January 9, 2026

Ningbo Ranor Medical 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: K253142
Trade/Device Name: Arm Blood Pressure Monitor
(MJ1D,MJ1DS,MJ3D,MJ5D,MJ6D,MJ8D,RN3D,MJ4D,RN1D,RN2D)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: September 25, 2025
Received: September 25, 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,

for HETAL B. ODOBASIC -S

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
OHT2: 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.	K253142

Please provide the device trade name(s).

Arm Blood Pressure Monitor (MJ1D,MJ1DS,MJ3D,MJ5D,MJ6D,MJ8D,RN3D,MJ4D,RN1D,RN2D)

Please provide your Indications for Use below.

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.

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

K253142

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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Tel: 86-574-89258788
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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.10,2025

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): MJ1D、MJ1DS、MJ3D、MJ5D、MJ6D、MJ8D、RN3D、MJ4D、RN1D、RN2D
Production code: DXN
Regulation number: 21 CFR 870.1130
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Manufacturer: Ningbo Ranor Medical Science & Technology Co., Ltd.
Trade/Device name: Arm Blood Pressure Monitor, RN-032A,RN-032C

510(k) number: K193456

4.0 Indication for Use Statement

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.

5.0 Device Description

The subject device, Arm Blood Pressure Monitor, is an automatic non-invasive blood pressure monitor which can be driven by dry batteries. 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 proposed device consists of the main body and the arm belt, suitable for home use for measuring blood pressure and pulse rate.

This blood pressure monitor has the memory function of 60 groups of measuring data of two people, which can save the data separately. It can display the average reading of the latest 3 groups of measurement results.

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.

The subject device includes model MJ1DS/MJ1D/MJ3D/MJ5D/MJ6D/MJ8D/RN3D/ MJ4D/RN1D/RN2D. These models are identical in terms of software design, cuff type, measurement range and function, principle, the core algorithm of the software, the key components. The schematic circuit diagrams are identical in all models. The PCB layout are identical in all models because of different appearance such as structure, buttons layout.

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.

Biocompatibility Testing

The proposed Arm Blood Pressure Monitor does not introduce any new direct or indirect patient contacting materials including new color additive, as compared to the previous clearance predicate Arm Blood Pressure Monitor. So the biocompatibility testing reports provided and reviewed in K193456 remain valid and can support the subject Arm Blood Pressure Monitor.

Software Verification and Validation Testing

The subject devices utilize the same software version, software algorithm, measurement logic and functionality as the cleared predicate devices (RN-032A and RN-032C, K193456). No code changes or new functions were introduced. The software safety classification remains unchanged. The verification and validation testing previously reviewed in K193456 continues to support the subject devices, as the software operates identically to the predicate. Therefore, no additional software verification and validation testing is required to demonstrate substantial equivalence.

7.0 Clinical Test Conclusion

As the subject device utilizes the same monitoring technology as the predicate device, there is no change on the sensors, cuffs, algorithms, measurement accuracy of the subject device, additional testing was not considered necessary to support the substantial equivalence.

8.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K253142	Predicate Device K193456	Remark
Manufacturer	Ningbo Ranor Medical Science & Technology Co., Ltd.	Ningbo Ranor Medical Science & Technology Co., Ltd.	/
Product Name	Arm Blood Pressure Monitor MJ1D、MJ1DS、MJ3D、MJ5D、MJ6D、MJ8D、RN3D、MJ4D、RN1D、RN2D	Arm Blood Pressure Monitor RN-032A,RN-032C	/
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.	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.	Same
Application Site	Upper Arm	Upper Arm	Same
Arm Circumference	22cm ～ 32cm	220mm ～ 320mm	Same
Patients Contacting Materials	Patient contact materials of the cuff: Nylon TPU (Cuff) According to ISO-10993	Patient contact materials of the cuff: Nylon TPU (Cuff) According to ISO-10993	Same
Patient Population	Adult	Adult	Same
Measurements Item	SYS,DYS,Pulse	SYS,DYS,Pulse	Same
Display	Segment LCD Display , Segment LED Display(MJ1DS)	Segment LCD Display	Same
Design Method	Oscillometric Method	Oscillometric Method	Same

Table 2 Performance Comparison

Item	Subject Device K253142	Predicate Device K193456	Remark
Max Cuff pressure	294 mmHg	300mmHg	Different
BP Range	Systolic: 60–249 mmHg Diastolic: 30–170 mmHg	0 ~ 299 mmHg	
BP Accuracy	±3 mmHg	±3 mmHg	Same
PR Range	40-190 beats/min	40 ~ 180 beats/min	Different
Pulse Accuracy	±5% of reading value	±5% of reading value	Same
Inflation Method	Automatic by electronic pump	Automatic by electronic pump	Same
Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	Same

Memory Size	2x60 sets of data	2x60 sets of data	Same
Operation Condition	5-40 ℃ 15%-80% RH 80kPa～106kPa	5～40℃, Humidity: 15%-80% Atmospheric: 80kPa～106kPa	Same
Storage Condition	-20°C～55 °C Humidity: ≤95% (noncondensing) 50kPa～106kPa	-20℃~ 55℃, ≤95% (noncondensing) 50kPa～106kPa	Same
Power Supply	4 AAA dry batteries	4 AAA dry batteries	Same
Performance Standard	Comply with IEC 80601-2-30	Comply with IEC 80601-2-30	Same

Table 3 Safety Comparison

Item	**Subject Device K253142**	**Predicate Device K193456**	**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.