June 26, 2025

JOYTECH Healthcare Co., Ltd.
Cong Jing
RA Manager
No.365, Wuzhou Road
No.502, Shunda Road
Hangzhou, Zhejiang 311100
China

Re: K250548
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitors (DBP-6286B, DBP-6186)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 25, 2025
Received: May 27, 2025

Dear Cong Jing:

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,

for Robert T. Kazmierski -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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K250548

Device Name

Arm-type Fully Automatic Digital Blood Pressure Monitors (DBP-6286B, DBP-6186)

Indications for Use *(Describe)*

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.

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.***

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# Substantial Equivalence Comparison

## 1. Sponsor's Identification

Name: JOYTECH Healthcare Co., Ltd.

Address 1: No. 365. Wuzhou Road, Hangzhou, Zhejiang 311100, China.

Address 2: No. 502. Shunda Road, Hangzhou, Zhejiang 311100, China.

Contact Person: Cong Jing

Email address: Jingc@sejoy.com

## 2. Name of the device

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

| | |
|---|---|
| Arm-type | DBP-6186, DBP-6286B |

Common Name: Blood Pressure Monitor

Classification name: Non-invasive blood pressure measurement System

## 3. Classification information

Regulation Number: 21 CFR 870.1130

Product Code: DXN

Device Class: II

Panel: 74 Cardiovascular

## 4. Predicate device information

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

| 510(k) number | Predicate device model | Product code | Manufacturer |
|---|---|---|---|
| K212115 | DBP-6286B | DXN | JOYTECH Healthcare Co., Ltd. |

Note: As for the subject device in this submission are derived from the DBP-6286B, DBP-6186 in cleared K212115. Compared to the previous device, the subject device has added two cuffs and also the device unit has changed the power supply voltage, air pump, bluetooth module, and appearance. Therefore we resubmitted a new traditional 510 (k).

## 5. Device description

The Arm-type Blood Pressure Monitor (BPM) series is an automatic, non-invasive, blood pressure measurement system for over-the-counter (OTC) use in 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 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 per minute.

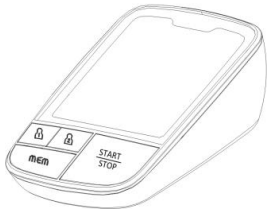
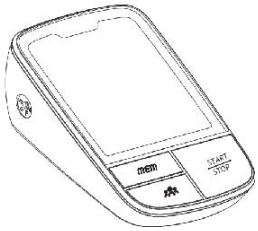
The DBP-6286B embed bluetooth module to transfer data to APP. With the use of software (including APP) and Bluetooth communication module, the wireless software function and hardware function are solely intended to transfer, store, convert formats, or display medical device data and results (blood pressure 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.

## 6. Indications for 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 to the predicate device

| **Comparison items** | **Subject devices (DBP-6186, DBP-6286B)** | **Predicate device DBP-6286B (K212115)** | **Judgement** |
|---|---|---|---|
| Manufacturer | JOYTECH Healthcare Co., Ltd. | JOYTECH Healthcare Co., Ltd. | Same |
| Trade name | Arm-type Fully Automatic Digital Blood Pressure Monitor | Arm-type Fully Automatic Digital Blood Pressure Monitor | Same |
| Recommended classification regulation | 21CFR 870.1130 | 21CFR 870.1130 | Same |
| Regulatory class | Class II | Class II | Same |
| Product code | DXN | DXN | Same |
| Indications 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. | Same Note 1 |

| | | | |
|---|---|---|---|
| Intended patient | Adults and adolescents over 12 years of age | Adults and adolescents over 12 years of age | Same |
| Intended use environment | Home and Professional healthcare facility environment. | Home and Professional healthcare facility environment. | Same |
| Working principle | Oscillometric method | Oscillometric method | Same |
| Measurement type | Determined during inflation | Determined during inflation | Same |
| Cuff location | Upper arm | Upper arm | Same |
| Cuff circumference | Fits arm circumference 22-42cm and 40-56cm | Fits arm circumference 22-36 cm | Similar Note 1 |
| Appearance |  |  | Similar Note 2 |
| Solenoid valve | Solenoid valve | Solenoid valve | Same |
| Sensor | Silicon pressure transducer | Silicon pressure transducer | Same |
| Pump | Air pump | Air pump | Similar Note 3 |
| Display screen | LCD | LCD | Same |

