May 2, 2025

Shenzhen AOJ Medical Technology Co., Ltd.
Jack Wang
Deputy Chief
Room 301&4F, Block A, Building A, Jingfa Intelligent Manufac
cturing Park Xiaweiyuan, Gushu Community, Xixiang Street,
Shenzhen, Guangdong 518126
China

Re: K250161
Trade/Device Name: Wrist Blood Pressure Monitor (Models: AOJ-35A, AOJ-35B, WRS-35B, AOJ-35D, AOJ-35E, AOJ-35F, AOJ-35G, WRS-35G, WRS-35H, WRS-35K, WRS-35N, WRS-35P, WRS-35S)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 3, 2025
Received: April 3, 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)*
K250161

Device Name
Wrist Blood Pressure Monitor (Models: AOJ-35A, AOJ-35B, WRS-35B, AOJ-35D, AOJ-35E, AOJ-35F, AOJ-35G, WRS-35G, WRS-35H, WRS-35K, WRS-35N, WRS-35P, WRS-35S)

Indications for Use *(Describe)*
The Wrist Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique by an inflatable cuff wrapped around the wrist 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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.

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 | Wrist Blood Pressure Monitor |
| Model | models AOJ-35A,AOJ-35B,WRS-35B,AOJ-35D,AOJ-35E,AOJ-35F, AOJ-35G,WRS-35G,WRS-35H,WRS-35K,WRS-35N,WRS-35P, WRS-35S |
| 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: Wrist Blood Pressure Monitor, models AOJ-35A,AOJ-35B,AOJ-35C,AOJ-35D and AOJ-35E.

510(K) Number: K213503

**4. Device Description**

The Wrist 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 wrist 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 the same intended use, same measurement principle, same blood pressure core algorithm and similar product design. All the models can be used with one cuff size 13.5~19.5 cm (5.3-7.7inches).

The main differences are appearance, Dimensions and some specifications which will not affect the safety and effectiveness of the device.

**5. Intended use & Indication for use**

The Wrist Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique by an inflatable cuff wrapped around the wrist at medical facilities or at home.

**6. Comparison to the Predicate Device**

| **ITEM** | **Proposed Device**<br>**Wrist Blood Pressure Monitor**<br>**AOJ-35A,AOJ-35B,WRS-35B,**<br>**AOJ-35D,AOJ-35E,AOJ-35F,**<br>**AOJ-35G,WRS-35G,WRS-35H,**<br>**WRS-35K,WRS-35N,WRS-35P,**<br>**WRS-35S** | **Predicate Device**<br>**Wrist Blood Pressure Monitor**<br>**AOJ-35A,AOJ-35B,AOJ-35C,**<br>**AOJ-35D,AOJ-35E/ K213503** | **Comparison Result** |
|---|---|---|---|
| Manufacturer | Shenzhen AOJ Medical Technology Co., Ltd. | Shenzhen AOJ Medical Technology Co., Ltd. | Same |
| Intended Use/Indications for Use | The Wrist Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique by an inflatable cuff wrapped around the wrist at medical facilities or at home. | The Wrist Blood Pressure Monitor is intended to measure the systolic pressure and diastolic pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique by an inflatable cuff wrapped around the wrist at medical facilities or at home. | 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 | Wrist | Wrist | Same |
| Blood pressure measurement range | 0-295 mmHg | 0-295 mmHg | Same |
| Accuracy | ± 3 mmHg | ± 3 mmHg | Same |
| Heart rate measurement range | 40-199 bpm | 40-199 bpm | Same |
| Accuracy | ± 5% of reading | ± 5% of reading | Same |
| Cuff size | 13.5 - 19.5 cm | 13.5 - 19.5 cm | Same |
| Display | Blood Pressure (Systolic and Diastolic), Pulse rate,Time, Date,BP Indicating Bar, Low Battery Icon,Heart Icon, Memory Record Number | Blood Pressure (Systolic and Diastolic), Pulse rate,Time, Date,BP Indicating Bar, Low Battery Icon,Heart Icon, Memory Record Number | Same |
| Screen | **LCD:** AOJ-35A,AOJ-35B,WRS-35B,AOJ-35D,AOJ-35E,AOJ-35F, AOJ-35G,WRS-35G,WRS-35H,WRS- | LCD | |

