December 19, 2025

Ningbo Ranor Medical Science & Technology 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: K251143
Trade/Device Name: Arm Blood Pressure Monitor (Model MJ1L, MJ2L, RN3L, RN4L, RN5L)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 1, 2025
Received: December 1, 2025

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 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,
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Office of Cardiovascular Devices
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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)*
K251143

Device Name
Arm Blood Pressure Monitor(Model MJ1L, MJ2L, RN3L, RN4L,RN5L)

Indications for Use *(Describe)*
The Arm Blood Pressure Monitor is used for measuring blood pressure and pulse rate. The monitor can be used in hospitals, families, schools and medical centers. It is suitable for adult, not for neonate or pregnancy.

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.

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510(k) Summary

K251143

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: Ningbo Ranor Medical Science & Technology 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: Dec.19,2025

2.0 Device Information

Trade name: Arm Blood Pressure Monitor
Common name: Noninvasive Blood Pressure Measurement System
Classification name: Noninvasive Blood Pressure Measurement System
Model(s): MJ1L, MJ2L, RN3L, RN4L,RN5L
Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Trade/Device name: Electronic Blood Pressure Monitor, YE620B, YE620D, YE660E, YE660F and YE680B

510(k) number: K200939

4.0 Indication for Use Statement

The Arm Blood Pressure Monitor is used for measuring blood pressure and pulse rate. The monitor can be used in hospitals, families, schools and medical centers. It is suitable for adult, not for neonate or pregnancy.

5.0 Device Description

The subject device, Arm Blood Pressure Monitor, is an automatic non-invasive blood pressure monitor. It uses an inflatable cuff which is wrapped around the patient's upper arm to measure the systolic and diastolic blood pressure as well as the pulse rate of adult, not for neonate or pregnancy.

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.

The unit stores the blood pressure and pulse rate in the memory after completing a measurement each time. 2x60 sets of measurement values can be stored automatically. The unit also calculates an average reading based on the values of the latest 3 times measurement.

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

No operation for 1 minute the device will shut down automatically.

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.
- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- FDA guidance: Content of Premarket Submissions for Device Software Functions, dated July 20, 2023

7.0 Clinical Test Conclusion

1) Blood Pressure Clinical Validation

The clinical testing was conducted to demonstrate that the subject device meets the performance specifications for its intended use. The clinical trials for the Arm Blood Pressure Monitor were performed in accordance with ISO 81060-2:2018+A1:2020, Non-Invasive Sphygmomanometers – Part 2: Clinical Validation of Automated Measurement Type.

A total of 150 adult subjects were enrolled to evaluate blood pressure measurement accuracy. Auscultatory measurements obtained using a calibrated mercury sphygmomanometer served as the reference standard. Subjects with conditions that could interfere with accurate non-invasive blood pressure measurement or with study participation, such as significant arrhythmias, implanted cardiac rhythm devices, or inability to undergo standardized cuff-based measurement, were excluded in accordance with the clinical protocol and the applicable standard.

The results demonstrated that the accuracy of the subject device met the requirements of ISO 81060-2:2018 within ±5 mmHg. No adverse effects or complications were observed during the study.

2) Pulse Rate Clinical Validation

A clinical validation study was conducted to evaluate the pulse rate (PR) measurement accuracy of the subject device by comparison with manually annotated electrocardiogram (ECG) recordings. A total of 85 adult subjects (age range: 24–73 years) were enrolled and included in the analysis. The PR validation was conducted within the validated pulse-rate range of 50–100 bpm.

Subjects were excluded if they had implanted pacemakers or implantable cardioverter-defibrillators, known severe arrhythmias, or any medical condition or circumstance that, in the judgment of the investigator, could interfere with reliable pulse-rate measurement or ECG interpretation.

