May 14, 2026

Shenzhen Urion Technology Co., Ltd.
Fraser Liu
Regulation Assistant
Floor 4-6th Of Bldg. D, Jiale Science & Technology
Industrial Zone, #3, Chuang Wei Rd., Heshuikou Community
Shenzhen, Guangdong 518106
China

Re: K254048
Trade/Device Name: Wrist Watch Electronic Blood Pressure Monitor (U16H, U16L, U16P, U16W, U19M, U19R, U19S, and U19T)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 3, 2026
Received: May 4, 2026

Dear Fraser Liu:

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

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)*
K254048

Device Name
Wrist Watch Electronic Blood Pressure Monitor (U16H, U16L, U16P, U16W, U19M, U19R, U19S, and U19T)

Indications for Use *(Describe)*
The Wrist Watch Electronic Blood Pressure Monitor uses the oscillometric method to measure diastolic blood pressure, systolic blood pressure. It is intended for use in adults with a wrist circumference between 15-21 cm who do not have arrhythmias (such as atrial fibrillation) and who are not pregnant. The values are for reference purposes and do not constitute a diagnosis.

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

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

**1. Submitter:**

Shenzhen Urion Technology Co., Ltd.

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**Contact Person:** Xiaona Guo

**Prepare date:** 2025-09-10

**2. Device name and classification:**

**Device Name:** Wrist Watch Electronic Blood Pressure Monitor

**Model:** U16H, U16L, U16P, U16W, U19M, U19R, U19S, and U19T

**Classification Name:** Noninvasive Blood Pressure Measurement System

21 CFR 870.1130 System, measurement, blood-pressure, non-invasive

Product code: DXN

**Regulatory Class:** Class Ⅱ

**3. Predicate Device(s):**

Wrist Electronic Blood Pressure Monitor

K231367/Shenzhen Finicare Co., Ltd.

**4. Device Description:**

This device is a digital self-monitor intended for use in measuring blood pressure in adult population with wrist circumference ranging from 15.0 cm to 21.0 cm. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure of adult person at wrist within its claimed range and accuracy via the oscillometric technique.

The Wrist Watch Electronic Blood Pressure Monitor consists of a main unit, watch strap(including an airbag), and a charging cable.

**5. Indications for Use:**

The Wrist Watch Electronic Blood Pressure Monitor uses the oscillometric method to measure diastolic blood pressure, systolic blood pressure. It is intended for use in adults with a wrist circumference between 15-21 cm who do not have arrhythmias (such as atrial fibrillation) and who are not pregnant. The values are for reference purposes and do not constitute a diagnosis.

## 6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

The differences between the subject device and predicate device include physical specifications, and color. All above differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

## 7. Effectiveness and Safety Considerations:

**Clinical test:**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use.

The clinical trials for the Wrist Watch Electronic Blood Pressure Monitor were performed according the standard of ISO 81060-2:2018+AMD1:2020+AMD2:2024, Non-Invasive Sphygmomanometers -Part 2: Clinical Validation of Automated Measurement Type, and relevant volunteers were collected to conduct actual clinical trial of blood pressure measurement.

There were 103 subjects been selected to participate in the trial, and Auscultation was applied as gold standard with the qualified calibrated mercurial sphygmomanometer used as control group for comparison with the subject device.

The results demonstrated that the clinical performance of the proposed device met the requirements of ISO 81060-2:2018+AMD1:2020+AMD2:2024. The mean deviation for systolic blood pressure was 1.3 mmHg with a standard deviation of 6.2 mmHg, and the mean deviation for diastolic blood pressure was -1.5 mmHg with a standard deviation of 4.9 mmHg. These results are well within the standard' s acceptance criteria, which require a mean deviation $\leqslant \pm 5.0$ mmHg and a standard deviation $\leqslant 8.0$ mmHg. Consequently, the subject device is confirmed to have clinical accuracy equivalent to the reference manual auscultation method.

**Non-clinical test:**

The following safety standards are conducted on the subject device:

The proposed devices were tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Wrist Watch Electronic Blood Pressure Monitor – Premarket Notification [510(k)] Submission issued on March 5, 2004

The test results demonstrated that the proposed device complies with the following standards:

ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R) 2012(Cons. Text) [Incl. AMD2:2021] - Medical electrical equipment - Part 1: General

requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-11:2020, 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

IEC 80601-2-30:2018, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non Invasive Sphygmomanometers.

EN 300328:2019 Electromagnetic compatibility and Radio spectrum Matters (ERM);Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques.

EN 301489-1:2019 ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1:Common technical requirements.

EN 301489-17:2020 Electromagnetic compatibility and Radio spectrum Matters (ERM);ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17:Specific conditions or Broadband Data Transmission Systems.

