April 28, 2026

Joytech Healthcare Co. , Ltd.
Chaojie Guo
Primary Correspondent
#365, Wuzhou Rd.
#502, Shunda Rd.
Hangzhou, Zhejiang 311100
China

Re: K252501
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-62E3B, DBP-62E2B, DBP-62E1B, DBP-61E3, DBP-61E2, DBP-61E1, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 30, 2026
Received: March 30, 2026

Dear Chaojie Guo:

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

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)*
K252501

Device Name
Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-62E3B, DBP-62E2B, DBP-62E1B, DBP-61E3, DBP-61E2, DBP-61E1, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L)

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 36cm or 22cm to 42cm or 32cm to 48cm.

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

The assigned 510(k) number is: _____

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: Chaojie Guo

Email:guocj@sejoy.com

2. Name of the Device:

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

Arm-type	DBP-62E1B, DBP-62E2B, DBP-62E3B, DBP-61E1, DBP-61E2, DBP-61E3, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L

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 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
K230566	DBP-6279B	DXN	JOYTECH Healthcare Co., Ltd.

5. Device Description:

The Arm-type Fully Automatic Digital Blood Pressure Monitor (BPM) series is 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-61D7G with 4G function can allow users receive measurement result on mobile phone via message after entering correct phone number.

DBP-62E3B, DBP-61E3, DBP-62E2B andDBP-61E2 also has trend chart function to better view the recent measurement trending on the LCD display.

DBP-62E1B, DBP-62E2B, DBP-62E3B, DBP-6281L, DBP-6282L, DBP-6285L 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 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, 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-62E1B, DBP-62E2B, DBP-62E3B, DBP-61E1, DBP-61E2, DBP-61E3, DBP-61D7G,DBP-6281L, DBP-6282L, DBP-6285L are listed below:

Function	**DBP-62E3B**	**DBP-61E3**	**DBP-62E2B**	**DBP-61E2**	**DBP-62E1B**	**DBP-61E1**	**DBP-61D7G**	**DBP-6281L**	**DBP-6282L**	**DBP-6285L**
Blood Pressure measurement	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Pulse rate measurement	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Irregular Heartbeat Detection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Memory	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
WHO Classification Indicator	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Last 3 Test Average	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Triple measurement function	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Low Battery Detection	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Automatic Power-Off	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Voice	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Backlight	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Trend chart	Y	Y	Y	Y	N	N	N	N	N	N
Arm shake indicator	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Cuff loose indicator	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Bluetooth function	Y	N	Y	N	Y	N	N	Y	Y	Y
4G function	N	N	N	N	N	N	Y	N	N	N

Note: Y: Yes; N: No

6. Indication for use/Intended Use:

DBP-62E1B, DBP-61E1, DBP-62E3B, DBP-61E3, DBP-62E2B, DBP-61E2, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L: 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 36cm or 22cm to 42cm or 32cm to 48cm.

7. Comparison of Technological Characteristics with predicate device:

The arm-type blood pressure monitor for model DBP-62E1B, DBP-61E1, DBP-62E3B, DBP-61E3, DBP-62E2B, DBP-61E2, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L manufactured by JOYTECH have the same arm cuff type, similar features and specifications with the DBP-6279B, whose 510k number is K230566, therefore we choose the device act as the predicate device. The detail comparison of technical characteristic as below:

Comparison item	Subject device for Model(DBP-62E1B, DBP-61E1, DBP-62E3B, DBP-61E3, DBP-62E2B, DBP-61E2, DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L)	Predicate device for DBP-6279B (K230566)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Arm-type Fully Automatic Digital Blood Pressure Monitor	Same
Manufacturer	JOYTECH Healthcare Co., Ltd.	JOYTECH Healthcare Co., Ltd.	Same
Recommended classification regulation	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	Same
Regulatory class	II	II	Same
Panel	74 Cardiovascular	74 Cardiovascular	Same
Product code	DXN	DXN	Same
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 36cm or 22cm to 42cm or 32cm to 48cm.	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 36cm or 22cm to 42cm or 32cm to 48cm.	Same
Measuring principle	Oscillometric method	Oscillometric method	Same
Measurement type	Determined during inflation	Determined during inflation	Same
Cuff location	Upper arm	Upper arm	Same

