemia and lack of oxygen to the heart.

（3）Do not use this device if you have diabetes. This device has not been studied inpeople with diabetes.

（4）Do not use this device if you are pregnant.

（5）Patients with implanted pacemaker,Please consult your doctor prior to using the unit if you suffer from illnesses.

（6）Those who have arrhythmia, blood circulation or apoplexy problem,please use under the physician's instruction,lest cause disease exacerbation.

（7）Do not use this device if you have premature ventricular beats (PVC) oratrial fibrillation or other irregular heart rhythms.

（8）This device should not be used if you have peripheral arterial disease. Also do not use this device on the same side of a mastectomy or arterio-venous shunt.

（9）This device is not intended to assess the pulse rate in paced rhythms.

7. SE Comparison

Table 1. Substantial Equivalence Comparison

Device Name	Automatic Electronic Blood Pressure Monitor	Upper Arm Electronic Blood Pressure Monitor	NA

Device Model	U90B series (models including U90B,U90B Pro,U90B Plus,U90B Ultra,U90C,U90C Pro,U90C Plus,U90C Ultra).	U87Y series (includingU80Y.U81Y,U82Y,U83Y,U86Y,U80N,U81NH), U86E series(including U82E,U80E,U80EH,U81E,U83E,U85E,U80L,U87E), U81X series (includingU81X,U80X,U82X,U83X,U81D,U82D,U83D,U81RH, U82RH U83Z series (including U83Z,U80Z,U81Z,U82Z,U85Z, U86Z and U87Z)	NA
Manufacturer	Shenzhen Urion Technology Co.,LTD	Shenzhen Urion Technology Co.,LTD	NA
Intended Use/ Indication for Use	This automatic blood pressure ls intended to measure systolic pressure, diastolic pressure and pulse rate through upper am. Are expected to use in the home or in the hospital, intended for people over 12 years old.	The subject device intended tomeasure the diastolic, systolic blood pressures and pulse rate ofan adult individual who over the age of 12 in medical facilities or athome by using a non-invasive oscillometric technique with asingle upper arm cuff (22-42 cm)The Subject device is notintended to be diagnostic device.	Same
Intended Population	Adult person over 12	Adult person over 12	same
Intended Anatomical site	upper arm	upper arm	same
Prescription & OTC	OTC	OTC	same
Working Principle	Oscillometric method	Oscillometric method	same
Pressurization Source	Automatic internal pump	Automatic internal pump	same
Power supply	4*AA batteries/Type-C 5V 2A power supply	Four AA or AAA batteries or AC adapter	Similar Note01
Cuff Size	220mm~400mm	220mm~420mm	Similar Note02
Measuring range	0-299mmHg(0-39.9KPa)	0-299mmHg(0-39.9KPa)	Same
	SYS:50 to 255mmHg DIA: 30 to 200 mmHg	SYS:50 to 255mmHg DIA: 30 to 200 mmHg	
	Pulse: 40 to 199 beat/minute	Pulse: 40 to 199 beat/minute	
Irregular heartbeat prompt function	Yes	Yes	Same
Mesauring resolution	1 mmHg	1 mmHg	Same
Accuracy	Pressure: ±3mmHg; Pulse: ±5%	Pressure: ±3mmHg; Pulse ±5%.	Same
Operating	5~40℃,	5~40℃,	Similar

Environment	15%~93%RH	15%~85%RH	Note 03

Note01: Both the subject device and the predicate device are powered by batteries and AC adapter. The difference is some modes for the subject device are powered by AAA batteries. The subject device comply with the requirement of standard IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 80601-2-30. This difference will not cause any safety or performance issue.

Note02: The subject devices have the larger arm circumference than predicate device. The subject device has also been validated according to IEC 80601-2-30 and ISO 81060-2. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

Note03： There is a little difference on the operating environment. The measuring rage has been validated on the claimed operating environment for the subject device. The difference does not raise any issues concerning safety and effectiveness.

