February 13, 2026

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

Re: K252685
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P, DBP-61D9L,DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P, DBP-62F4L, DBP-62F4B, DBP-61F4,DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 31, 2025
Received: December 31, 2025

Dear Jing Cong:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Jackson Hair -S

for

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)*
K252685

Device Name
Arm-type Fully Automatic Digital Blood Pressure Monitor(DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P, DBP-61D9L, DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P, DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)

Indications for Use *(Describe)*
Arm-type Fully Automatic Digital Blood Pressure Monitors(Model: DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L) 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.

Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model: DBP-61D2L-P, DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)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. The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.

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.

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510(k) Summary

The assigned 510(k) number is: K252685

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:Jingc@sejoy.com

2. Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor

Arm-type	DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P,DBP-61D9L, DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P,DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P

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
Primary Predicate	K232621	TMB-2092-G	DXN	Guangdong Transtek Medical Electronics Co., Ltd.
Reference	K230566	DBP-6279B	DXN	JOYTECH Healthcare Co., Ltd.

5. Device Description:

Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model: DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L, DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L,) 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.

Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model:DBP-61D2L-P,DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)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. The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.

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%.The devices are not intended to detect atrial fibrillation or any other arrhythmias. The Irregular heartbeat indicator is solely intended as a technical error/indicator. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure.

DBP-62F4L, DBP-62F4B, DBP-62F4L-P, DBP-62F4B-P 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.

DBP-63D2L, BP-63D9L, DBP-63D2L-P, DBP-63D9L-P with additional WiFi function can also allow users better receive measurement result on mobile phone.

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-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P,DBP-61D9L, DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P,DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P are listed below:

Function	**DBP-61D2L DBP-61D2L-P**	**DBP-61D9L, DBP-61D9L-P**	**DBP-63D2L, DBP-63D2L-P**	**DBP-63D9L, DBP-63D9L-P**	**DBP-62F4L, DBP-62F4L-P**	**DBP-62F4B, DBP-62F4B-P**	**DBP-61F4L, DBP-61F4L-P,**	**DBP-61F4, DBP-62F4-P**
Blood Pressure measurement*[1]	Y	Y	Y	Y	Y	Y	Y	Y
Pulse rate measurement	Y	Y	Y	Y	Y	Y	Y	Y
Irregular Heartbeat Indicator	Y	Y	Y	Y	Y	Y	Y	Y
Memory	Y	Y	Y	Y	Y	Y	Y	Y
WHO Classification Indicator	Y	Y	Y	Y	Y	Y	Y	Y
Last 3 Test Average	Y	Y	Y	Y	Y	Y	Y	Y
MVM function*[2]	Y	Y	Y	Y	Y	Y	Y	Y
Low Battery Detection	Y	Y	Y	Y	Y	Y	Y	Y
Automatic Power-Off	Y	Y	Y	Y	Y	Y	Y	Y
Voice	Y	Y	Y	Y	Y	Y	Y	Y
Backlight	N	N	N	N	Y	Y	Y	Y
Arm shake indicator	Y	Y	Y	Y	Y	Y	Y	Y
Cuff loose indicator	Y	Y	Y	Y	Y	Y	Y	Y
Bluetooth function	N	N	Y	Y	Y	Y	N	N
WiFi	N	N	Y	Y	N	N	N	N

Note: Y: Yes; N: No

*1. User's arm should be bare during measurements.

2. MVM function is designed to provide a more reliable and accurate blood pressure reading by automatically performing three consecutive measurements and calculating the average result.

6. Indication for use/Intended Use:

Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model: DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L, DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L,) 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.

Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model:DBP-61D2L-P,DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)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. The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.

