August 26, 2026

JOYTECH Healthcare Co., Ltd.
Yingting Lan
#502, Shunda Rd., Hangzhou, Zhejiang 311100, China
#365, Wuzhou Rd., Hangzhou, Zhejiang 311100, China
Hangzhou, Zhejiang 311100
China

Re: K261394
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 31, 2026
Received: July 31, 2026

Dear Yingting Lan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

CDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261394

Please provide the device trade name(s).

Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus)

Please provide your Indications for Use below.

The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm and 40cm to 56cm.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☒ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary

The assigned 510(k) number is: K261394

1. Sponsor's Identification

Name: JOYTECH Healthcare Co., Ltd.

Address 1: No.502, Shunda Road, Hangzhou, Zhejiang 311100, China.

Address 2: No.365, Wuzhou Road, Hangzhou, Zhejiang 311100, China.

Contact Person: Yingting Lan

Email:lanyt@sejoy.com

2. Name of the Device:

Trade Name: Arm-type Fully Automatic Digital Blood Pressure Monitor

Arm-type	DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus

Common Name: Blood Pressure Monitor

Classification name: Non-invasive blood pressure measurement System

21 CFR 870-1130, Class II, 74-DXN.

3. Classification Information:

Regulation Number: 870.1130

Product Code: DXN

Device Class: II

Panel: 74 Cardiovascular

4. Predicate/Reference Device Information:

The Arm-Type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the following devices:

Device	510(k) number	Predicate device model	Product code	Manufacturer
Predicate	K250548	DBP-6286B, DBP-6186	DXN	JOYTECH Healthcare Co., Ltd.

5. Device Description:

The Arm-type Fully Automatic Digital Blood Pressure Monitors(DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus) are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm and 40cm to 56cm.

They are automatic, non-invasive, blood pressure measurement system for over-the-counter (OTC) use at home and clinical environment . The systolic and diastolic pressures are determined using the oscillometric method, where the cuff is inflated with an integral controllable piezoelectric pump and deflates via an electric automatic rapid deflation valve. During inflation measurements, an electric pump within the main unit slowly inflates the arm cuff, generating cuff pressure which is monitored and from which pulse waveform data is extracted. This waveform data is analyzed by software algorithms within the microprocessor to determine pulse rate, systolic pressure, and diastolic pressure. The cuff can measure pressure range from 0 to 299mmHg, and the pulse rate range from 30 to 180 beats/min. The pulse rate measurement is compare the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.
DBP-6286B Plus, DBP-62E3B Plus, DBP-62E2B Plus with bluetooth function can be used as a stand-alone unit to finish the blood pressure measurement or in conjunction with the APP through embed a 2.4GHz BLE module that allow users to connect with nearby BT receiving terminal. Once measurement is over, the LCD display of the device appears results. And the device will start to transmit data to the pair-up terminal automatically.

With the use of software (including APP) and wireless communication module, the wireless software function and hardware function are solely intended to transfer, store, convert formats, or display medical device data and results (blood pressure and pulse rate readings), without

controlling or altering the functions or parameters of any connected medical devices, which is not be intended for active patient monitoring, therefore, based on the FDA guidance titled 'Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices' (issued on September 28, 2022.), this software function is belong to Non-device-MDDS, and the hardware function is belong to Device-MDDS, they are not subject to FDA laws and regulations applicable to devices.

The function for DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus are listed below:

Function	**DBP-6186 Plus**	**DBP-6286B Plus**	**DBP-61E3 Plus**	**DBP-61E2 Plus**	**DBP-62E3B Plus**	**DBP-62E2B Plus**
Blood Pressure measurement	Y	Y	Y	Y	Y	Y
Pulse rate measurement	Y	Y	Y	Y	Y	Y
Irregular Heartbeat Indicator	Y	Y	Y	Y	Y	Y
Memory	Y	Y	Y	Y	Y	Y
WHO Classification Indicator	Y	Y	Y	Y	Y	Y
Last 3 Test Average	Y	Y	Y	Y	Y	Y
MVM function	Y	Y	Y	Y	Y	Y
Low Battery Detection	Y	Y	Y	Y	Y	Y
Automatic Power-Off	Y	Y	Y	Y	Y	Y
Voice	Y	Y	Y	Y	Y	Y
Backlight	Y	Y	Y	Y	Y	Y
Arm shake indicator	Y	Y	Y	Y	Y	Y
Cuff loose indicator	Y	Y	Y	Y	Y	Y
Bluetooth function	N	Y	N	N	Y	Y
Trend Chart	Y	Y	Y	Y	Y	Y

