August 13, 2026

JOYTECH Healthcare
Ms. Yuanyan Xu
RA
No. 365. Wuzhou Road, Hangzhou City,
311100 Zhejiang, China

Re: K253425
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-6194-P, DBP-6294B-P, DBP-6195P, DBP-6295B-P, DBP-6196P, DBP-6296B-P, DBP-61E1-P, DBP-62E1B-P, DBP-62E3B-P, DBP-61E2-P, DBP-62E2B-P, DBP-61E3-P, DBP-6173-P, DBP-6273B-P,.DBP-6179-P, DBP-6279B-P)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 04, 2026
Received: May 04, 2026

Dear Ms. Yuanyan Xu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253425

Please provide the device trade name(s).

Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-6194-P,DBP-6294B-P,DBP-6195P,DBP-6295B-P, DBP-6196P,DBP-6296B-P,DBP-61E1-P, DBP-62E1B-P,DBP-62E3B-P,DBP-61E2-P,DBP-62E2B-P,DBP-61E3-P,DBP-6173-P,DBP-6273B-P,DBP-6179-P,DBP-6279B-P)

Please provide your Indications for Use below.

The Arm-type Fully Automatic Digital Blood Pressure monitors are intended to measure blood pressure(systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 36 cm or 22cm to42cm or 32cm to 48cm.
The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.

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

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

510(k) Summary

The assigned 510(k) number is: K253425

1. Date Prepared: 2026.07.30

2.1 Subjectter's Identification:

Name: JOYTECH Healthcare Co., Ltd.

Add.: No. 365. Wuzhou Road, Hangzhou City, 311100 Zhejiang, China.

Contact Person: Yuanyuan Xu

Phone: +86-571-81957767

Fax: +86-571-81957750

Email: xuyy@sejoy.com

2.2 Name of the Device:

Trade Name: Arm-type Fully Automatic Digital Blood Pressure Monitor (DBP-6194-P,DBP-6294B-

P,DBP-6195P,DBP-6295B-P, DBP-6196P,DBP-6296B-P,DBP-61E1-P, DBP-62E1B-P,DBP-62E3B-P DBP-61 E2-P DBP-62E2B-P DBP-61 E3-P DBP-6173-P DBP-6273B-P.DBP-6179-P DBP-6279B-P)

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
K232621	TMB-2092-G	DXN	Guangdong Transtek Medical Electronics Co., Ltd.
K230566	DBP-61A0, DBP-62A1B, DBP-61A2, DBP-62A2B, DBP-61A3,DBP-62A3B, DBP-61A4, DBP-62A4B, DBP-6194, DBP-6294B, DBP-6195, DBP-6295B, DBP-6196,DBP-6296B, SBM53,DBP-6279B, DBP-6179,DBP-6273B, DBP-6173	DXN	JOYTECH Healthcare Co., Ltd.

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 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/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%.

Meanwhile, these blood pressure monitor devices can be used as a stand-alone unit to finish the blood pressure measurement or in conjunction with the “JoyTech” APP through the 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 trend graphs of measured systolic and diastolic

blood pressure and pulse rate, 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.

The all models of this application are DBP-6194-P,DBP-6294B-P,DBP-6195-P,DBP-6295B-P, DBP-6196-P,DBP-6296B-P,DBP-61E1-P,DBP-62E1B-P,DBP-62E3B-P,DBP-61E2-P,DBP-62E2B-P,DBP-61E3-P,DBP-6173-P,DBP-6273B-P,DBP-6179-P,DBP-6279B-P. The device is not intended for use in patients with severe arrhythmia.

The detail comparisons among the Arm-Type series are listed in table below:

Models Features	A	B	C	D	E	F	G	H	I	J	K	L	M	N	P
DBP-6273B-P	3*1.5V AAA or adaptor;	2*60	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	142.5 x 107.2 x 44mm	Y	N
DBP-6173-P	3*1.5V AAA or adaptor;	2*60	Y	Y	Y	Y	Y	N	N	Y	Y	Y	142.5 x 107.2 x 44mm	Y	N
DBP-6279B-P	3*1.5V AAA or adaptor;	2*60	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	142.5 x 107.2 x 44mm	Y	N
DBP-6179-P	3*1.5V AAA or adaptor;	2*60	Y	Y	Y	Y	Y	N	N	Y	Y	Y	142.5 x 107.2 x 44mm	Y	N
DBP-6194-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	110.2*101.9*57.3mm	Y	N
DBP-6294B-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	110.2*101.9*57.3mm	Y	N
DBP-6195-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	140.2*103.3*51.1mm	Y	N
DBP-6295B-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	140.2*103.3*51.1mm	Y	N
DBP-6196-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	103*93*51mm	Y	N
DBP-6296B-P	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	103*93*51mm	Y	N
DBP-61E1-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	N
DBP-62E1B-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	N
DBP-61E2-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	Y
DBP-62E2B-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	Y