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

The arm-type blood pressure monitor for model DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P, DBP-61D9L,DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P, DBP-62F4L, DBP-62F4B, DBP-61F4,DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P manufactured by JOYTECH have the same arm cuff circumference and design, features and specifications with the DBP-6279B(K230566) . K232621 is selected as primary predicate device, since the main change is adding the pregnant population to indicated use, compared with K230566. The detailed comparison of technical characteristic is as below:

Comparison item	Subject Device, K252685 (DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P, DBP-61D9L, DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P, DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)	Primary Predicate device (TMB-2092-G, K232621)	Reference device (DBP-6279B, K230566)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Blood pressure monitor	Arm-type Fully Automatic Digital Blood Pressure Monitor	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	Guangdong Transtek Medical Electronics 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	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	Identical
Regulatory class	II	II	II	Identical
Panel	74 Cardiovascular	74 Cardiovascular	74 Cardiovascular	Identical
Product code	DXN	DXN	DXN	Identical
Indication for use/Intended use	The Arm-type Fully Automatic Digital Blood Pressure Monitors(Model:(DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L) 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. Arm-Type Fully Automatic Digital Blood Pressure Monitor(Model:DBP-61D2L-P,DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P)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. The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.	This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch) or 22 to 45cm (8.6 to 17.7 inch). Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia. Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia. It is intended indoor use only	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.	Similar, See Note 1
Measuring principle	Oscillometric method	Oscillometric method	Oscillometric method	Identical

Measurement type	Determined during inflation	Determined during inflation	Determined during inflation	Identical
Classification of installation and use	Portable	Portable	Portable	Identical
Cuff location	Upper arm	Upper arm	Upper arm	Identical
Specification				
Measuring range	Systolic Pressure: 60mmHg～260 mmHg; Diastolic Pressure: 40mmHg～200 mmHg; Cuff pressure: 0mmHg～299 mmHg; Pulse rate: 30~180 Beats/Minute;	Blood Pressure Measurement 0mmHg ~ 299mmHg, Pulse rate: 40-199 beat/minute	Systolic Pressure: 60mmHg～260 mmHg; Diastolic Pressure: 40mmHg～200 mmHg; Cuff pressure: 0mmHg～299 mmHg; Pulse rate: 30~180 Beats/Minute;	Similar, See Note 2
Accuracy	Pressure deviation:±3 mmHg; Pulse deviation: ±5%	Presssure deviation: ±3 mmHg Pulse deviation:±5%	Pressure deviation:±3 mmHg; Pulse deviation: ±5%	Identical
Pressure release	By solenoid valve	By solenoid valve	By solenoid valve	Identical
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric pressure:80kPa~106kPa	Temperature: 5℃~ 40℃ Relative Humidity: 15%~90%RH, Atmospheric Pressure: 70KPa~106KPa.	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric pressure:80kPa~106kPa	Similar, See Note 2
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temperature: -4°F to +140°F (20°C to +60°C) Relative humidity: ≤93%, noncondensing, at a water vapour pressure up to 50hPa Atmospheric pressure: 500hPa to 1060hPa	Temp.: -25℃~55℃ Humidity: ≤93% RH	Similar, See Note 2
Cuff circumference	22-42 cm	16-45cm	22-42 cm	Similar, See Note 3
Supply power source	DBP-61D2L, DBP-61D2L-P, DBP-63D2L, DBP-63D2L-P, DBP-61D9L, DBP-61D9L-P, DBP-63D9L, DBP-63D9L-P, DBP-62F4L, DBP-62F4L-P, DBP-61F4L, DBP-61F4L-P: Lithium battery 3.7V or DC 5.0v, 1000mA medical external power supply(DC5.0V, 1000mA) DBP-62F4B, DBP-61F4, DBP-61F4-P, DBP-62F4B-P: 4 AAA batteries or DC 5.0V, 1000mA medical external power supply(DC 5.0V, 1000mA)	Battery mode: 6VDC (4 * 1.5V batteries) AC adapter mode: Input 100–240V, 50–60Hz, 0.2A max; Output 6VDC, 1A	3*AAA battery or Medical AC adaptor	Similar, See Note 4

Wireless transmission function	DBP-61D2L, DBP-61D2L-P,DBP-61D9L, DBP-61D9L-P, DBP-61F4L, DBP-61F4L-P, DBP-61F4, DBP-61F4-P: None DBP-62F4L, DBP-62F4L-P, DBP-62F4B, DBP-62F4B-P:BLE DBP-63D2L, DBP-63D2L-P, DBP-63D9L, DBP-63D9L-P: WiFi+BLE	GSM, LTE	BLE	Similar. See Note 5
Sterilization	Not applicable	Not applicable	Not applicable	Identical
Feature				
Irregular heartbeat	Yes	Yes	Yes	Identical
Cuff loose indicator	Yes	Yes	Yes	Identical
Memory	2*150 Memories in Two Groups	500	2*150 Memories in Two Groups	Different, See Note 6