Note: Y: Yes; N: No

6. Indication for use/Intended Use:

The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm and 40cm-56cm

7. Comparison of Technological Characteristics with Predicate/Reference Device:

The arm-type blood pressure monitor for model DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus manufactured by JOYTECH have the same indication for use and similar technological characteristics with the DBP-6286B, DBP-6186(K250548). And the main change is the subject device include extra function. Therefore, we select DBP-6286B, DBP-6186 in K250548 as Predicate device. The detailed comparison of technical characteristic is as below:

Comparison item	Subject Device (DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus)	Primary Predicate device(DBP-6286B, DBP-6186, K250548)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Blood pressure monitor	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	JOYTECH Healthcare Co., Ltd.	/
Recommended classification regulation	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	Identical
Regulatory class	II	II	Identical
Panel	74 Cardiovascular	74 Cardiovascular	Identical
Product code	DXN	DXN	Identical
Indication for use/Intended use	The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm and 40cm-56cm	The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm and 40cm-56cm	Identical
Intended use environment	Home and Professional healthcare facility environment.	Home and Professional healthcare facility environment.	Identical
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during inflation	Determined during inflation	Identical
Cuff location	Upper arm	Upper arm	Identical
Specification			

Comparison item	Subject Device (DBP-6186 Plus, DBP-6286B Plus, DBP-61E3 Plus, DBP-61E2 Plus, DBP-62E3B Plus, DBP-62E2B Plus)	Primary Predicate device(DBP-6286B, DBP-6186, K250548)	Comparison result / Explanation
Measuring range	Systolic Pressure: 60mmHg～260 mmHg; Diastolic Pressure: 40mmHg～200 mmHg; Cuff pressure: 0mmHg～299 mmHg; Pulse rate: 30~180 Beats/Minute;	Systolic Pressure: 60mmHg～260 mmHg; Diastolic Pressure: 40mmHg～200 mmHg; Cuff pressure: 0mmHg～299 mmHg; Pulse rate: 30~180 Beats/Minute;	Identical
Accuracy	Pressure deviation:±3 mmHg; Pulse deviation: 40-180Beats/Minute, ±5%; 30-39Beats/Minute, ±5bpm	Pressure deviation: ±3 mmHg Pulse deviation: 40-180Beats/Minute, ±5%; 30-39Beats/Minute, ±5bpm	Identical
Pressure release	By solenoid valve	By solenoid valve	Identical
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric pressure:80kPa~106kPa	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric pressure:80kPa~106kPa	Identical
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.: -25℃~55℃ Humidity: ≤93% RH	Identical
Cuff circumference	22-42 cm, 40-56cm	22-42cm, 40-56cm	Identical
Sterilization	Not applicable	Not applicable	Identical
Supply power source	4 AAA batteries or Medical AC Adapter	4 AAA batteries or Medical AC Adapter	Identical
Function			
Wireless transmission function	DBP-6186 Plus, DBP-61E3 Plus, DBP-61E2 Plus: No DBP-62E3B Plus, DBP-62E2B Plus, DBP-6286B Plus: Bluetooth	DBP-6186: No DBP-6286B: Bluetooth	Similar. See Note 1
Memory	2*150 Memories in Two Groups	2*150 Memories in Two Groups	Identical
Other function	Blood Pressure measurement Pulse rate measurement Irregular Heartbeat Indicator WHO Classification Indicator Last 3 Test Average MVM function Low Battery Detection Automatic Power-Off Voice Backlight Arm shake indicator Cuff loose indicator Trend chart	Blood Pressure measurement Pulse rate measurement Irregular Heartbeat Indicator WHO Classification Indicator Last 3 Test Average MVM function Low Battery Detection Automatic Power-Off Voice Backlight Arm shake indicator Cuff loose indicator	Similar, See note 2

Note 1: The wireless function is different between the subject devices and the predicate devices .However, it serves the same purpose, that is to transfer measurement results. As for the wireless technology of the subject device, it is same, which has also been validated according to IEC 60601-1-2, Part 15 Subpart C, ANSI C63.27. As demonstrated in relevant test reports as well, the difference here does not raise different questions of safety and effectiveness, and subject devices are as safe and effective as the predicate device.