EN 62479:2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHZ to 300 GHZ )

IEC 62304:2015 standard and FDA Guidance for the Content of Pre-MarketSubmission for Software Contained in Medical Devices standard.

Table 1 Performance Comparison

| **Device** | **Proposed Device** | **Predicate Device K231367** | **Result** |
|---|---|---|---|
| Max Cuff pressure | 300 mmHg | 300 mmHg | Same |
| BP Range | 0-299 mmHg | 0-299 mmHg | Same |
| BP Accuracy | ±3 mmHg | ±3 mmHg | Same |
| Irregular heartbeat detection | More than ±25% to the mean interval of pulse intervals | More than ±25% to the mean interval of pulse intervals | Same |
| Inflation Method | Automatic inflation by pump | Automatic inflation by pump | Same |

| | | | |
|---|---|---|---|
| Deflation Method | Automatic rapid deflation | Automatic rapid deflation | Same |
| Memory Size | U16H:4x50 set of data<br>U16W:1x25 set of data<br>U16P:2x25 set of data<br>U16L:3x25 set of data<br>U19M:4x25 set of data<br>U19R:1x50 set of data<br>U19S:2x50 set of data<br>U19T:3x50 set of data | 2x120 set of data | Similar(1) |
| Operation Condition | Temperature: 5°C ~ 40°C<br>Relative Humidity: 15% RH ~ 85% RH (no condensation)<br>Atmospheric Pressure: 80.0 kPa ~ 106.0 kPa | Temperature: 10~40℃<br>Humidity: 15~85%RH<br>Atmospheric pressure: 70 -106kPa | Similar(2) |
| Storage Condition | Temperature: -20°C ~ 55°C<br>Humidity: 10% RH ~ 93% RH (no condensation)<br>Atmospheric Pressure: 70.0 kPa ~ 106.0 kPa | Temperature: -20~60 ℃<br>Humidity: 10 to 95% RH | Similar(3) |
| Power Supply | lithium battery DC 3.85V | 2 AAA alkaline batteries, DC3V | Similar(4) |
| Performance Standard | Comply with IEC 80601-2-30 | Comply with IEC 80601-2-30 | Same |
| Blood pressure classification | Accordance with the AHA hypertension guidelines | / | Slight different(1) |

**Similarities**

(1) Memory Size:Both the subject device and the predicate device have been defiend the memory size, The difference is some modes for the subject device and the predicate device has only one memory size. 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.
(2) Operation Condition:Both the subject device and the predicate device have been defiend the similar operation condition, 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.
(3)Storage Condition:Both the subject device and the predicate device have been defiend the similar storage condition, The subject device comply with the requirement of standard ASTM D4169-23.This difference will not cause any safety or performance issue.
(4)Power Supply:Both the subject device and the predicate device are powered by 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.

**Difference**
Blood pressure classification of subject device is determined accordance with the AHA hypertension guidelines. But the predicate device have no this classification.

Table 2 Performance testing

| **Item** | **Proposed device** | **Result** |
|---|---|---|
| IEC 60601-1:2005/AMD2: 2020 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| IEC 60601-1-2:2014 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| IEC 60601-1-11:2015/ AMD1:2020 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| IEC 80601-2-30:2019 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| IEC 62368-1:2024 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| FCC CFR Title 47 Part 15 Subpart C § 15.247 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| ANSI/USEMCSC C63.27 2021 AAMI TIR69:2017(R2020) | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| ISO81060-2:2018+AMD1:2020+AMD2:2024 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| EN 300328:2019 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| EN 301489-17:2020 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| EN 62479:2010 | Wrist Watch Electronic Blood Pressure Monitor | Pass |

| | | |
|---|---|---|
| IEC 60601-1-11:2015 | Wrist Watch Electronic Blood Pressure Monitor | Pass |
| IEC 62133-2:2017<br>IEC 62133-2:2017/AMD1:<br>2021 | Wrist Watch Electronic Blood Pressure Monitor | Pass |

Table 3 Biocompatibility testing

| **Item** | **Proposed device** | **Result** |
|---|---|---|
| Cytotoxicity | Under the conditions of the study, the device is noncytotoxic. | Pass |
| Irritation | Under the conditions of the study, the device is nonirritating. | Pass |
| Sensitization | Under the conditions of the study, the device is nonsensitizing | Pass |

## 8. Substantially Equivalent Determination

Verification and validation testing was conducted on the Wrist Watch Electronic Blood Pressure Monitor. This premarket notification submission demonstrates that Wrist Watch Electronic Blood Pressure Monitor is substantially equivalent to the predicate devices.