



June 18, 2026

Shenzhen Ziqing Medical Equipment Co., Ltd.  
% Boyle Wang  
General manager  
Shanghai Truthful Information Technology Co., Ltd.  
Room 1801, No. 161 East Lu Jiazui Rd, Pudong  
Shanghai, 200120  
China

Re: K253126

Trade/Device Name: Wrist Blood Pressure Monitor (XW-05)  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: May 22, 2026  
Received: May 22, 2026

Dear Boyle 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jackson Hair -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

## 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.

K253126

?

Please provide the device trade name(s).

?

Wrist Blood Pressure Monitor (XW-05)

Please provide your Indications for Use below.

?

This wrist blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The blood pressure monitor uses the oscillometric measurement method to inflate the cuff and pressurize it, detect the blood flow in the wrist arteries, and then convert your blood pressure into a digital reading through this device. The device is simple and convenient to use, and the patient can complete the measurement by themselves. This device is suitable for non-invasive monitoring of blood pressure and pulse rate in adults (18 years and above), and is limited to auxiliary measurements in home and medical environments, and cannot be used as the sole basis for clinical diagnosis.

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

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

?

# 510(k) Summary

## K253126

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

### **1.0 Submitter's Information**

Name: Shenzhen Ziqing Medical Equipment Co., Ltd.  
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Community, Shijing Street, Pingshan District, Shenzhen, China  
Tel: +86-13612876322  
Contact: Chen Yongsheng

### **Designated Submission Correspondent**

Contact: Mr. Boyle Wang  
Name: Shanghai Truthful Information Technology Co., Ltd.  
Address: Room 1801, No. 161 East LuJiazui Rd., Pudong, Shanghai,  
200120 China  
Tel: +86-21-50313932  
Email: [Info@truthful.com.cn](mailto:Info@truthful.com.cn)

Date of Preparation: July 16, 2026

### **2.0 Device Information**

Trade name: Wrist Blood Pressure Monitor (XW-05)  
Common name: Noninvasive Blood Pressure Measurement System  
Classification name: System, Measurement, Blood-pressure, Non-invasive  
Model(s): XW-05  
Production code: DXN  
Regulation number: 21 CFR 870.1130  
Classification: Class II  
Panel: Cardiovascular

### **3.0 Predicate Device Information**

Manufacturer: Shenzhen Jumper Medical Equipment Co., Ltd.  
Trade/Device name: Electronic Blood Pressure Monitor

510(k) number: K231310

#### **4.0 Indication for Use Statement**

This wrist blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The blood pressure monitor uses the oscillometric measurement method to inflate the cuff and pressurize it, detect the blood flow in the wrist arteries, and then convert your blood pressure into a digital reading through this device. The device is simple and convenient to use, and the patient can complete the measurement by themselves. This device is suitable for non-invasive monitoring of blood pressure and pulse rate in adults (18 years and above), and is limited to auxiliary measurements in home and medical environments, and cannot be used as the sole basis for clinical diagnosis.

#### **5.0 Device Description**

The subject device, Wrist Blood Pressure Monitor, is an automatic non-invasive blood pressure monitor. It uses an inflatable cuff which is wrapped around the patient's wrist to measure the systolic and diastolic blood pressure as well as the pulse rate of adults for home use.

The unit uses the oscillometric method of blood pressure measurement. It means the unit detects the blood flow in the wrist arteries, and then converts the user's blood pressure into a digital reading. The device is simple and convenient to use because a stethoscope is not needed while using an oscillometric monitor.

The unit stores the blood pressure and pulse rate in the memory after completing a measurement each time. 2x90 sets of measurement values can be stored automatically. The earliest record will be deleted automatically to save the latest measurement value when more than 2x90 sets are stored. The unit also automatically calculates an average reading based on the values of the latest three measurements.

This blood pressure monitor has the function of blood pressure classification according to WHO recommendation, which helps users judge whether their blood pressure is normal or not.

This blood pressure monitor has voice broadcast function. It supports intuitive operations through touch controls, LED display, and voice broadcast, with customizable settings (units, voice mode).

There is a maximum pressure safety setting at 290 mmHg. The device monitors pressure levels during inflation (up to 290 mmHg) and triggers deflation upon

reaching optimal measurement pressure.

The device features battery status monitoring, low-power alert and automatic shutdown after 60 seconds of inactivity.

The device includes model XW-05. It is composed of a main unit, a cuff, and a lithium battery.

## **6.0 Non-Clinical Test Conclusion**

Non-clinical tests were conducted to verify that the subject device met all design specifications for substantial equivalence (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010+A1:2013+A2:2020, Medical electrical equipment Part 1-6 General requirements for safety-Collateral Standard:Usability
- IEC 60601-1-11:2015,AMD 1:2020, 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 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- 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
- FDA guidance: Content of Premarket Submissions for Device Software Functions, dated July 20, 2023

## **7.0 Clinical Test Conclusion**

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

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

There were 88 subjects selected to participate in the trial, and auscultation was applied as a gold standard with the calibrated mercury sphygmomanometer used as a control group for comparison with the subject device.

The results show that the accuracy of the subject device meets the requirements of ISO 81060-2:2018 within  $\pm 3$  mmHg. No adverse effects and/or complications were found in this study. And the subject device complies with the standard requirements

and the accuracy claimed by the manufacturer.