DBP-61E3-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	Y
DBP-62E3B-P	4*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	160.4 × 99 ×47.5mm	Y	Y

A = Powered Source
B= Memory Size with Time & Date
C = WHO (World Health Organization) Classification Indicator
D = Last 3 Results Average
E = Irregular Heartbeat Detection
F = Arm Shake Detection
G = Cuff Loose Detection
H = Bluetooth Function
I = MVM function
J = Voice
K = Backlight
L = LCD display
M= Size (Viewing Area in unit mm)
N= Cuff Size (22-36cm,22-42cm,32-48cm)
P=Trend chart
Note:
Y= Yes
N = No

The devices are all designed and manufactured according to AAMI/ANSI/IEC80601-2-30:2018, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

The subject device models (DBP-6279B-P, DBP-6173-P, DBP-6273B-P, DBP-6179-P, DBP-6194-P, DBP-6294B-P, DBP-6195-P, DBP-6295B-P, DBP-6196-P and DBP-6296B-P) are respectively equivalent to the predicate device 2 models (DBP-6279B, DBP-6173, DBP-6273B, DBP-6179, DBP-6194, DBP-6294B, DBP-6195, DBP-6295B, DBP-6196 and DBP-6296B) in both hardware and software.

The key factors, such as the pump, the sensors, and the core algorithms are the same between DBP-61E1-P, DBP-62E1B-P, DBP-62E3B-P, DBP-61E2-P, DBP-62E2B-P, DBP-61E3-P, DBP-61A3, DBP-62A3B, DBP-61A4, and DBP-62A4B.

2.6 Indication for use/Intended Use:

The Arm-type Fully Automatic Digital Blood Pressure monitors are intended to measure blood pressure(systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 36 cm or 22cm to42cm or 32cm to 48cm.

The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm.

2.7 Comparison of Technological Characteristics with predicate device:

Comparison item	Subject device in present application	Predicate device 1 K232621 (model:TMB-2092-G)	Predicate device 2 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	/
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
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	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	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	Similar Note 1

	22cm to 36 cm or 22cm to42cm or 32cm to 48cm. The device is also indicated in pregnant women with normotension, gestational hypertension, or preeclampsia with circumference ranging from 22cm to 42cm. .	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 preeclampsia. 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.	22cm to 36cm or 22cm to 42cm or 32cm to 48cm. The Wrist-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 13.5cm to 21.5cm.	
Patient Populations	Cuff 22 ~ 36cm/22cm ~ 42cm/32cm ~ 48cm: adults and adolescents over 12 years of age Cuff 22 ~ 42cm: Adult	Cuff model AC1636-01:at least 3 years of age or older; Cuff model AC2245-021:Adult	at least 12 years of age or older	Similar Note 1

	population or those who with normotension, gestational hypertension, or preeclampsia.	population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.		
Principle	Oscillometric Measuring method	Oscillometric Measuring method	Oscillometric Measuring method	Identical
Anatomical sites	Upper Arm	Upper Arm	Upper Arm	Identical
Where used (hospital, home, ambulance, etc.)	Home and Clinical	Home	Home and Clinical	Identical as predicate device 2
Energy used and /or delivered	DBP-6194-P,DBP-6294B-P,DBP-6195-P,DBP-6295B-P,DBP-6196-P,DBP-6296B-P,DBP-6279B-P,DBP-6179-P, DBP-6273B-P, DBP-6173-P: 3*1.5V AAA battery or Medical AC adaptor	Battery mode: 6VDC (4 * 1.5Vbatteries) AC adapter mode: Input 100-240V, 50-60Hz, 0.2A max; Output 6VDC,1A	DBP-6194,DBP-6294B,DBP-6195,DBP-6295B,DBP-6196,DBP-6296B,DBP-6279B,DBP-6179,DBP-6273B, DBP-6173: 3*1.5V AAA battery or Medical AC adaptor	Identical as predicate device 2
	DBP-61E1-P,DBP-62E1B-P,DBP-61E2-P,DBP-62E2B-P,DBP-61E3-P,DBP-62E3B-P: 4*1.5V AAA battery or		DBP-61A2,DBP-62A2B,DBP-61A3,DBP-62A3B,DBP-61A4, DBP-62A4B: 4*1.5V AAA battery or	

