August 25, 2023

Joytech Healthcare Co.,Ltd
Yunhua Ren, General Manager
No.365, Wuzhou Road
Yuhang Economic Development Zone, Hangzhou City
Hangzhou, Zhejiang 311100
China

Re: K230566
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor, Wrist-type Fully Automatic Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 27, 2023
Received: July 27, 2023

Dear Yunhua Ren:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Robert T. Kazmierski -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230566

Device Name
Fully Automatic Digital Blood Pressure Monitor
Including
Arm-type: 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;
Wrist-type: DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B, DBP-8197, DBP-8297B, DBP-8198, DBP-8298B, DBP-8199, DBP-8299B;

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.

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.

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: _____

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: Yunhua Ren

Phone: +86-571-81957767

Fax: +86-571-81957750

Email: renyh@sejoy.com

2.2 Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor

Arm-type	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
Wrist-type	DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B, DBP-8197, DBP-8297B, DBP-8198, DBP-8298B, DBP-8199, DBP-8299B

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 device:

510(k) number	Predicate device model	Product code	Manufacturer
K212115	DBP-6279B	DXN	JOYTECH Healthcare Co., Ltd.

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

510(k) number	Predicate device model	Product code	Manufacturer
K212115	DBP-8278B	DXN	JOYTECH Healthcare Co., Ltd.

2.5 Device Description:

The Arm-type and Wrist-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/wrist 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 “JoyHealth” 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-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,DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B, DBP-8197, DBP-8297B, DBP-8198, DBP-8298B, DBP-8199, DBP-8299B.

And DBP-6279B,DBP-6179, DBP-6273B, DBP-6173 already have 510k number of K212115. But now these models have changed specifications on cuff size and measuring range of diastolic Pressure.So we are applying for new 510K.

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
DBP-61A0	3*1.5V AAA or Adaptor	1*30	Y	Y	Y	Y	Y	N	N	Y	Y	Y	98×90×61.8mm	Y
DBP-62A1B	3*1.5V AAA or Adaptor	1*30	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	98×90×61.8mm	Y
DBP-61A2	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	124*92*43mm	Y
DBP-62A2B	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	124*92*43mm	Y
DBP-61A3	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	124*92*43mm	Y
DBP-62A3B	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	124*92*43mm	Y
DBP-61A4	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	124*92*43mm	Y
DBP-62A4B	4*1.5V AAA or Adaptor	2*120	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	124*92*43mm	Y
DBP-6194	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	110.2*101.9*57.3 mm	Y
DBP-6294B	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	110.2*101.9*57.3 mm	Y
DBP-6195	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	140.2*103.3*51.1 mm	Y
DBP-6295B	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	140.2*103.3*51.1 mm	Y
DBP-6196	3*1.5V AAA or	2*150	Y	Y	Y	Y	Y	N	N	Y	Y	Y	103*93*51mm	Y

	Adaptor													
DBP-6296B	3*1.5V AAA or Adaptor	2*150	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	103*93*51mm	Y
SBM53	4*1.5V AAA	2*120	Y	N	Y	N	Y	N	N	Y	Y	Y	125 X 95 X 44mm	Y
DBP-6279B	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
DBP-6179	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
DBP-6273B	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
DBP-6173	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

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 = MAM fucntion
J = Voice
K = Backlight
L = LCD display
M= Size (Viewing Area in unit mm)
N= Cuff Size (22-36cm,22-42cm,32-48cm)
Note:
Y= Yes
N = No

