April 30, 2025

Shenzhen AOJ Medical Technology Co., LTD
Jack Wang
Deputy Chief
Room 301&4F, Block A, Bldg A,ingfa Intelligent Manafacturing
Park Xiaweiyuan,Gushu Community, Xixiang Str Bao'an District
Shenzhen, Guangdong 518126
China

Re: K244000
Trade/Device Name: Arm Blood Pressure Monitor (Models ARM-30A+, ARM-30G2, ARM-30Q, ARM-30E+, ARM-3010, ARM-3011, ARM-3012, ARM-3013, ARM-3110, ARM-30G+, ARM-30M, ARM-30S, ARM-30T, ARM-HA101, ARM-3040, ARM-30V, AMR-30W, SBM 15, BU 518, ARM-30U, ARM-3030, ARM-30Y, BU 520, ARM-3120, ARM-3020, ARM-3021, ARM-3022 and ARM-3023)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 28, 2025
Received: March 28, 2025

Dear Jack 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,
Diagnostics, and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K244000

Device Name
Arm Blood Pressure Monitor (Models ARM-30A+, ARM-30G2, ARM-30Q, ARM-30E+, ARM-3010, ARM-3011, ARM-3012, ARM-3013, ARM-3110, ARM-30G+, ARM-30M, ARM-30S, ARM-30T, ARM-HA101, ARM-3040, ARM-30V, AMR-30W, SBM 15, BU 518, ARM-30U, ARM-3030, ARM-30Y, BU 520, ARM-3120, ARM-3020, ARM-3021, ARM-3022 and ARM-3023)

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/02/26

1. Submission sponsor

Name: Shenzhen AOJ Medical Technology Co., Ltd.

Address: Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Contact person: Jack Wang

Title: Deputy Chief

TEL: 86 755-27786026

2. Subject Device Information

Trade/Device Name	Arm Blood Pressure Monitor
Model	models ARM-30A+,ARM-30G2,ARM-30Q,ARM-30E+, ARM-3010,ARM-3011,ARM-3012,ARM-3013,ARM-3110, ARM-30G+,ARM-30M,ARM-30S,ARM-30T,ARM-HA101, ARM-3040,ARM-30V,AMR-30W,SBM 15,BU 518,ARM-30U, ARM-3030,ARM-30Y,BU 520,ARM-3120,ARM-3020,ARM-3021, ARM-3022 and ARM-3023
Common Name	Automatic Blood Pressure Monitor
Regulatory Class	Class II
Product Code	DXN
Submission type	Traditional 510(K)

3. Predicate Device

Manufacturer: Shenzhen AOJ Medical Technology Co., Ltd.

Device name: Arm Blood Pressure Monitor, models AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G.

510(K) Number: K222125

4. Device Description

The Arm Blood Pressure Monitor is designed as a battery driven automatic non-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.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The device also has low voltage indication, which will be triggered when the battery is low.

The proposed device is intended to be used in medical facilities or at home. And the effectiveness of this sphygmomanometer has not been established in pregnant (including pre-eclamptic) patients.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

All the models included in this submission follow the the same intended use, same measurement principle, same blood pressure core algorithm and similar product design. The main differences are appearance, Dimensions and some function which will not affect the safety and effectiveness of the device.

5. 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.

6. Comparison to the Predicate Device

ITEM	**Proposed Device** **Arm Blood Pressure Monitor** **ARM-30A+,ARM-30G2,ARM-30Q, ARM-30E+,ARM-3010,ARM-3011, ARM-3012,ARM-3013,ARM-3110, ARM-30G+,ARM-30M,ARM-30S, ARM-30T,ARM-HA101,ARM-3040, ARM-30V,AMR-30W,SBM 15, BU 518,ARM-30U,ARM-3030, ARM-30Y,BU 520,ARM-3120, ARM-3020,ARM-3021,ARM-3022, ARM-3023 / K244000**	**Predicate Device** **Arm Blood Pressure Monitor** **AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G / 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	No known contraindication existing	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
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	**1)** 6Vdc (4*1.5V AAA batteries): ARM-30A+,ARM-30G2, ARM-30Q,ARM-30E+,ARM-3010, ARM-3011,ARM-3012,ARM-3013, ARM-3110,ARM-30G+,ARM-30M, ARM-30S,ARM-30T,ARM-HA101, ARM-3040,ARM-30V,AMR-30W, SBM 15,ARM-30U,ARM-3030, ARM-30Y,ARM-3120,ARM-3020, ARM-3021,ARM-3022,ARM-3023 **2)** 6Vdc (4*1.5V AA batteries): BU 518,BU 520	6Vdc (4*1.5VAAA batteries)	Different[1]
Weight	SBM 15: About 175g ARM-30V / ARM-30W: About 209g ARM-30Q: About 193g ARM-30A+: About 316g ARM-30G2: About 263g ARM-30G+: About 234g ARM-30M: About 280g ARM-HA101: About 290g ARM-3040: About 235g ARM-30Y:About 265g ARM-3030:About 266g BU 518: About 270g BU 520: About 286g ARM-30S / ARM-30T / ARM-30U: About 221g	AOJ-30A /AOJ-30B /AOJ-30G: (262 ±5)g without battery AOJ-30C: (316 ±5)g without battery AOJ-30D: (349 ±5)g without battery AOJ-30E: 220 g without battery AOJ-30F: 220 g without battery	Different[2]