| | | | |
|---|---|---|---|
| | 35K,WRS-35N,WRS-35P<br>**LED:** WRS-35S | | |
| Auto shutdown | YES | YES | Same |
| Operating environment | Temperature: 5°C~40°C<br>Humidity: 15%-90% RH,<br>Atmospheric pressure: 70 kPa -106 kPa | Temperature: 5°C~40°C<br>Humidity: 15%-90% RH,<br>Atmospheric pressure: 70 kPa -106 kPa | Same |
| Storage environment | Ambient Temperature: -20°C to 55°C<br>Relative Humidity: 10-93% RH,<br>Atmospheric pressure:<br>70 kPa -106 kPa | Ambient Temperature: -20°C to 55°C<br>Relative Humidity: 10-93% RH,<br>Atmospheric pressure:<br>70 kPa -106 kPa | Same |
| Power Source | **1)**3Vdc (2*AAA batteries):<br>AOJ-35A,AOJ-35B,AOJ-35D,<br>WRS-35H,WRS-35K,WRS-35N,<br>WRS-35B,WRS-35S,WRS-35P<br>**2)**3Vdc (2*AAA batteries) or AC/DC Adapter (DC 5V,1A)<br>AOJ-35E<br>**3)**Lithium-ion battery, D.C. 3.7V or AC/DC Adapter (DC 5V,1A)<br>AOJ-35F,AOJ-35G,WRS-35G | 3Vdc (2 *AAA batteries) | Different[1] |
| Weight | AOJ-35A: About 126g<br>AOJ-35B: About 126g<br>AOJ-35D: About 128g<br>AOJ-35E: About 127g<br>AOJ-35F: About 141g<br>AOJ-35G: About 126g<br>WRS-35G: About 126g<br>WRS-35H: About 140g<br>WRS-35K: About 138g<br>WRS-35N: About 140g<br>WRS-35B: About 126g<br>WRS-35S: About 125g<br>WRS-35P: About 113g | Approx. 126 g without battery | Different[2] |
| Dimensions | AOJ-35A/AOJ-35B/WRS-35B/AOJ-35D:<br>90mm×66mm×28.5mm<br>AOJ-35E/AOJ-35F: 84mm×70mm×29.3mm<br>AOJ-35G/WRS-35G:<br>77.6mm×67mm×28.8mm<br>WRS-35H/WRS-35N/WRS-35P:<br>83.9mm×65.9mm×25.5mm<br>WRS-35K: 84mm×64mm×29mm<br>WRS-35S: 92mm×67.9mm×28.4mm | AOJ-35A/AOJ-35B/AOJ-35D:<br>90 mm×66 mm×28.5 mm<br>AOJ-35C/AOJ-35E:<br>79.6 mm×70 mm×26.8 mm | |
| Patient Contacting | Surface-contacting,<br>Less than 24 h | Surface-contacting,<br>Less than 24 h | Same |
| Biocompatibility evaluation | Cytotoxicity, skin sensitization and | Cytotoxicity, skin sensitization and | Same |

| | | | |
|---|---|---|---|
| | irritation | irritation | |
| Electrical safety | IEC 60601-1<br>IEC 60601-1-11<br>ISO 80601-2-30 | IEC 60601-1<br>IEC 60601-1-11<br>ISO 80601-2-30 | Same |
| EMC | IEC 60601-1-2 | IEC 60601-1-2 | Same |
| Biocompatibility | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10 | Same |
| Data transmission | Not available | Not available | Same |

**Justification for the differences:**

1) Different kind of Power Source

Although the device power sources among the predicate devices and subject device are different, they are all complied with IEC 60601-1,IEC 60601-1-2, IEC 60601-1-11 and EC 80601-2-30.So the minor difference do not affect the safety and effectiveness.

2) Different Weight and Dimensions

The subject and the predicate are has slight difference in weight and dimensions due to different outlook.These minor differences do not affect the safety and effectiveness.

Moreover, such engineering design has been verified during the international standards, so such minor different ill not raise any safety and effectiveness questions.

**7. Non-clinical Data**

**Biocompatibility testing**

Biocompatibility testing performed with the subject device which was provided in previous 510(k)s remains applicable since the device is identical in materials/formulation and processing to the legally marketed device cleared by K213503.

**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, 13 submitted models were divided into 3 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 | AOJ-35A, AOJ-35B, WRS-35B | 100 | 47 | 53 | 22 to 80 |
| 2 | AOJ-35E, AOJ-35D,WRS-35H, WRS-35K, WRS-35N, WRS-35P, WRS-35S | 100 | 54 | 46 | 18 to 78 |
| 3 | AOJ-35F, AOJ-35G, WRS-35G | 100 | 44 | 56 | 19 to 80 |

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.