December 1, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Jack Wang
Deputy Chief
Room 301&4F, Blk A, Building A, Jingfa IM Park
Xiaweiyuan, Gushu Community, Xixiang, Baoan
Shenzhen, Guangdong 518126
China

Re: K222125
Trade/Device Name: Arm Blood Pressure Monitor, models AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 25, 2022
Received: October 31, 2022

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 (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,

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)*
K222125

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

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

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:	Jack Wang
Prepare date:	October 18, 2022
2. Device name and classification:	Device Name: Arm Blood Pressure Monitor Models: AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G 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:	Change to the previous cleared device AOJ-30A and AOJ-30B, and new application of AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G without previous submission.
3. Class III device statement	Not applicable, the subject device is a non-IVD Class II medical device.
4. Predicate Devices:	Shenzhen AOJ Medical Technology Co., Ltd., AOJ-30B Electronic Blood Pressure Monitor cleared under K191180. The predicate has not been subject to any recall before.
5. Device Description:	AOJ-30 series 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 similar software, same measurement principle and same specifications. The differences existed between different models included in this submission will not affect the safety and effectiveness of the device.

AOJ-30A and AOJ-30B include the Bluetooth transmission functionality which can transfer data for Application in the external instruments, and the measuring data, including systolic diastolic pressures and pulse rate can be displayed, stored and reviewed by the Application in the external instruments without any control feature, therefore, no interoperability happened. This function is not available for other models.

6. 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.

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 AOJ-30B and the subject device

ITEM	**Proposed Device AOJ-30 series**	**Predicate Device AOJ-30B/K191180**	**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 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
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% of reading	± 5% of reading	Same
Cuff size	22 ~ 42 cm	22~36 cm	Different
Display	Blood Pressure (Systolic and Diastolic), Pulse rate, Date,	Blood Pressure (Systolic and Diastolic), Pulse rate, Date,	Same

	Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Time, WHO BP Classification Indicating Bar, Low Battery 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	6Vdc (4 *1.5V AAA batteries)	6Vdc (4 *1.5V AAA batteries)	Same
Weight	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: About 220 g without battery AOJ-30F: About 220 g without battery	Approx. 483.8 g without battery	Different
Dimensions	AOJ-30A/AOJ-30B/ AOJ-30G: 127 mm * 93 mm * 73 mm AOJ-30C: 108 mm * 139 mm * 62 mm AOJ-30D: 136 mm * 113 mm * 68 mm AOJ-30E/AOJ-30F: 118 mm * 98 mm * 61mm	138 mm * 120 mm * 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
Data transmission	Has wireless function with Bluetooth and available for AOJ-30A and AOJ-30B only	Not available	Different

As seen in the comparison tables, the subject and predicate devices have almost the similar design features and performance specifications. 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 IEC 81060-2: 2013 *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type* on the upgraded AOJ-30A, AOJ-30C, AOJ-30D and AOJ-30E, and the clinical validation data on the three models can cover all the models included in this submission.

Summary

Regarding the clinical validation required in clause 201.106 Clinical accuracy of IEC 80601-2-30, it has been validated per ISO 81060-2:2018. The Same Arm Sequential Method was chosen and performed on the upgraded AOJ-30A, AOJ-30C, AOJ-30D and AOJ-30E sperately, 100 subjects were involved for each study. Detailed information about the Subject number, Gender distribution, Age distribution, Limb size distribution, Blood pressure distribution, Subject preparation, Observer preparation, Reference determination, Clinical investigation methods and Data analysis are referred to ISO 81060-2: 2018 without any deviation.

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-30 series Arm Blood Pressure Monitor is substantially equivalent to the predicate devices.