Note 1: For DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L, DBP-62F4L, DBP-62F4B, DBP-61F4,DBP-61F4L in the subject devices, these models has the similar intended use with the predicate device(K232621), covered by the predicate; same intended use(adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm) with reference device (K230566) . The clinical data of K230566 is leveraged to support the use of subject devices .
For DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P,DBP-61D2L-P, DBP-63D2L-P, DBP-61D9L-P,DBP-63D9L-P in the subject devices has an additional population of pregnant women with normotension, gestational hypertension, or preeclampsia compared to the population mentioned above. The additional indications of the subject device may necessitate new performance testing(clinical study), but they do not change the overall intended use of the device. Furthermore, the population is covered by predicate device (K232621). Used on its intended population, such kind of matched cuff has also been validated according to IEC 80601-2-30 and ISO 81060-2. 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: Although the Measuring range, Operating Temp. &humidity, Storage Temp.& humidity , memory sizes are different between subject device and predicate device 1(K232621), these characteristics are same with reference device . Meanwhile, they all meet the requirements of standard IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-30. This difference does not affect the normal measuring function of the blood pressure monitor. Thus, the difference does not raise different questions of safety and effectiveness, and subject devices are as safe and effective as the predicate device.

Note 3:Although the cuff circumference of subject device is different from the predicate device 1(K232621), it is covered by the predicate device, and same with the reference device, which has been validated following ISO 81060-2 and internal bench testing. So this difference does not raise different questions of safety and effectiveness, and subject devices are as safe and effective as the predicate device.

Note 4: The subject device can be powered by different batteries with predicate.The subject device with its matched battery and adapter has been validated according to IEC 60601-1, IEC 60601-1-11, IEC 80601-2-30 and IEC 60601-1-2. The (lithium) battery has passed the standard IEC 62133-2 test and the AC adaptor also has passed the IEC60601-1 test. As demonstrated in relevant test reports, 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 5: The wireless module employed is different between the subject device 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 has also been validated according to Part 15 Subpart C, FCC 47 CFR Part 2.1093, ANSI C63.27. As demonstrated in relevant test reports, 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 subject devices are as safe and effective as the predicate device in the intended environment of use, supported by testing that was conducted.

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 47 CFR Part 2.1093
- 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 the General Population (Leveraged from Previously Cleared Device):

The accuracy and performance of the subject devices intended for the general population (Models: DBP-61D2L, DBP-63D2L, DBP-61D9L, DBP-63D9L, DBP-62F4L, DBP-62F4B, DBP-61F4, DBP-61F4L, DBP-61D2L-P,DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P, DBP-62F4B-P) 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 Pregnant Women(New Study):

A new clinical study was performed to validate the accuracy of the blood pressure monitors for use in pregnant women. The study included 115 subjects (with one exclusion), following ISO 81060-2:2018 and its Amendment 1:2020. Model DBP-6279B was used as the representative test device. The study results confirmed the device's stable performance, meeting clinical use requirements with no adverse events reported. This clinical data supports the pregnant woman indication for models DBP-61D2L-P, DBP-63D2L-P, DBP-61D9L-P, DBP-63D9L-P, DBP-61F4-P, DBP-61F4L-P, DBP-62F4L-P and DBP-62F4B-P.

Equivalence Justification via Bench Testing:

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

Equivalence between the two cuff designs (binding-type and curling-type) used with both Predicate DBP-6279B and representative subject devices(DBP-62F4B-P). Binding-type and curling-type cuffs are equivalent to one another.

Equivalence between the subject device models and the previously cleared model 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 cleared by JOYTECH. Both devices require user's arm should be bare during measurements. Combined with the bench testing equivalence proof between the subject models, the previously cleared model DBP-6279B, and the new clinical data for pregnancy, it is well demonstrated that subject devices are as safe and effective as the predicate device. The above clinical studies can cover the subject devices. No additional study is needed.

10. Conclusions:

The subject devices 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 different questions of safety and effectiveness, and subject devices are as safe and effective as the predicate device.Therefore, the new models as mentioned on this submission are considered substantially equivalent to the predicate device.