Specification			
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;	Same
Accuracy	Pressure deviation:±3 mmHg; Pulse deviation: ±5%	Pressure deviation:±3 mmHg; Pulse deviation: ±5%	Same
Inflation	By air pump	By air pump	Same
Pressure release	By solenoid valve	By solenoid valve	Same
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	Same
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.: -25℃~55℃ Humidity: ≤93% RH	Same
Cuff circumference	Fits arm circumference 22-36 cm or 22-42cm or 32-48cm;	Fits arm circumference 22-36 cm or 22-42cm or 32-48cm;	Same
Supply power source	DBP-62E1B, DBP-61E1, DBP-62E3B, DBP-61E3, DBP-62E2B, DBP-61E2: 4 AAA batteries or Medical AC Adapter DBP-61D7G, DBP-6281L, DBP-6282L, DBP-6285L: Lithium battery 3.7V or Medical AC Adapter	3*AAA battery or Medical AC adaptor	Similar, Note 1
Wireless transmission function	DBP-62E1B, DBP-62E2B, DBP-62E3B, DBP-6281L, DBP-6282L, DBP-6285L: Bluetooth DBP-61D7G:4G/ LTE DBP-61E1, DBP-61E2, DBP-61E3: None	DBP-6279B: Bluetooth	Similar, Note 2
Biocompatibility	ISO 10993-1 Bio-compatible	ISO 10993-1 Bio-compatible	Same
Applicable standards	IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 80601-2-30 and ISO 81060-2	IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 80601-2-30 and ISO 81060-2	Same
Sterilization	Not applicable	Not applicable	Same
Features			
Major Function	Measure blood pressure value Measure pulse rate Memory Irregular Heartbeat Detection WHO Classification Indicator Last 3 Test Average Low Battery Detection Automatic Power-Off Voice Backlight Arm shake indicator Cuff loose indicator	Measure blood pressure value Measure pulse rate Memory Irregular Heartbeat Detection WHO Classification Indicator Last 3 Test Average Low Battery Detection Automatic Power-Off Voice Backlight Arm shake indicator Cuff loose indicator	Similar Note 2

	Trend chart(DBP-62E3B, DBP-62E2B, DBP-61E3, DBP-61E2) Bluetooth function(DBP-62E1B, DBP-62E2B, DBP-62E3B, DBP-6281L, DBP-6282L, DBP-6285L) 4G function(DBP-61D7G)	Bluetooth function	
Memory	2*150	2*150	Same

Note 1: The Lithium battery has passed the standard IEC 62133-2 test and the AC adaptor also has passed the IEC60601-1 test.
Note 2: The subject devices have been verified according to IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 80601-2-30 and ISO 81060-2. Thus, the difference brought by additional function does not raise different questions of safety and effectiveness. Especially, for the wireless function, devices with wireless transmission function have also conducted FCC, RF and wireless coexistence test to prove its wireless performance.

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
- FCC Part 2, 22 (H), 27
- RF Exposure Evaluation

Wireless Coexistence

- ANSI C63.18-2014
- 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"
- The Cybersecurity verification and validation was provided in accordance with the 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"

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.

Model DBP-6279B was selected as representative for testing. It was conducted according to ISO 81060-2 Non-Invasive Sphygmomanometers - Part2: Clinical Investigation Of Automated Measurement Type.

For cuff with circumference 22-42cm, the subject demographics include total of 95 subjects meeting the inclusion criteria, all 95 include subjects are all older than 12 years.

For cuff with circumference 22-36cm and 32-48cm, the subject demographics include total of 88 subjects meeting the inclusion criteria, all 88 include subjects are all older than 12 years.

Same arm sequential method was adopted during the 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 results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2:2018+AMD2020.

The applicable part of subject devices in this submission and previous arm-type blood pressure monitor models submitted by JOYTECH are both upper-arm. The only difference is that current subject devices are body-worn but previous submitted are portable. All new design elements have been successfully validated and the results fully demonstrate that the device has good safety and effectiveness.

Therefore, there is no need to carry out clinical research on the new design, and the clinical results of DBP-6279B can cover the current submitted models.

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 in adult population 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.