	Medical AC adaptor		Medical AC adaptor	
Human factors	Blood pressure	Blood pressure	Blood pressure	Identical
Performance	Measuring systolic and diastolic blood pressure and pulse rate of patients at least 12 years of age or older, including irregular pulse rhythm detection.	Measuring systolic and diastolic blood pressure and pulse rate of patients at least 3 years of age or older, including irregular pulse rhythm detection.	Measuring systolic and diastolic blood pressure and pulse rate of patients at least 12 years of age or older, including irregular pulse rhythm detection.	Identical
Biocompatibility	Cuff, according to ISO-10993	Cuff, according to ISO-10993	Cuff, according to ISO-10993	Identical
Operation Environment	Temperature: 10℃~ 40℃ Relative Humidity: 15%~93%RH, Atmospheric Pressure: 800hPa~1060hPa	Temperature: 5℃~ 40℃ Relative Humidity: 15%~90%RH, Atmospheric Pressure: 700hPa~1060hPa	Temperature: 10℃~ 40℃ Relative Humidity: 15%~93%RH, Atmospheric Pressure: 800hPa~1060hPa	Identical as predicate device 2
Storage and transportation environment	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temperature: -4 ° F to +140 ° F (-20 ° C to +60 ° C) Relative humidity: ≤ 93%, noncondensing,	Temp.: -25℃~55℃ Humidity: ≤93% RH	Identical as predicate device 2

		at a water vapour pressure up to 50hPa Atmospheric pressure: 500hPa to 1060hPa		
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1	Identical
Blood Pressure Measurement	Pressure: 0mmHg ～ 299 mmHg Pressure: ±3mmHg	0mmHg ~ 299mmHg, 5 ℃ - 40 ℃ within ± 3mmHg(0.4kPa)	Pressure: 0mmHg ～ 299 mmHg Pressure: ±3mmHg	Identical as predicate device 2
Pulse rate measurement	30~180 Beats/Minute ±5%	40 ~ 199 beat/minute ±5%	30~180 Beats/Minute ±5%	Identical as predicate device 2
Cuff Deflation	Automatic deflation	Automatic deflation	Automatic deflation	Identical
PCB or Electrical scheme	DBP-6194-P, DBP-6294B-P, DBP-6195-P, DBP-6295B-P, DBP-6196-P,DBP-6296B-P: BP94PCB DBP-61E1-P,DBP-62E1B-P: BPE1PCB DBP-61E2-P,DBP-62E2B-P, DBP-62E3B-P,DBP-61E3-P:	Unknown	DBP-6194, DBP-6294B, DBP-6195, DBP-6295B, DBP-6196, DBP-6296B: BP94PCB DBP-6179,DBP-6273, DBP-6173,DBP-6279B: BP73PCB DBP-61A0, DBP-62A1B:	Similar The different in the specification is documented and tested

	BPE3PCB DBP-6173-P,DBP-6273B-P, DBP-6179-P,DBP-6279B-P: BP73PCB		BPA0PCB DBP-61A2, DBP-62A2B, DBP-61A3, DBP-62A3B, DBP-61A4, DBP-62A4B: BPA4PCB SBM53: SBM53PCB	
Bump	Micro air pump	Unknown	Micro air pump	Identical as predicate device 2
Valve	Solenoid-controlled valve	Unknown	Solenoid-controlled valve	Identical as predicate device 2
Product Sensor	Silicon integrate pressure sensor	Unknown	Silicon integrate pressure sensor	Identical as predicate device 2
Main chip	SZC900H	Unknown	SZC900H	Identical as predicate device 2
Display Time & Date	Yes	Yes	Yes	Identical
Measure heart rate	Yes	Yes	Yes	Identical
Battery Indicator	Yes	Yes	Yes	Identical