The subject device is as same as predicate device in Working Principle, Intended patient population, intended application site, measuring accuracy. Only their cuff size, power supply and operating environment are a little bit different. However, the differences would not raise any safety or effectiveness issue based on tests in this submission.

8 Brief discussions of the non-clinical tests

Performance testing:

The subject device conforms to the following guidances and standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirement for basic safety and essential performance-Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 80601-2-30: Medical electrical equipment-Particular requirements for basic safety and essential performance of automated non-invasives phygmomanometers.
- 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

Biocompatibility testing:

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, " Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ". The biocompatibility testing includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

9 Brief discussions of clinical tests

U90B series (models including U90B,U90B Pro,U90B Plus,U90B Ultra,U90C,U90C Pro,U90C Plus,U90C Ultra). family digital blood pressure monitors pass the clinical and non-clinical evaluation based on the followed table.

Non-clinical Test Summary:

This monitor is clinically investigated according to the requirements of ISO 81060-2-2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. In the clinical validation study, the cuff were tested for clinical accuracy with the main unit, 85 subjects were used for determination of blood pressure for each cuff.

The age range of subjects was over 12 years old;

Among the 85 subjects, at least 30% were male and at least 30% were female.

Hypertensive patients were also included in clinical testing. Pregnant women were not included in clinical testing.

The test summary of clinical validation: no safety problems and adverse events were found during the clinical test. The test result show that the Automatic Electronic Blood Pressure Monitor meets the requirement of IEC 80601-2-30:2018 and ISO 81060-2:2018+A1(2020).

Table 1.Subject distribution requirements

Clinical Test Summary based on ISO 81060-2:2018 and ISO81060-2:2018/Amd.2:2024:

Distribution conditions	Number of subjects (case)	Distribution requirements (%)
Gender distribution		

Male		≥26	≥30%
Female		≥26	≥30%
Arm circumference distribution			
≥22.00cm and ≤26.50cm		≥17	≥20%
>26.50cm and ≤31.00cm		≥17	≥20%
>31.00cm and ≤35.50cm		≥17	≥20%
>35.50cm and ≤40.00cm		≥17	≥20%
≥22.00cm and ≤24.25cm		≥9	≥10%
≥37.7cm and ≤40.00cm		≥9	≥10%
Blood pressure distribution (based on readings of reference device)			
Systolic blood pressure	Systolic blood pressure≤100mmHg	/	≥5%
	Systolic blood pressure≥160mmHg	/	≥5%
	Systolic blood pressure≥140mmHg	/	≥20%
Diastolic blood pressure	Diastolic blood pressure≤60mmHg	/	≥5%
	Diastolic blood pressure≥100mmHg	/	≥5%
	Diastolic blood pressure≥85mmHg	/	≥20%

The mean difference between the subject device and the reference device for systolic /diastolic BP was -2.66 mmHg/-1.95 with a SD of 3.7/3.24, and that the HR had a mean difference of -1.84 and a SD of 3.13 bpm.

U90B series of blood pressure monitors have the following similarities to the predicate devices, The U87Y series blood pressure monitors, which previously received the 510(k) clearance.

- ●Same intended use.
- ●Same oscillometric method to determine the blood pressure & pulse rate.
- ●Same inflation method- automatic internal pump.
- ●Same deflation method - standard exhaust valveSame materials, no new materials used.
- ●Same manufacturing processes at the same facility.

Clinical Testing:

According to the evaluation results, the test device measures systolic blood pressure.diastolic blood pressure and pulse rate via the upper arm, and its accuracy meets the requirements of the IS0 81060-2:2018 and IS0 81060-2:2018/Amd.2:2024 completely; thedevice with stable performance, convenient operation, and without device defects, thus thinkthe overall

effectiveness and safety of test device in the population with arm circumferenceamong 22cm~40cm can meet the requirements for home and clinical use.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device: Automatic Electronic Blood Pressure Monitor manufactured by Shenzhen Urion Technology Co., Ltd is respectively substantially equivalent to the predicate device (K243115).