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

Models Features	A	B	C	D	E	F	G	H	I	J	K	L	M	N
DBP-81A5	2*1.5V AAA	2*100	Y	Y	Y	Y	N	N	N	Y	Y	Y	86*64*30mm	Y
DBP-82A5B	2*1.5V AAA	2*100	Y	Y	Y	Y	N	Y	N	Y	Y	Y	86*64*30mm	Y
DBP-81A6	2*1.5V AAA	2*100	Y	Y	Y	Y	N	N	N	Y	Y	Y	86*64*30mm	Y
DBP-82A6B	2*1.5V AAA	2*100	Y	Y	Y	Y	N	Y	N	Y	Y	Y	86*64*30mm	Y
DBP-8197	2*1.5V AAA	2*150	Y	Y	Y	Y	N	N	N	Y	Y	Y	83×64×30.7mm	Y
DBP-8297B	2*1.5V AAA	2*150	Y	Y	Y	Y	N	Y	N	Y	Y	Y	83×64×30.7mm	Y
DBP-8198	2*1.5V AAA	2*150	Y	Y	Y	Y	N	N	N	Y	Y	Y	82.3×63.8×27.5mm	Y
DBP-8298B	2*1.5V AAA	2*150	Y	Y	Y	Y	N	Y	N	Y	Y	Y	82.3×63.8×27.5mm	Y
DBP-8199	2*1.5V AAA	2*150	Y	Y	Y	Y	N	N	N	Y	Y	Y	83×64×30.7mm	Y
DBP-8299B	2*1.5V AAA	2*150	Y	Y	Y	Y	N	Y	N	Y	Y	Y	83×64×30.7mm	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 = MAM function
J = Voice
K = Backlight
L = LCD display
M= Size (Viewing Area in unit mm)
N= Cuff Size (13.5-21.5cm)
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.

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 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.

2.7 Comparison of Technological Characteristics with predicate device:

2.7.1 Arm-type

The arm-type blood pressure monitor manufactured by JOYTECH Healthcare Co., Ltd. have the same features and specifications with the JOYTECH blood pressure monitor DBP-6279B which 510k number is K212115, therefore we choose the device act as the predicate device. The detail comparison of technical characteristic as below:

Comparison item	Subject device in present application	Predicate device K212115 (model: DBP-6279B)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Arm-type Fully Automatic Digital Blood Pressure Monitor	Identical
Manufacturer	JOYTECH Healthcare 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	Identical
Regulatory class	II	II	Identical
Panel	74 Cardiovascular	74 Cardiovascular	Identical
Product code	DXN	DXN	Identical
Indication for use	The Arm-type Fully Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age.	The Arm-type Fully Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age.	Identical
Measuring principle	Oscillometric method	Oscillometric measurement	Identical
Measurement type	Determined during inflation	Determined during inflation	Identical
Cuff location	Upper arm	Upper arm	Identical
Specification			
Measuring range	Systolic Pressure: 60mmHg ～ 260 mmHg Diastolic Pressure:40mmHg ～ 200 mmHg Pressure: 0mmHg～299 mmHg Pressure: ±3mmHg Pulse:30~180 Beats/Minute Pulse: ±5%	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure:30mmHg～200 mmHg Pressure: 0mmHg～299 mmHg Pressure: ±3mmHg Pulse:30~180 Beats/Minute Pulse: ±5%	Similar, The difference has tested with qualified results.
Inflation	By air pump	By air pump	Identical
Pressure release	By solenoid valve	By solenoid valve	Identical
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric: 800hPa~1060hPa	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric: 800hPa~1060hPa	Identical
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.: -25℃~55℃ Humidity: ≤93% RH	Identical
Cuff circumference	Fits arm circumference 22-36 cm or 22-42cm or 32-48cm;	Fits arm circumference 22-36 cm	Similar, only the cuff size is different
Supply power source	DBP-61A0,DBP-62A1B,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	3*1.5V AAA battery or Medical AC adaptor;	Similar, The different power has tested with qualified results.