Memory Size	DBP-6194-P,DBP-6294B-P, DBP-6195-P,DBP-6295B-P, DBP-6196-P,DBP-6296B-P, DBP-61E1-P,DBP-62E1B-P, DBP-62E2B-P,DBP-61E3-P, DBP-62E3B-P: 2*150 Memories	500	DBP-6194,DBP-6294B, DBP-6195,DBP-6295B, DBP-6196, DBP-6296B: 2*150 Memories	Identical as predicate device 2
	DBP-6279B-P,DBP-6179-P, DBP-6273B-P,DBP-6173-P, : 2*60 Memories		DBP-61A2,DBP-62A2B, DBP-61A3,DBP-62A3B, DBP-61A4,DBP-62A4B,: 2*120 Memories	
			DBP-6279B,DBP-6179, DBP-6273B,DBP-6173: 2*60 Memories	
Wireless	DBP-6294B-P,DBP-6295B-P, DBP-6296B-P,DBP-62E1B-P, DBP-62E3B-P,DBP-62E2B-P, DBP-6273B-P,DBP-6279B-P: Bluetooth	GSM, LTE	DBP-6279B,DBP-6273B, DBP-62A2B,DBP-62A3B, DBP-62A4B: Bluetooth	Identical as predicate device 2

Note 1: For the general population, the subject device is identical to predicate device 2 (the arm type).

For pregnant women, the subject device is similar to the predicate device 1 (cuff model AC2245-021). The subject device's 22 – 42 cm cuff is smaller

than the 22 – 45 cm cuff of the predicate device, and the predicate device 1 has a wider range of application groups. In addition, the subject device has been verified according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-6, and it also has been validated according to ISO 80601-2-30 and ISO 81060-2. Thus, the differences between the subject device and the predicate devices do not raise different questions of safety and effectiveness.

2.8. Performance Data:

Testing information demonstrating subject devices are as safe and effective as the predicate 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 for the General Population:

This device was tested to ISO 81060-2:20118/Amd.1:2020 Non-invasive sphygmomanometers -Part 2: Clinical investigation of intermittent automated measurement type AMENDMENT 1.

We are applying for 3 different size Arm cuff under 22cm~36cm, 22cm~42cm and 32cm~48cm of this submission.

For cuff 22cm~36cm, 22cm~42cm and 32cm~48cm which are suitable for general subjects, we cite the clinical investigation report of K230566 which already registered. The applicable part of subject devices in this submission and previous arm-type blood pressure monitor models submitted by JOYTECH are both upper-arm. All new design elements have been successfully validated and the results fully demonstrate that the device has as good safety and effectiveness as the predicative device.

Clinical Validation for the Pregnant Women:

A new clinical study was performed to validate the accuracy of the blood pressure monitor for use in pregnant women. The study included 115 subjects (with one exclusion, resulting in a Full Analysis Set of 114 pregnant subjects), following FDA recognized clauses of ISO 81060-2:2018 and its Amendment 1:2020. Model DBP-6279B was used as the representative test device. Subjects were distributed equally across three clinical subgroups: gestational normotension (n=38), gestational hypertension (n=38), and preeclampsia (n=38), with arm circumferences ranging from 22 cm to 42 cm. A total of 342 sets of valid blood pressure measurements were collected across 114 subjects (≥3 sets per subject). The mean difference for systolic blood pressure was -0.89 mmHg (SD: 5.60 mmHg) and for diastolic blood pressure was -0.17 mmHg (SD: 4.65 mmHg), both meeting the ISO 81060-2:2018 accuracy requirements. 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-6194-P, DBP-6294B-P, DBP-6195-P, DBP-6295B-P, DBP-6196-P, DBP-6296B-P, DBP-61E1-P, DBP-62E1B-P, DBP-62E3B-P, DBP-61E2-P, DBP-62E2B-P, DBP-61E3-P, DBP-6173-P, DBP-6273B-P, DBP-6179-P, and DBP-6279B-P.

Note: Model DBP-6279B was selected as the worst-case representative device for the clinical study, as it incorporates Bluetooth functionality and the largest display in its model family. The accuracy results therefore support the pregnant woman indication across all submitted "-P" models.

Pulse Rate Clinical Validation:

A clinical validation study was conducted to evaluate the pulse rate (PR) measurement accuracy of the subject device by comparison with a reference device. A total of 85 adult subjects were enrolled. Statistical results showed that the mean bias was within ±5% of the mean heart rate measured by the reference device, the root-mean-square error (RMSE) was less than 3 bpm, and the proportion of discrete points falling outside the 95% limits of agreement in the Bland-Altman analysis was less than 5%. These metrics collectively indicate that the device provides accurate pulse-rate measurements within its specified intended use.

2.11. 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.

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