April 24, 2025

Shenzhen AOJ Medical Technology Co., Ltd
% Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K250116
Trade/Device Name: Arm Blood Pressure Monitor (ARM-30H); Arm Blood Pressure Monitor (ARM-30J); Arm Blood Pressure Monitor (ARM-30K); Arm Blood Pressure Monitor (ARM-90B)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 16, 2025
Received: March 21, 2025

Dear Jie Yang:

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250116

Device Name
Arm Blood Pressure Monitor (ARM-30H);Arm Blood Pressure Monitor (ARM-30J);
Arm Blood Pressure Monitor (ARM-30K);Arm Blood Pressure Monitor (ARM-90B)

Indications for Use *(Describe)*
The Arm 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 in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/01/17

1. Submission sponsor

Name: Shenzhen AOJ Medical Technology Co., Ltd.
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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Arm Blood Pressure Monitor
Model	models ARM-30H, ARM-30J, ARM-30K and AOJ-90B
Common Name	Automatic Blood Pressure Monitor
Regulatory Class	Class II
Product Code	DXN
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Shenzhen AOJ Medical Technology Co., Ltd.

Device name: Arm Blood Pressure Monitor, model AOJ-30B

510(K) Number: K222125

5. Device Description

Arm blood pressure monitor, models(models ARM-30H, ARM-30J, ARM-30K and AOJ-90B), are designed as a battery driven automatic no-invasive blood pressure monitor. It 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 at upper arm within its claimed range and accuracy via the oscillometric technique. The result will be displayed in the international unit mmHg or Kpa.

All the models included in this submission follow the similar software, same measurement principle and same specifications. All the models can be used with one cuff size 22~42 cm (8.6~16.5 inches). AOJ-90B has extra 4G network except for other models.

6. Intended use & Indication for use

The Arm 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 in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.

7. Comparison to the Predicate Device

ITEM	**Proposed Device ARM-30H, ARM-30J, ARM-30K and AOJ-90B/K250116**	**Predicate Device AOJ-30B/K222125**	**Comparison Result**
Manufacturer	Shenzhen AOJ Medical Technology Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	Same
Intended Use/Indications for Use	The Arm 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 in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.	The Arm 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 in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.	Same
Contraindications	Not known	Not Known	Same
Application scenario	Medical Facilities and Home Use	Medical Facilities and Home Use	Same
Operational Specifications			
Principle	Oscillometric	Oscillometric	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Patient population	Adult	Adult	Same
Measurement site	Upper arm	Upper arm	Same
Blood pressure measurement range	30-255 mmHg	30 - 255 mmHg	Same

Accuracy	± 3 mmHg	± 3 mmHg	Same
Heart rate measurement range	40-199 bpm	40-199 bpm	Same
Accuracy	± 5%	± 5%	Same
Cuff size	22 - 42 cm	22 - 42 cm	Same
Display	Blood Pressure (Systolic and Diastolic), Pulse rate, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse rate, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Same
Auto shutdown	YES	YES	Same
Operating environment	Temperature: 5°C~40°C Humidity: 15%-90% RH, Atmospheric pressure: 70 kPa -106 kPa	Temperature: 5°C~40°C Humidity: 15%-90% RH, Atmospheric pressure: 70 kPa -106 kPa	Same
Storage environment	Ambient Temperature: -20°C to 55°C Relative Humidity: 10-93% RH, Atmospheric pressure: 70 kPa -106 kPa	Ambient Temperature: -20°C to 55°C Relative Humidity: 10-93% RH, Atmospheric pressure: 70 kPa -106 kPa	Same
Battery type	Lithium-ion battery, d.c.3.7V	6Vdc (4*1.5VAAA batteries)	Similar
Weight	ARM-90B: About 263g ARM-30J: About 281g ARM-30K: About 280g ARM-30H: About 195g	(262 ±5)g without battery	Similar
Dimensions	ARM-90B:130mm×100mm×60mm ARM-30J: 130mm×100mm×60mm ARM-30K: 129mm×112mm×58.5mm ARM-30H: 12 mm×89.8mm×30.8mm	127mm×93mm×73mm	
Patient Contacting	Surface-contacting, Less than 24 h	Surface-contacting, Less than 24 h	Same

Biocompatibility evaluation	Cytotoxicity, skin sensitization and irritation	Cytotoxicity, skin sensitization and irritation	Same
Electrical safety	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10	Equivalent
Data transmission	ARM-90B:4G ARM-30H, ARM-30J, ARM-30K:N/A	Bluetooth	Similar

8. Non-clinical Data

Biocompatibility testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Bench testing

The device has been tested according to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: 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: Medical electrical equipment – Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
- IEC 60601-1-11: 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
- FDA Guidance for Non-Automated Sphygmomanometer.

Wireless testing:

- ANSI C63.27: 2017: American National Stand for Evaluation of Wireless Coexistence.
- AAMI TIR69: 2017 Risk management of radio-frequency wireless coexistence for medical devices and systems.
- Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)

9. Clinical data

Two studies were performed on ARM-30H and ARM-90B separately according to ISO 81060-2 Third edition 2018-11 [Including AMD1:2020] Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)]. The clinical validation data on ARM-90B can cover ARM-30K and ARM-30J. The Same Arm Sequential Method was chosen for both studies.

ARM-90B study included 100 adult subjects (61 females, 39 males) with an age range of 19 to 77 years.

ARM-30H study included 100 adult subjects (54 females, 46 males) with an age range of 18 to 80 years

All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2 Third edition 2018-11 [Including AMD1:2020]. No adverse effect and/or complication is found in this study.

10. Conclusion

It is concluded form the non-clinical and clinical tests that demonstrate that the subject devices are as safe, as effective, and performs as well as the legally marketed predicate device identified above.