| | | | |
|---|---|---|---|
| Power supply source | 4 x1.5V AAA batteries or Medical AC adaptor (DC 5V, 1A, recommend but not provide) | 3x1.5V AAA battery or Medical AC adaptor (DC 5V, 1A, recommend but not provide) | Similar Note 4 |
| Bluetooth module | DBP-6286B applicable Frequency range: 2.4 GHz (2402-2480 MHz) Modulation type: GFSK Version 5.2 (BLE only) | requency range: 2.4 GHz (2402-2480 MHz) Modulation type: GFSK Version 5.0 (BLE only) | Similar Note 5 |
| Measuring range | Systolic Pressure: 60mmHg ～ 260 mmHg Diastolic Pressure:40mmHg ～ 200 mmHg Pressure: 0mmHg～299 mmHg Pressure: ±3mmHg Pulse:30~180 Beats/Minute | Systolic Pressure: 60mmHg ～ 260 mmHg Diastolic Pressure:40mmHg ～ 200 mmHg Pressure: 0mmHg～299 mmHg Pressure: ±3mmHg Pulse:30~180 Beats/Minute | Same |
| Accuracy | Pressure: ±3mmHg Pulse: 40-180Beats/Minute, ±5%; 30-39Beats/Minute, ±5bpm | Pressure: ±3mmHg Pulse: 40-180Beats/Minute, ±5%; 30-39Beats/Minute, ±5bpm | Same |
| Main function | Measure blood pressure value Measure pulse rate Irregular Heartbeat Detection Memory WHO Classification Indicator Last 3 Test Average Low Battery Detection Automatic Power-Off Voice abroad Backlight Arm shake indicator | Measure blood pressure value Measure pulse rate Irregular Heartbeat Detection Memory WHO Classification Indicator Last 3 Test Average Low Battery Detection Automatic Power-Off Voice abroad Backlight Arm shake indicator | Same |

| | | | |
|---|---|---|---|
| | Cuff loose indicator<br>Bluetooth function (DBP-6286B applicable) | Cuff loose indicator<br>Bluetooth function (DBP-6286B applicable) | |
| Operating condition | 10℃-40℃（50℉~104℉）<br>15%-93% RH<br>800hPa-1060hPa | 10℃-40℃（50℉~104℉）<br>15%-93% RH<br>800hPa-1060hPa | Same |
| Storage condition | -25℃-55℃<br>（-13℉~158℉）<br>≤93% RH | -25℃-55℃<br>（-13℉~158℉）<br>≤93% RH | Same |
| Biocompatibility | ISO 10993-1<br>Bio-compatible | ISO 10993-1<br>Bio-compatible | Same |
| Applicable standards | IEC 60601-1<br>IEC 60601-1-11<br>IEC 60601-1-2<br>ISO 80601-2-30<br>ISO 81060-2 | IEC 60601-1<br>IEC 60601-1-11<br>IEC 60601-1-2<br>ISO 80601-2-30<br>ISO 81060-2 | Same |

Note 1: The subject device has the same intended purpose and principle with cleared devices (K212115 ). Compare with predicate device, the modification of cuff is occur in only add two cuffs, 22-42cm and 40-56cm. Adding new cuffs generally does not result in changes in electrical safety and EMC, and its corresponding clinical accuracy has been confirmed through clinical trials according to ISO 81060-2 . Thus, the difference between the subject device and the cleared predicate device do not raise different issues of safety and effectiveness.

Note 2: The subject device was added number of buttons based on predicate device. At the same time, The USB adapter jack type has no changed, the interface location of the power adapter has been changed from the right side to the top. These changes have passed electrical safety testing and will not cause new safety and effectiveness issues.

Note 3: Compared with cleared predicate device, the external dimensions and rated working voltage of the both air pump are not consistent, but the structural composition of the both air pump is the same.This subject device has passed IEC 60601-1, IEC 60601-1-2,

and ISO 80601-2-30 standard testing,which will not result in new safety and effectiveness issues.

Note 4: The battery type of subject devices and predicates are the same,which all of them are AAA batteries. The main difference lies in the voltage. The voltage of the subject device is 6V, and the risks caused by different voltages have been controlled through electrical safety and electromagnetic compatibility testing, without bringing new safety and effectiveness issues.

Note 5: The difference of model DBP-6286B and DBP-6186 is only bluetooth. The BLE module version of DBP-6286B was updated from V5.0 to V5.2 by adding a shield cover. The subject device DBP-6286B has been verified the safety by IEC 60601-1, IEC 60601-11, IEC 60601-1-2, FCC and Wireless coexistence test report, which those of difference between subject device and predicate device do not raise new issues of safety and effectiveness comparing with the predicated 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 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance

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 10993-5:2009, 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 skin sensitization

ISO 10993-23:2021, Biological evaluation of medical devices Part 23: Tests for irritation

**FCC Test**

FCC Part15 Subpart C
RF Exposure valuation

**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"

The test result all meet or exceed the requirement of these standards.

## 9. Discussion of Clinical Tests Performed

Clinical Validation:

- ISO81060-2:2018+AMD2020 Non-invasive sphygmomanometers Part 2: Clinical investigation of intermittent automated measurement type.

**For cuff with arm circumstance 22-42cm**

Compared with Arm-type Fully Automatic Digital Blood Pressure Monitor DBP-6279B which manufactured by our company, although the subject device is different in appearance from DBP-6279B, the key factors affecting the clinical accuracy are the same. For example, both of them have the same principle and measurement type (determined by inflation), and they have the same core algorithm, same pressure sensor, same MCU, and same cuff size and material. Therefore, we believe that the clinical report of DBP-6279B can cover the subject devices.

Model DBP-6279B was selected as representative for testing. 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 91 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.

**For cuff with arm circumstance 40-56cm**

Model DBP-6286B was selected as representative for testing. 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.

## 10. Conclusion

The subject devices and predicate devices have the same intended use, measuring principle, measuring method, performance and most technical characteristic.
The difference between the subject and the predicate devices does not: (1)

affect the intended use or (2) alter the fundamental scientific technology of the device. 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.