## **8.0 Technological Characteristic Comparison Table**

**Table1-General Comparison**

<b>Item</b>	<b>Subject device K253126</b>	<b>Predicate Device K231310</b>	<b>Remark</b>
Manufacturer	Shenzhen Ziqing Medical Equipment Co., Ltd.	Shenzhen Jumper Medical Equipment Co., Ltd.	/
Product Name	Wrist Blood Pressure Monitor XW-05	Electronic Blood Pressure Monitor (HWA11, HWA10)	/
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Intended Use/Indication for Use	This wrist blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The blood pressure monitor uses the oscillometric measurement method to inflate the cuff and pressurize it, detect the blood flow in the wrist arteries, and then convert your blood pressure into a digital reading through this device. The device is simple and convenient to use, and the patient can complete the measurement by themselves. This device is suitable for non-invasive monitoring of blood pressure and pulse rate in adults (18 years and above), and is limited to auxiliary measurements in home and medical environments, and cannot be used as the sole basis for clinical diagnosis.	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.	Different Note1
Application Site	Wrist	Wrist	Same
Wrist Circumference	About 13.5 cm - 19.5 cm	13.5 - 21.5 cm	Different Note 2
Patients Contacting Materials	All patient contact parts meet the requirements of ISO 10993	All patient contact parts meet the requirements of ISO 10993	Same
Patient Population	Adults (18 years and above)	Adults	Same
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	Same
Display	LED screen display	LCD digital display	Different Note 3
Design Method	Oscillometric Method	Oscillometric Method	Same

**Table 2 Performance Comparison**

<b>Item</b>	<b>Subject device K253126</b>	<b>Predicate Device K231310</b>	<b>Remark</b>
Max Cuff	290 mmHg	295 mmHg	Different

pressure			Note 4
BP Range	(0 - 38.66 kPa) 0 - 290 mmHg	0 - 295 mmHg	
BP Accuracy	$\pm 3$ mmHg ( $\pm 0.4$ kPa)	$\pm 3$ mmHg	Same
PR Range	40-180 beats/min	40-199 beats/minute	Different Note 4
Pulse Accuracy	$\pm 5$ %	Within $\pm 5$ % of reading	Same
Inflation Method	Automatic inflation	Automatic inflation with electric pump	Same
Deflation Method	Automatic deflation	Automatic rapid deflation valve	Same
Memory Size	2x90	199 groups	Different Note 5
Operating Conditions	Temperature: 5 °C - 40 °C Relative Humidity: 15 % - 85 % Atmospheric pressure:(80 -105) kPa	Temperature: 5 °C - 40 °C(41 to 104 °F); Relative Humidity: 15 to 85 %RH (non-condensing); Atmospheric:700 hPa - 1060 hPa	Different Note 6
Storage Conditions	Temperature: -20°C - 55°C Relative Humidity: 10% - 93 % RH	Temperature:-20 to 55 °C (-4 to 131 ° F); Relative humidity:10 to 93 %RH (non-condensing); Atmospheric:700 hPa - 1060 hPa	
Power Supply	Built-in Battery: 3.7V/300 mAh	Two AAA batteries	Different Note 7
Performance Standard	Complies with IEC 80601-2-30	Complies with IEC 80601-2-30	Same

Justification for difference:

Note 1:Although there are some differences between the Intended Use / Indication for Use of the subject device and predicate device, it is only expressed differently, and the general meaning is the same, and they are both used for measuring blood pressure and pulse rate. Thus, the difference here does not raise any issues concerning safety and effectiveness.

Note 2:The difference of Cuff Circumference between the subject device and the predicate device is that the subject device has a cuff circumference range of 13.5 cm~19.5 cm , while the predicate device ranges from 13.5-21.5 cm. The cuff circumference of the subject device falls within the range of the predicate device. This difference has been verified in clinical trials conducted on the subject device in accordance with ISO 81060-2, and the trial results comply with ISO 81060-2. Therefore, this difference between the subject device and predicate device HWA11, HWA10 (K231310) will not affect safety and effectiveness.

Note 3:The display of the subject device is different from that of the predicate device HWA11, HWA10, and this difference will not affect the safety and effectiveness.

Note 4: The pressure range and pulse range are narrower than the predicate device. Both contain the blood pressure and pulse range of most people, and the measurement range of the subject device is fully verified according to IEC 80601-2-30. Therefore, the differences do not bring additional risks.

Note 5: The Memory Size of the subject device is different from that of the predicate device HWA11, HWA10, and this difference will not affect the safety and effectiveness.

Note 6: All the differences in operation conditions and storage/transportation conditions do not affect the safety and effectiveness which are concluded after all the required testing, thus, these differences do not raise different questions of safety and effectiveness.

Note 7: The difference in power source will not affect the safety and effectiveness of the subject device. IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2 can demonstrate that the subject device can maintain the safety and performance. Thus, this difference does not raise different questions of safety and effectiveness.

**Table 3 Safety Comparison**

<b>Item</b>	<b>Subject device K253126</b>	<b>Predicate Device K231310</b>	<b>Remark</b>
Electrical Safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Same
Home Use	Complies with IEC 60601-1-11	Complies with IEC 60601-1-11	Same
EMC	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Same
Biocompatibility	Complies with ISO 10993-1, FDA Guidance	Complies with ISO 10993-1, FDA Guidance	Same

## **9.0 Conclusion**

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device and raises no new questions of safety or effectiveness. The differences between the two devices are insignificant in terms of safety and effectiveness.