	DBP-61A2,DBP-62A2B,DBP-61A3,DBP-62A3B,DBP-61A4, DBP-62A4B: 4*1.5V AAA battery or Medical AC adaptor SBM53: 4*1.5V AAA battery		
PCB or Electrical scheme	BP94PCB BP97PCB BP98PCB BPA0PCB BPA4PCB BPA5PCB BPA6PCB BP73PCB SBM53PCB	BP73PCB	Similar, The different in the PCB is documented and tested
Display component	1.Device LCD; 2.iOS device or Android device	1.Device LCD; 2.iOS device or Android device	Identical
Bluetooth Module version	V5.0	V5.0	Identical
System requirement	Bluetooth 4.0 or later/ Android 5.0 or later/ IOS 9.0 or later	Bluetooth 4.0 or later/ Android 5.0 or later/ IOS 9.0 or later	Identical
Bluetooth features	Transmit data to smart phone via Bluetooth	Transmit data to smart phone via Bluetooth	Identical
Function on APP	Storage test result/ Announce test result/ Read memories in App/ Empty memories in App/ Draw curve/ Set the personal information in app	Storage test result/ Announce test result/ Read memories in App/ Empty memories in App/ Draw curve/ Set the personal information in app	Identical
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0.5dBi	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0dBi	Equivalent, The difference have verified by FCC test
Sterilization	Not applicable	Not applicable	Identical
Features			
Irregular heart beat	Yes	Yes	Identical
Blood Pressure categories	WHO classification	WHO classification	Identical
Arm shake indicator	DBP-6194,DBP-6294B,DBP-6195,DBP-6295B,DBP-6196,DBP-6296B,DBP-61A0,DBP-62A1B,DBP-61A2,DBP-62A2B,DBP-61A3,DBP-62A3B,DBP-61A4,DBP-62A4B,DBP-6279B,DBP-6179, DBP-6273B, DBP-6173	Yes	Yes	Identical
	SBM53	No		

Cuff loose indicator	Yes	Yes	Identical
Memory	DBP-6194,DBP-6294B,DBP-6195,DBP-6295B,DBP-6196,DBP-6296B: 2*150 Memories	2*60 Memories	Similar, Note 1
	DBP-61A0,DBP-62A1B: 1*30 Memories		
	DBP-61A2,DBP-62A2B,DBP-61A3,DBP-62A3B,DBP-61A4,DBP-62A4B,SBM53: 2*120 Memories		
	DBP-6279B,DBP-6179, DBP-6273B, DBP-6173: 2*60 Memories		
Material	ABS for the case and plastic foil for the labels of the device. Bio-compatibility materials are used for the applied parts (Cuff containing a interal bladder)	ABS for the case and plastic foil for the labels of the device. Bio-compatibility materials are used for the applied parts (Cuff containing a interal bladder)	Identical

Note 1: 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.

2.7.2 Wrist-type

The wrist-type blood pressure monitor manufactured by Joytech Healthcare Co.,Ltd have the same wrist cuff type, features and specifications with the Joytech blood pressure monitor DBP-8278B which 510k number is K212115, therefore we choose the device act as the predicate device. The detail comparison of technical characteristic as below:

Comparison item	Subject device in present application	Predicate device K212115 (Model: DBP-8278B)	Comparison result / Explanation
The trade name	Wrist-type Fully Automatic Digital Blood Pressure Monitor	Wrist-type Fully Automatic Digital Blood Pressure Monitor	/
Manufacturer	JOYTECH Healthcare 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	Identical
Regulatory class	II	II	Identical
Panel	74 Cardiovascular	74 Cardiovascular	Identical
Product code	DXN	DXN	Identical
Indication for use	The Fully Automatic Blood Pressure Monitors are intended to measure blood pressure	The Fully Automatic Blood Pressure Monitors	Identical

	(systolic and diastolic) and pulse rate of adults and adolescents over 12 year of age.	are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 year of age.	
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during inflation	Determined during inflation	Identical
Cuff location	Wrist	Wrist	Identical
Specification			
Measuring range	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 40mmHg～200 mmHg Pulse:30~180 Beats/min	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 30mmHg～200 mmHg Pulse:30~180 Beats/min	Identical
Cuff circumference	Fits wrist circumference 13.5-21.5cm	Fits wrist circumference 13.5-21.5cm	Identical
Accuracy	Static Pressure:± 3mmHg Pulse: ± 5%	Static Pressure:± 3mmHg Pulse: ± 5% of display reading	Identical
Inflation	By air pump	By air pump	Identical
Pressure release	By solenoid valve	By solenoid valve	Identical
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric: 800hPa~1060hPa	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric: 800hPa~1060hPa	Identical
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.: -25℃~55℃ Humidity: ≤93% RH	Identical
Supply power source	DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B, DBP-8197, DBP-8297B, DBP-8198, DBP-8298B, DBP-8199, DBP-8299B: 2*1.5V AAA battery	2*1.5V AAA battery	Identical
Display component	1.Device LCD; 2.iOS device or Android device	1.Device LCD; 2.iOS device or Android device	Identical
Bluetooth Module version	V5.0	V5.0	Identical
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0.5dBi	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0 dBi	Equivalent, The difference have verified by FCC test.
Bluetooth features	Transmit data to smart phone via Bluetooth	Transmit data to smart phone via Bluetooth	Identical
Function on APP	Storage test result/ Announce test result/ Read memories in App/	Storage test result/ Announce test result/	Identical

