February 21, 2025

Shenzhen Urion Technology Co.,Ltd.
Janice Ou
Regulation Manager
Floor 4-6th of Building D, Jiale Science & Technology Indust
rial Zone, No.3, Chuang Wei Road, Heshuikou Community, MaTi
Shenzhen, Guangdong 518106
China

Re: K243115
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor (U87Y series (models including U80Y, U81Y, U82Y,U83Y,U86Y U80N, U81NH), U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) and U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z))
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 30, 2024
Received: January 21, 2025

Dear Janice Ou:

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,

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

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.

Submission Number *(if known)*

K243115

Device Name

Upper Arm Electronic Blood Pressure Monitor (U87Y series (models including U80Y, U81Y, U82Y,U83Y,U86Y U80N, U81NH), U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) and U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z))

Indications for Use *(Describe)*

intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual who over the age of 12 in medical facilities or at home by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm).
The Subject device is not intended to be diagnostic device.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

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

1 Administrative Information

Submission Date	Feb. 20th, 2025
Manufacturer information	Submitter's Name: Shenzhen Urion Technology Co.,Ltd Address: Floor 4-6th of Building D, Jiale Science & Technology Industrial Zone, No.3, Chuang Wei 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 Janice Ou E-Mail: 411070313@qq.com

2 Device Information

Common name of the device	System, Measurement, Blood-Pressure, Non-Invasive
Trade name of the device	Upper Arm Electronic Blood Pressure Monitor
Type/Model of the device	U87Y series (models including U80Y, U81Y, U82Y,U83Y,U86Y U80N, U81NH), U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) and U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z)
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:	Electronic Blood Pressure Monitor
510(K) Number:	K160019

4 Device Descriptions

The device has four series : U87Y series (models including U80Y, U81Y, U82Y,U83Y,U86Y U80N, U81NH), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) , U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z) and U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E).

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 420 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

intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual who over the age of 12 in medical facilities or at home by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm).

The Subject device is not intended to be diagnostic device.

6 SE Comparison

Table 1. Substantial Equivalence Comparison

Device Name	Upper Arm Electronic Blood Pressure Monitor	Electronic Blood Pressure Monitor	NA
Device Model	U87Y series (including U80Y,U81Y,U82Y,U83Y,U86Y,U80N,U81NH), U86E series (including U82E, U80E, U80EH, U81E, U83E, U85E, U80L, U87E), U81X series (including U81X, U80X, U82X, U83X, U81D, U82D, U83D, U81RH, U82RH) and U83Z series (including U83Z, U80Z, U81Z, U82Z, U85Z, U86Z and U87Z)	U80 series, including U80A, U80AH, U80B, U80BH	NA
Manufacturer	Shenzhen Urion Technology Co.,LTD	Shenzhen Urion Technology Co.,LTD	NA
Intended Use/ Indication for Use	The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual who over the age of 12 in medical facilities or at home by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm). The Subject device is not intended to be diagnostic device.	The U80 Series Upper Arm Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36cm.Suitable for adults who over the age of 12.	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	Four AA or AAA batteries or AC adapter	Four AA batteries or AC adapter	Similar Note 01
Cuff Size	220mm~420mm	220mm~360mm	Similar Note 02
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 heart beat prompt function	Yes	Not publicly available	Different Note 03
Measuring resolution	1 mmHg	1 mmHg	same
Accuracy	Pressure: ±3mmHg; Pulse: ±5%	Pressure: ±3mmHg; Pulse ±5%.	same
Operating Environment	5~40℃,	10~40℃,	Similar Note 04
	15%~85%RH	15%~93%RH	

Note 01: 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.

Note 02: 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.

Note 03: Irregular heart beat prompt does not influence the accuracy, and this function has been verified by performance testing. So the difference will not raise safety or effectiveness issue.

Note 04: There's 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.

7 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-invasive sphygmomanometers.
- 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

8 Brief discussions of clinical tests

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, 92 subjects were used for determination of blood

pressure for each cuff.

The age range of subjects was over 12 years old;

Among the 92 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 Upper Arm Electronic Blood Pressure Monitor meets the requirement of IEC 80601-2-30:2018 and ISO 81060-2:2018+A1(2020).

9 Other information (such as required by FDA guidance)

No other information.

10 Conclusions

The subject device: Upper Arm Electronic Blood Pressure Monitor manufactured by Shenzhen Urion Technology Co., Ltd is respectively substantially equivalent to the predicate device (K160019).