For each subject, three consecutive PR measurements were obtained under resting

conditions, and the mean value was paired with a manually annotated ECG reference. Across all 85 subjects, the mean PR error was 0.43 bpm with a standard deviation of 0.91 bpm, and the overall RMSE was approximately 1.0 bpm. Bland–Altman analysis demonstrated good agreement between the device PR outputs and the ECG reference values, with measurement differences consistently distributed within clinically acceptable limits across the validated range.

These findings confirm that the subject device meets the safety and performance requirements for both blood pressure and pulse-rate measurement within the validated conditions of use.

8.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K251143	Predicate Device K200939	Remark
Manufacturer	Ningbo Ranor Medical Science & Technology Co., Ltd.	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.	/
Product Name	Arm Blood Pressure Monitor MJ1L, MJ2L, RN3L, RN4L,RN5L	Electronic Blood Pressure Monitor YE620D	/
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	The Arm blood pressure monitor is for home use for measuring blood pressure and pulse rate. It is suitable for adult, not for neonate or pregnancy.	Electronic blood pressure monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia).	Same
Application Site	Upper Arm	Upper Arm	Same
Arm Circumference	220mm ～ 420mm	Type A (22cm~32cm, 22-45cm optional) Type B (22cm~ 32cm, 22-45cm optional)	Same
Patients Contacting Materials	Patient contact materials of the cuff: Brushed Fabric According to ISO-10993	Patient contact materials of the cuff have been tested in accordance with ISO10993 and FDA guidance.	Same
Patient Population	Adult	Adult	Same
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	Same
Display	LCD Digital Display	LCD	Same
Design Method	Oscillometric Method	Oscillometric Method	Same

Table 2 Performance Comparison

Item	Subject Device K251143	Predicate Device K200939	Remark
Max Cuff pressure	295 mmHg	300mmHg	Different (1)
BP Range	0-294 mmHg	0 ~ 300 mmHg	
BP Accuracy	±3 mmHg	±3 mmHg	Same
PR Range	50-100 beats/min	40 ~ 200 beats/min	Different (1)
Pulse Accuracy	±5% of reading value	±5% of reading value	Same
Inflation Method	Automatic inflation by air pump	Automatic Internal Pump	Same
Deflation Method	By solenoid valve	Semiconductor Pressure Sensor	Different (2)
Memory Size	2x60 set of data	Up to 2x60sets of data	Same
Operation Condition	10~40℃ Humidity: 15~85%RHz Atmospheric pressure: 70 - 106kPa	5～40℃, Humidity:15～90％RH Atmospheric: 106kPa~80kPa	Different (3)
Storage Condition	-20~55 ℃ 15~90%RH (noncondensing)	-20℃~ 55℃, 15~90%RH (noncondensing)	
Power Supply	Li-ion Rechargeable battery, 3.7V 800mA	4 AA batteries or 6V/600mA AC adapter	Different (4)
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same

Analysis:

1) The Blood Pressure Range of the subject device has minor difference with the blood pressure range of predicate devices, the measuring range of the subject device was validated according to ISO 80601-2-30, the difference does not raise different questions of safety and effectiveness. The pulse rate measurement range of the subject device is within that of the predicate device. In addition, the PR measurement performance of the subject device was clinically validated using manually annotated ECG as the reference method. Therefore, the differences between the subject device and the predicate device do not affect the safety or effectiveness of the subject device.

2) The subject device utilizes a solenoid valve for cuff deflation, whereas the predicate device uses a semiconductor pressure sensor to control the deflation process. This difference represents an implementation difference in the deflation control mechanism and does not change the fundamental oscillometric blood pressure measurement principle.
The subject device was verified through performance testing in accordance with IEC 80601-2-30 and clinical validation conducted per ISO 81060-2. The test results demonstrated that the subject device meets the specified blood pressure accuracy

and performance requirements. Therefore, the difference in deflation methods does not affect the safety or effectiveness of the subject device.

3) All the differences in operation 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.

4)The difference in power source will not affect the safety and effectiveness of the subject device. IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 62133-2 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	**Subject Device K251143**	**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.