Note 2: The subject devices have additional trend chart function. Also, the subject devices with such design has been verified according to IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, ISO

80601-2-30, and internal bench testing. Therefore, the difference here does not raise different questions of safety and effectiveness, and subject devices are as safe and effective as the predicate device

8. Performance Data:

Testing information demonstrating safety and effectiveness of the device in the intended environment of use is supported by testing that was conducted.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices.

The following National and International Standards were utilized for testing the subject device.

Electrical Safety and performance requirements:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.
- AAMI ES60601-1:2005+AMD1:2012+AMD2:2021, Medical Electrical Equipment.
- IEC 80601-2-30:2018, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

Home-used medical equipment requirements and environmental test:

- IEC 60601-1-11:2015+AMD1:2020, 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

Electromagnetic Compatibility Requirements:

- IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Bio-compatibility Evaluation for patient contacting components:

- ISO 10993-1:2018, Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices--Part 23: Tests for irritation

FCC Test

- FCC Part15 Subpart C
- RF Exposure Evaluation

Wireless Coexistence

- ANSI C63.27-2021

Guidance Document:

- The software/firmware verification and validation was provided in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Biological evaluation was made in accordance with "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Electromagnetic Compatibility (EMC) of Medical Devices

The test results all meet the requirement of these standards.

9. Discussion of Clinical Tests Performed:

Clinical Validation for 22-42cm Cuff (Leveraged from Previously Cleared Device):

The accuracy and performance of the subject devices intended for the use with 22-42cm cuff are leveraged and supported by clinical data from the model DBP-6279B, previously cleared device in K230566, which is unchanged from subject device models intended for the general population. No new clinical testing was conducted for these models on the general populations.

The leveraged clinical study was performed according to ISO 81060-2:2018+AMD2020, "Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type." This study involved 95 subjects aged over 12 years using the same-arm sequential method with a manual mercury sphygmomanometer as reference. The results

demonstrated that the accuracy of the model DBP-6279B was within the acceptable limits specified by the standard.

Clinical Validation for 40-56cm Cuff(Leveraged from Previously Cleared Device)

The accuracy and performance of the subject devices intended for use with 40-56cm cuff are leveraged and supported by clinical data from the model DBP-6286B, previously cleared device in K250548. No new clinical testing was conducted for these models with 40-56cm cuff.

Model DBP-6286B was model for clinical study. It was conducted according to ISO 81060-2：2018+AMD2020 standard. Same arm sequential method was adopted during clinical testing. The manual Mercury Sphygmomanometer was used as a reference device. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any AE or side-effect. The subject demographics include 85 valid subjects data were used to analysis. The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2:2018+AMD2020.

Equivalence Justification via Bench Testing:

Comprehensive bench testing and internal simulation analyses were conducted to demonstrate equivalence. The testing confirmed:

Equivalence between the subject device models and the previously cleared model DBP-6286B from K250548, DBP-6279B from K230566, as they share the same core algorithm and essential performance characteristics.

Clinical Coverage Discussion:

The subject devices share the same upper-arm application site as previous portable models DBP-6279B, DBP-6286B cleared by JOYTECH. Combined with the bench testing equivalence proof between the subject models, the previously cleared model DBP-6279B, DBP-6286B, the safety and effectiveness of all subject devices are adequately demonstrated. The above clinical studies can cover the subject devices. No additional study is needed.

10. Conclusions:

The subject device and predicate devices have same Measuring principle, measuring method, are designed for the measurement of blood pressure, pulse rate and detection of irregular pulses

for home use. The minor difference between the subject devices and the predicate devices have been evaluated and determined to not raise any new issues of safety or effectiveness. Therefore, the new models as mentioned on this submission are considered substantial equivalent to the predicate devices.