February 11, 2025

Guangdong Xinyu Electronic and Technology Co., Ltd.
Rita Long
Manager
Number 42, CuiCheng Road, Cuiheng New District
Zhongshan, Guangdong 528400
China

Re: K241634
Trade/Device Name: Wrist Blood Pressure Monitor (XY-W01A, XY-W01B)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 14, 2025
Received: January 14, 2025

Dear Rita Long:

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,

Robert T. Kazmierski -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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K241634

Device Name
Wrist Blood Pressure Monitor (XY-W01A, XY-W01B)

Indications for Use *(Describe)*

The Wrist 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 at medical facilities or at home. The intended wrist circumference is 13.5-21.5 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.**

**510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

**1. Summary Prepared Date**

20 May 2024

**2. Submitter's Information**

**Sponsor**

- Company Name: Guangdong Xinyu Electronic and Technology Co., Ltd.
- Address: Number 42, CuiCheng Road, Cuiheng New District Zhongshan Guangdong 528400 China
- Phone: 86-760-88818598
- Contact Person (including title): Ms. Rita Long (Regulatory Manager)
- E-mail: zcy_cg@163.com

**Application Correspondent:**

- Company Name: Guangdong Xinyu Electronic and Technology Co., Ltd.
- Address: Number 42, CuiCheng Road, Cuiheng New District Zhongshan Guangdong 528400 China
- Phone: 86-760-88818598
- Contact Person (including title): Ms. Rita Long (Regulatory Manager)
- E-mail: zcy_cg@163.com

**3. Subject Device Information**

- Type of 510(k) submission: Traditional
- Common Name: Noninvasive blood pressure measurement system
- Trade Name: Wrist Blood Pressure Monitor
- Model: XY-W01A, XY-W01B
- Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
- Review Panel: Cardiovascular
- Product Code: DXN
- Regulation Number: 870.1130
- Regulation Class: II

**4. Predicate Device Information**

- 510(k) number: K231310
- Sponsor: Shenzhen Jumper Medical Equipment Co., Ltd.
- Trade Name: Electronic Blood Pressure Monitor
- Classification Name: System, Measurement, Blood-Pressure, Non-Invasive

- Model: HWA11, HWA10
- Review Panel: Cardiovascular
- Product Code: DXN
- Regulation Number: 21 CFR 870.1130
- Regulation Class: II

## 5. Device Description

The Wrist Blood Pressure Monitor, including XY-W01A and XY-W01B, can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person with wrist circumference of 135-215mm through oscillometric method.
The initial inflation pressure of the cuff is zero pressure. When start the device, the cuff will be inflated and deflated.
The Wrist Blood Pressure Monitor is composed of monitor unit and wrist cuff. Of which the monitor unit contains main control circuit board, air pump, deflation valve, LCD and shell. The two models XY-W01A and XY-W01B have the same intended use, working principle, measuring range, accuracy, cuff, and conformance standard, except for product appearance. The devices are powered by 2 AAA batteries.
The Wrist Blood Pressure Monitor has a memory function that automatically stores 90 sets data of the latest measurements.

## 6. Indications for Use

The Wrist 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 at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm.

## 7. Comparison to Predicate Device

Compare to the predicate devices, the subject device has same intended use, similar product design, same performance, same safety as the predicate device, the summarized comparison information is listed in the following table:

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Manufacturer | Guangdong Xinyu Electronic and Technology Co., Ltd. | Shenzhen Jumper Medical Equipment Co., Ltd. | - |
| 510 (k) Number | - | K231310 | |
| Product name | Wrist Blood Pressure Monitor | Electronic Blood Pressure Monitor | - |
| Models | XY-W01A, XY-W01B | HWA11, HWA10 | - |
| Product Code | DXN | DXN | Same |
| Regulation No. | 21 CFR 870.1130 | 21 CFR 870.1130 | Same |
| Class | II | II | Same |
| Indication for use | The wrist 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 at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm. | The 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 at medical facilities or at home. The intended wrist circumference is 13.5-21.5 cm. | Same |
| Environment of use | Medical Facilities /Home Use | Medical Facilities /Home Use | Same |
| Patient population | Adult | Adult | Same |
| Over-The-Counter (OTC) | Yes | Yes | Same |
| Measurement method | Cuff oscillometric method | Cuff oscillometric method | Same |
| Wrist cuff circumference | 13.5-21.5 cm | 13.5-21.5 cm | Same |
| Measurement range | Pressure: 0mmHg ～295mmHg(0kPa ～39.33kPa)<br>Pulse rate: 40 to 180 beats/min | Pressure:0 to 295 mmHg<br>Pulse rate: 40 to 199 beats/min | Different Note 1 |
| Pressure sensor | Piezo resistance sensor | Piezo resistance sensor | Same |
| Accuracy of pressure | Blood Pressure: ±3mmHg | Blood Pressure: ±3mmHg | Same |
| Accuracy of pulse rate | Pulse Rate: ±5% of reading | Pulse Rate: ±5% of reading | Same |
| Inflation method | Automatic inflation with electric pump | Automatic inflation with electric pump | Same |
| Deflation method | Automatic rapid deflation valve | Automatic rapid deflation valve | Same |
| Display | LCD | LCD | Same |
| Power source | 2*AAA batteries | 2*AAA batteries | Same |
| Operation condition | +10° C~ +40° C<br>15% ~ 85% RH<br>860hPa~1060hPa | 5 to 40°C<br>15 to 85% RH<br>700 to 1060hPa | Different Note 2 |
| Storage/ Transportation | -20 ~ +55℃ | -20 to 55°C<br>10 to 93%RH | Different Note 2 |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| condition | 10% ~ 93% RH<br>500hPa~1060hPa | 700 to 1060hPa | |
| Dimensions | 73(W) x 65(H) x 88(D) mm | 61 (W) × 24.1(D) × 87 (H)mm | Different<br>Note 3 |
| Weight | Approx. 150g (without battery) | Approx. 111±5g (without batteries) | Different<br>Note 3 |

**Note 1**

The pulse rate is narrower than the predicate device, but it contains the pulse range of most of people and meets the requirements of IEC 80601-2-30. Therefore, the difference will not affect the safety and effectiveness of the subject device.

**Note 2**

All the differences in operation condition and storage/transportation condition don't affect the safety and effectiveness which is concluded after all the required testing, thus, this difference does not raise different questions of safety and effectiveness.

**Note 3**

Minor differences in the dimensions and weight do not impact the safety or performance of blood pressure or pulse rate measurements. Thus, the subject device is substantially equivalent to the predicate device

## 8. Performance Data

**Non-clinical data**

The Wrist Blood Pressure Monitor comply with:

1. IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-11:2015 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
3. 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
4. IEC 60601-1-2:2014+A1:2020 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests
5. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
6. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002".

FDA guidance: Content of Premarket Submissions for Device Software Functions, JULY 20, 2023

**Clinical test**

The clinical test was conducted to verify that the proposed device met the requirements of the ISO 81060-2 : 2018 . The study population consisted of 120 subjects (53 female and 67 male) with an age range of 12 to 85 years. For systolic and diastolic pressures , the mean error shall be + 5mmHg or less , with a standard deviation of 8mmHg or less, all data is not over the limits. No adverse effect and/or complication is found in this study.

## 9. Conclusion

Based on the nonclinical and clinical tests, the subject device Wrist Blood Pressure Monitor is as safe and

as effective as the predicated device(K231310).