June 3, 2026

Shenzhen Ziqing Medical Equipment Co., Ltd.
% Boyle Wang
General manager
Shanghai Truthful Information Technology Co., Ltd.
Rm. 1801, # 161 E. Lu Jiazui Rd., Pudong
Shanghai, 200120
China

Re: K253124
Trade/Device Name: Upper arm electronic blood pressure monitor (XB-01)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: May 19, 2026
Received: May 19, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JENNIFER W. SHIH -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.	K253124

Please provide the device trade name(s).

Upper arm electronic blood pressure monitor (XB-01)

Please provide your Indications for Use below.

This upper arm electronic blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The electronic blood pressure monitor adopts the oscillographic measurement method, inflates the cuff, detects the blood flow of the brachial artery in the upper arm, and then converts your blood pressure into a digital reading through the device. The device is simple and convenient to use, and patients 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

K253124

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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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date of Preparation: May.19,2026

2.0 Device Information

Trade name: Upper arm electronic blood pressure monitor
Common name: Noninvasive Blood Pressure Measurement System
Classification name: Noninvasive Blood Pressure Measurement System
Model(s): XB-01
Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Guangdong Transtek Medical Electronics Co., Ltd.
Trade/Device name: Blood Pressure Monitor (BBZ32-AA01)

510(k) number: K240832

4.0 Indication for Use Statement

This upper arm electronic blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The electronic blood pressure monitor adopts the oscillographic measurement method, inflates the cuff, detects the blood flow of the brachial artery in the upper arm, and then converts your blood pressure into a digital reading through the device. The device is simple and convenient to use, and patients 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

This upper arm electronic blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The electronic blood pressure monitor adopts the oscillographic measurement method, inflates the cuff, detects the blood flow of the brachial artery in the upper arm, and then converts your blood pressure into a digital reading through the device. The device is simple and convenient to use, and patients 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 unit uses the oscillometric method of blood pressure measurement. It means the unit detects the movement of your blood through your brachial artery, and converts your blood pressure into a digital reading. The unit is simple to use because a stethoscope is not needed while using an oscillometric monitor.

Stores measurement records (including date, time, SYS, DIA, and PUL) for each user. 2x99 sets of measurement values can be stored automatically. The earliest record will be deleted automatically to save the latest measurement value when more than 2x99 sets.Enables viewing of memory records and average values of the last 3 measurements (when records $\geqslant$3) via the "Memory" button.Supports deletion of all memory records for a selected user.

This blood pressure monitor has the function of blood pressure classification, which is convenient for you to judge whether your blood pressure is normal or not according to the World Health Organization/ International Society for hypertension(WHO/ISH) guidelines on the treatment of hypertension dated in 1999.

This blood pressure monitor has voice broadcast function (optional). During measurement and recall the memory, there will be voice operation tips.

There is a maximum pressure safety setting at 290 mmHg,monitors pressure levels during inflation (up to 290 mmHg) and triggers deflation upon reaching optimal measurement pressure.

Automatic shutdown after 60 seconds of inactivity.

The device includes model XB-01. 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 proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2020, 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.
- 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 Arm Blood Pressure Monitor were performed according 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 trial of blood pressure measurement.
There were 87 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 shown that the accuracy of proposed device meet the requirements of ISO 81060-2:2018 within the ±3 mmHg. No adverse effect and/or complication is found in this study. And the subject device comply with the standard requirements and the accuracy the manufacture declared.

8.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device	Predicate Device K240832	Remark
Manufacturer	Shenzhen Ziqing Medical Equipment Co., Ltd..	Guangdong Transtek Medical Electronics Co., Ltd.	/
Product Name	Upper arm electronic blood pressure monitor XB-01	Blood Pressure Monitor (BBZ32-AA01)	/
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 upper arm electronic blood pressure monitor is used to measure the systolic blood pressure, diastolic blood pressure and pulse rate of adults. The electronic blood pressure monitor adopts the oscillographic measurement method, inflates the cuff, detects the blood flow of the brachial artery in the upper arm, and then converts your blood pressure into a digital reading through the device. The device is simple and convenient to use, and patients 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.	This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm(about 8¾"-16½") or 22cm to 42cm(about 8¾"-16½"). It is intended for adult indoor use only.	Same
Application Site	Upper Arm	Upper Arm	Same
Arm Circumference	About 27.5-36.5cm	22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″)	Different (1)
Patients Contacting Materials	Patient contact materials of the cuff:non-woven fabrics & PVC According to ISO-10993	Allpatient contact parts meet the requirements of ISO-10993	Same
Patient Population	Adults (18 years and above)	Adult	Same
Measurements Item	SYS,DYS,Pulse	Measuring systolic and diastolic blood pressure and pulse rate of intended population, including irregular pulse rhythm detection.	Different (2)
Display	LED liquid crystal display	LCD	Same
Design Method	Oscillometric Method	Oscillometric Method	Same

Table 2 Performance Comparison

Item	Subject Device	Predicate Device K200939	Remark
Max Cuff pressure	290 mmHg	299mmHg	Different (3)
BP Range	(0-38.7kPa)0-290mmHg	0 ~ 299 mmHg;	
BP Accuracy	±3 mmHg(+0.4kPa)	±3mmHg (0.4kPa)	Same
PR Range	40-180 beats/min	40-199 beat/minute, ±5%	Different (4)
Pulse Accuracy	±5% of reading value	±5%	Same
Inflation Method	Automatic inflation	Automatic inflation	Same
Deflation Method	Automatic deflation	Automatic deflation	same
Memory Size	2x99	2x99	Same
Operation Condition	Temperature from + 5℃ ~ + 40℃, humidity from 15% ~ 85% RH. Atmospheric pressure:(80~105)kPa	Temperature: 5℃~40℃; Relative Humidity: 15%~90% RH; Atmospheric:700hPa~1060hPa	Different (5)
Storage Condition	Temperature: (-20~ + 55) ℃; humidity: ≤93% RH	Temperature: -20℃~60℃; Relative humidity≤93%RH, non-condensing; Atmospheric:500hPa~1060hPa	
Power Supply	Built-in lithium battery DC3.7V 750mah	4*1.5V AAA batteries	Different (6)
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same

Analysis:

1) The Measurements range of the subject device is within that of the predicate device. The difference between the predicate device and subject device will not affect the safety and effectiveness of the subject.

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

2)The Measurements Item of the subject device is within that of the predicate device. The difference between the predicate device and subject device will not affect the safety and effectiveness of the subject.

3) The Blood Pressure Range of the subject device has minor difference with the blood pressure range of predicate devices, the measuring rang of the subject device was validated according to ISO 80601-2-30, the difference does not raise different questions of safety and effectiveness.

4) The pulse rate of the subject device is within that of the predicate device. The difference between the predicate device and subject device will not affect the safety and effectiveness of the subject.

5)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.

6)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

Item	Proposed Device	Predicate Device K200939	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
Home Use	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply 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 predicated device and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.