	ARM-30E+ / ARM-3010 / ARM-3011 / ARM-3012 / ARM-3013 / ARM-3110: About 220g ARM-3120/ARM-3020/ ARM-3021/ ARM-3022/ ARM-3023:About 230g		
Dimensions	ARM-30A+ / ARM-3030: 108mm×139mm× 62mm ARM-30G2 / ARM-30G+: 130mm×100mm×60mm ARM-30Q: 100mm×100mm×59mm ARM-30M : 129mm×112mm×58.5mm ARM-HA101 : 130mm×112mm×58.3mm ARM-3040: 136mm×113mm×28mm ARM-30V / ARM-30W: 130mm×100mm×51mm SBM 15: 115.4mm×92mm×44.5mm ARM-30Y:140.8mm×110mm×61mm BU 518 / BU 520: 130mm×111.5mm×56mm ARM-30S / ARM-30T / ARM-30U: 130mm×100mm×49mm ARM-30E+ / ARM-3010 / ARM-3011 / ARM-3012 / ARM-3013 / ARM-3110: 118mm×98mm×62.5mm ARM-3120 /ARM-3020/ ARM-3021/ ARM-3022 / ARM-3023: 118mm×98mm×61mm	AOJ-30A /AOJ-30B /AOJ-30G: 127mm×93mm×73mm AOJ-30C: 108mm×139mm× 62mm AOJ-30D:136mm×113mm×68mm AOJ-30E /AOJ-30F：118mm×98mm×61mm	
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	Different[3]
Data transmission	Not available	Has wireless function with Bluetooth and available for AOJ-30A and AOJ-30B	Different[4]

Justification for the differences:

1) Different kind of power supply

The subject device powered by internal battery (AA or AAA) ,which both belong to alkaline battery.

It will not affect the safety and effective of subject device. The test results have been verified by verification testing.

2) Different Physical Specifications

The subject and the predicate device are of' different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor different ill not raise any safety and effectiveness questions.

3) Different Biocompatibility standard

The subject device has been tested 10993-5,10993-10,10993-23 according to the update of the standard.

4) Different data transmission function

The subject device has no data transmission function with Bluetooth.

7. Non-clinical Data

Biocompatibility testing

The biocompatibility evaluation for the Arm Blood Pressure Monitor were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin 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.

8. Clinical data

According to similar clinical characteristics, 28 submitted models were divided into 7 groups for clinical accuracy research.

The clinical accuracy test report and data analysis followed the requirements of the 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 Same Arm Sequential Method was chosen for all studies.

Group No.	Test model	Number of Subjects (a minimum of 85 subjects)	Male (at least 30 %)	Female (at least 30 %)	Age range (> 12 years old)
1	ARM-3030, ARM-30Y	100	49	51	17 to 78
2	ARM-3120, ARM-3020, ARM-3021, ARM-3022, ARM-3023	100	54	46	15 to 80
3	ARM-30A+, ARM-30G2, ARM-30E+, ARM-30Q, ARM-3010, ARM-3011, ARM-3012, ARM-3013, ARM-3110	100	41	59	19 to 78
4	ARM-30M, ARM-30G+, ARM-HA101, ARM-30S, ARM-30T, ARM-30U	100	54	46	17 to 71
5	ARM-3040	100	53	47	15 to 78
6	BU 520, BU 518	100	49	51	15 to 78
7	SBM 15, ARM-30V, ARM-30W	92	47	45	15 to 70

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.

9. 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.