January 13, 2025

JOYTECH Healthcare Co., Ltd.
Cong Jing
Official Correspondent
No. 365. Wuzhou Road, Yuhang Economic Development Zone
Hangzhou, 310000
China

Re: K241431
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-62D0L, DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN,
Dated: April 22, 2024
Received: May 21, 2024

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.

510(k) Number *(if known)*
K241431

Device Name
Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-62D0L, DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193)

Indications for Use *(Describe)*
The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood Pressure (systolic and diastolic) of adults and adolescents over 12 years of age with circumference ranging from 22cm to 24cm.

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.

510(k) Summary

The assigned 510(k) number is: K241431

2.1 Subjectter's Identification:

Name: JOYTECH Healthcare Co., Ltd.

Add.: No. 365. Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, China.

Contact Person: Cong Jing

Phone: +86-571-81957767

Fax: +86-571-81957750

Email: Jingc@sejoy.com

2.2 Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor

Arm-type	DBP-62D0L, DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193

Common Name: Blood Pressure Monitor

Classification name: Non-invasive blood pressure measurement System

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

2.3 Classification Information:

Regulation Number: 870.1130

Product Code: DXN

Device Class: II

Panel: 74 Cardiovascular

2.4 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
K162092	Evolv Model Bp7000	DXN	Omron Healthcare,Inc.

2.5 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 systolic pressure, and diastolic pressure. The cuff can measure pressure range from 0 to 299mmHg.

Meanwhile, some models whith 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 of the device displays results. And the device will start to transmit data to the pair-up terminal automatically. This app is only intended to display measurement results from the blood pressure monitor device, which does not provide any diagnostic or measurement functions, and does not interpret or analyze the data for medical decision making. Unlimited readings can be stored in the app for archiving and review by the user.

There are total 7 arm-type blood pressure monitor models we submitted: DBP-62D0L, DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193 and they are both body-worn medical devices.

2.5.1 The detail functions for DBP-62D0L, DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193 are listed in table below:

Model	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**
DBP-6193	Y	Y	Y	Y	Y	2*150 memories	Y	Y	N	N	Y	Y	Y	Y
DBP-6293B	Y	Y	Y	Y	Y	2*150 memories	Y	Y	N	Y	Y	Y	Y	Y
DBP-6293L	Y	Y	Y	Y	Y	2*150 memories	Y	Y	Y	Y	Y	Y	Y	Y

DBP-62D0L	Y	Y	Y	Y	Y	2*150 memories	Y	N	Y	Y	Y	Y	Y	Y
DBP-62D0B	Y	Y	Y	Y	Y	2*150 memories	Y	N	N	Y	Y	Y	Y	Y
DBP-61D0	Y	Y	Y	Y	Y	2*150 memories	Y	N	N	N	Y	Y	Y	Y
DBP-61D0L	Y	Y	Y	Y	Y	2*150 memories	Y	N	Y	N	Y	Y	Y	Y

A = Systolic pressure, Diastolic pressure measuring function
B = Automatic Power-Off
C =–WHO (World Health Organization) Classification Indicator
D = Last 3 Tests Average
E = Low Battery Detection
F = Memory
G = Voice
H = Backlight
I = lithium battery
J = Bluetooth Function
K = Arm Shake Detection
L = Cuff Loose Detection
M = Triple measurement function
N =Cuff size(22cm-42cm)

Note:
Y= Yes
N= No

2.6 Indication for use/Intended Use:

DBP-62D0L,DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193: The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm.

2.7 Comparison of Technological Characteristics with predicate device:

2.7.1 Arm-type

The arm-type blood pressure monitor for model DBP-62D0L,DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193 manufactured by JOYTECH have the same arm cuff type, features and specifications with the Omron Evolv model Bp 7000 Upper Arm Blood

Pressure Monitor which 510k number is K162092, 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-6193,DBP-6293B,DBP-6293L, DBP-62D0L,DBP-62D0B, DBP-61D0, DBP-61D0L, DBP-6293L, DBP-6293B, DBP-6193	Predicate device for Bp7000 (K162092)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	EVOLV Upper Arm Blood Pressure Monitor Model Bp7000	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	Omron Healthcare,Inc.	/
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 Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 inches to 17 inches (22cm to 42cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Similar
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during inflation	Determined during inflation	Identical
Classification of installation and use	body-worn	body-worn	Identical
Cuff location	Upper arm	Upper arm	Identical
Specification			
Measuring range	Systolic Pressure: 60mmHg～260 mmHg; Diastolic Pressure: 40mmHg～200 mmHg; Cuff pressure: 0mmHg～299 mmHg;	Pressure:0mmHg～299 mmHg; Pressure: 40 to 260 mmHg Pulse rate:40~180 Beats/Minute;	Similar Note 1
Accuracy	Pressure deviation:±3 mmHg;	Pressure deviation:±3 mmHg; Pulse deviation: ±5%	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℃ Relative humidity :15~90%RH Atmospheric pressure:800~1060hPa	Similar Note 2

Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.:-20℃~60℃ Relative Humidity: 10~90% RH(Non-condensing)	Similar Note 3
Cuff circumference	22-42 cm	22-42 cm	Identical
Supply power source	DBP-6193:3* AAA battery or Medical AC Adaptor; DBP-6293B:3*AAA battery or Medical AC Adaptor; DBP-6293L:Lithium battery or Medical AC Adaptor; DBP-62D0L: Lithium battery or Medical AC Adaptor; DBP-62D0B: 3*AAA battery or Medical AC Adaptor; DBP-61D0L: Lithium battery or Medical AC Adaptor; DBP-61D0: 3*AAA battery or Medical AC Adaptor;	3*AAA battery	Similar Note 4
Bluetooth transmission function	Yes	Yes	Identical
Sterilization	Not applicable	Not applicable	Identical
Features			
Cuff loose indicator	Yes	Yes	Identical
Memory	2*120 Memories in Two Groups	Memory Function	Similar. Note 5

Note 1: The measuring range of the subject device have been verified by 60601-1 and 80601-2-30 standard test. This difference will not bring any new risks.

Note 2: The operation environment of the subject device have been verified by IEC 60601-1 and 80601-2-30 standard test. This information is indicated in the instruction manual to remind the user and will not bring any new risks.

Note 3: The storage environment of the subject device have been verified by IEC 60601-1 and 80601-2-30 standard test.This information is indicated in the instruction manual to remind the user

Note 4: The Lithium battery has passed the standard IEC 62133-2 test and the AC adaptor also has passed the IEC60601-1 test.

Note 5: The quantity of storage readings is different between the subject device and predicate device. The change in the specification is documented, and the change does not affect the intended use or the fundamental scientific technology.

2.8. 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 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

FCC Test

- FCC Part15 Subpart C
- RF Exposure Evaluation

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.

2.10. 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. The subject demographics include total of 90 subjects meeting the inclusion criteria, all 90 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.

Meanwhile, through the verification of internal simulation tests, it prove that even if the appearance is different, but in the case of the same algorithm, the performance of the DBP-6279B and the current submitted models are the same. 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.

2.11. Conclusions:

The subject device and predicate devices have same Measuring principle, measuring method, are designed for the measurement of blood pressure 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.

--- End of this section---