February 18, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Queena Chen
Regulatory Director
Room 301&4F, Blk A, Building A, Jingfa IM Park, Xiaweiyuan,
Gushu Community, Xixiang, Baoan
Shenzhen, Guangdong 518126
China

Re: K213503
Trade/Device Name: Wrist Blood Pressure Monitor, models AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D, AOJ-35E
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 20, 2021
Received: December 22, 2021

Dear Queena Chen:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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)*
K213503

Device Name
Wrist Blood Pressure Monitor, models AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D and AOJ-35E

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

1. Submitter:	Shenzhen AOJ Medical Technology Co., Ltd. Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China TEL: 86 755-27786026
Contact Person:	Queena Chen
Prepare date:	December 18, 2021
2. Device name and classification:	Device Name: Wrist Blood Pressure Monitor Models: AOJ-35A, AOJ-35B, AOJ-35C, AOJ-35D and AOJ-35E Regulation No.: 21 CFR 870.1130 Review Panel: Cardiovascular Classification Name: Cardiovascular Diagnostic Devices Product code: DXN Regulatory Class: Class II
3. Reason for Submission:	New Application. No prior submission for this device before.
3. Class III device statement	Not applicable, the subject device is a Class II device.
4. Predicate Devices:	**Primary predicate:** Dongguan E-TEST Technology Co., Ltd., BW-602 Automatic Wrist Electronic Blood Pressure Monitor cleared under K193628. **Reference predicate:** Shenzhen AOJ Medical Technology Co., Ltd., AOJ-30B Electronic Blood Pressure Monitor cleared under K191180. The predicates has not been subject to any recall before.
5. Device Description:	AOJ-35 series wrist blood pressure monitor is designed as a battery driven automatic on-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. The device also has low voltage indication, which will be triggered when the battery is low. All the models included in this submission follow the same software, same measurement principle and same specifications. The main differences are color of the face shell and keys, which will not affect the safety and effectiveness of the device.
6. 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.

7. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate devices.

Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Table 1 Comparison between predicate BW-602 and the subject device

ITEM	**Proposed Device AOJ-35A series**	**Predicate Device BW-602/K193628**	**Comparison Result**
Manufacturer	Shenzhen AOJ Medical Technology Co., Ltd.	DONGGUAN E-TEST TECHNOLOGY CO., LTD	---
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.	Automatic Wrist Blood Pressure Monitor is for use by medical professionals or at home and is a non□invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 13.5 cm~19.5 cm.	Different
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 - 294 mmHg	Different
Blood pressure accuracy	± 3 mmHg	± 3 mmHg	Same
Pulse rate measurement range	40-199 bpm	40-199 bpm	Same
Pulse rate accuracy	± 5% of reading	± 5% of reading	Same
Cuff size	13.5~19 .5cm	13.5~19 .5cm	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, Date, Time, BP Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Same
Screen	LCD	LCD	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: 86 kPa - 106 kPa	Different
Storage environment	Ambient Temperature: -20°C to 55°C	Ambient Temperature: -20°C to 65°C	

	Relative Humidity: 10-93% RH, Atmospheric pressure: 70 kPa - 106 kPa	Relative Humidity: 15-95% RH, Atmospheric pressure: 86 kPa - 106 kPa	
Battery type	3Vdc (2 *AAA batteries)	3Vdc (2 *AAA batteries)	Same
Weight	Approx. 126 g without battery	Approx. 150 g without battery	Different
Dimensions	AOJ-35A/AOJ-35B/AOJ-35D: 90 mm x 66 mm x 28.5 mm AOJ-35C/AOJ-35E: 79.6 mm x 70 mm x 26.8 mm	72.69 mm x 64 mm x 28 mm	
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 10993-1 ISO 10993-5 ISO 10993-10	Same

Table 2 Comparison between predicate AOJ-30B and the subject device

ITEM	**Proposed Device AOJ-35A series**	**Predicate Device AOJ-30B/K191180**	**Comparison Result**
Manufacturer	Shenzhen AOJ Medical Technology Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	---
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 Electronic 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
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	Arm	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 .5cm	22~36cm	Different
Display	Blood Pressure (Systolic and Diastolic), Pulse rate, Date, Time, WHO BP Classification Indicating Bar, Low Battery	Blood Pressure (Systolic and Diastolic), Pulse rate, Date, Time, WHO BP Classification Indicating Bar, Low Battery	Same

	Icon, Heart Icon, Memory Record Number	Icon, Heart Icon, Memory Record Number	
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	
Battery type	3Vdc (2 *AAA batteries)	6Vdc (4 *AA batteries)	Different
Weight	Approx. 126 g without battery	Approx. 483.8 g without battery	Different
Dimensions	AOJ-35A/AOJ-35B/AOJ-35D: 90 mm x 66 mm x 28.5 mm AOJ-35C/AOJ-35E: 79.6 mm x 70 mm x 26.8 mm	138 mm x 120 mm x 59 mm	
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 10993-1 ISO 10993-5 ISO 10993-10	Same

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The differences between the subject and predicate devices will not raise different questions of safety or effectiveness. Moreover, as demonstrated in the bench testing, the different technological characteristics do not affect the safety and effectiveness of the subject device.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the device 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

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the IEC 60601-1 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, 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*, and the IEC 60601-1-2 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests* standard for EMC.

Bench Testing

Bench testing was conducted on the device, consisting of all the accessories in the system. The system complies with the ISO 80601-2-30 *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers* for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

The clinical testing has been conducted per ISO 81060-2: 2013 *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type* on the monitor. There are 100 subjects involved in the stufy, of which 49 femal and 51 male. All the subjects are aged greater than 12 years old. And the wrist size distribution meets the requirements described in clause 5.1.4 of the standard as shown in Table 3. Also the blood pressure distribution matches the requirements defined in clause 5.1.5 of the standard shown in the following Table 4. And themean value is less than 5.0 mmHg, and standard deviation is also less than 8.0 mmHg after final analyzed.

Table 3 Size distribution of the subjects

Size distribution	Pecentage	Compared to the requirements in standards
Upper half of the cuff	54%	At least 40%, complied
Lower half of the cuff	46%	At least 40%, complied
Upper quarter of the cuff	29%	At least 20%, complied
Lower quater of the cuff	24%	At least 20%, complied
Upper octal of the cuff	11%	At least 10%, complied
Lower octal of the cuff	10%	At least 10%, complied

Table 4 Blood pressure distribution of the subjects

	Range	Percentage	Compared to the requirements in standards
Systolic blood pressure	≤100 mmHg	12%	At least 5%, complied
	≥160 mmHg	13%	At least 5%, complied
	≥140 mmHg	33%	At least 20%, complied
Diastolic blood pressure	≥100 mmHg	16%	At least 5%, complied
	≤60 mmHg	10%	At least 5%, complied
	≥85mmHg	38%	At least 20%, complied

Summary

Based on the non-clinical performance data as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the AOJ-35 series Wrist Blood Pressure Monitor is substantially equivalent to the predicate devices.