	Empty memories in App/ Draw curve/ Set the personal information in app	Read memories in App/ Empty memories in App/ Draw curve/ Set the personal information in app	
Sterilization	Not applicable	Not applicable	Identical
Features			
Irregular heart beat	Yes	Yes	Identical
Body movement detection	Yes	Yes	Identical
WHO classification indicator	Yes	Yes	Identical
Memory	DBP-8197, DBP-8297B, DBP-8198, DBP-8298B, DBP-8199, DBP-8299B: 2*150 Memories; DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B: 2*100 Memories;	2*60 memories	Similar Note 1
Dimension of LCD display	DBP-8197, DBP-8297B:46mm×31.2mm DBP-8199, DBP-8299B: 45mm×30.5mm DBP-8198, DBP-8298B: 36.5mm×36.5mm DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B:47mm×38mm	44mm×42mm	Different Note 2
Dimension of device apperance	DBP-8197, DBP-8297B, DBP-8199, DBP-8299B: 83mm×64mm×30.7mm DBP-8198, DBP-8298B: 82.3mm×63.8mm×27.5mm DBP-81A5, DBP-82A5B, DBP-81A6, DBP-82A6B: 86mm×64mm×30mm	73mm×66mm×27.5mm	Different Note 3
Number of buttons	DBP-8197, DBP-8297B, DBP-8199, DBP-8299B, DBP-81A6, DBP-82A6B: 3 DBP-8198, DBP-8298B: 2 DBP-81A5, DBP-82A5B: 4	2	Similar Note 4

Note 1: 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.

Note 2: The dimension of LCD display is different between subject devices and predicate device, the difference does not affect the intended use or the fundamental scientific technology. And all subject devices models passed relevant IEC series standard. These differences will not bring any new risks.

Note 3: The dimension of device apperance is different between subject devices and predicate device. Differen apperance design to meet market's requirement. the difference does not affect the intended use or the fundamental scientific technology. And all subject devices models passed relevant IEC series standard. These differences will not bring any new risks.

Note 4: The number of buttons is different between subject devices and predicate device. the difference does not affect the intended use or the fundamental scientific technology. And all subject devices models passed relevant IEC series standard. These differences will not bring any new risks.

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.

2.9. Discussion of Clinical Tests Performed:

Clinical Validation:

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

Arm-type:

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

For 22cm~36cm, we cite the clinical investigation report of K212115 which already registered since the cuff is totally same.

For 22cm~42cm, we use a clinical investigation report from another submission. Because the cuff is totally same. In this report, there are 88 patients (47females and 41 males) with cuff 22cm~42cm participated in the clinical study.

For 32cm~48cm, Model DBP-6279B was selected as representative for testing. 85 patients (36 females and 49 males) participated in the clinical study.

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.

Wrist-type:

For Wrist-type blood pressure monitor of 10 Models only with one cuff size of 13.5cm~21.5cm.

we cite the clinical investigation report of K212115 which already registered since the cuff is totally same.

2.10. Conclusions:

This submitted arm-type series manufactured by JOYTECH Healthcare Co., Ltd. have been found to be respectively substantially equivalent to the predicate device (DBP-6279B) manufactured by JOYTECH Healthcare Co., Ltd. (K212115). Based on the information provided in this submission, differences between the subject device and predicate device have been tested and documented, it has been demonstrated that the subject devices are as safe and effective as the predicate device.

This submitted wrist-type series manufactured by JOYTECH Healthcare Co., Ltd. have been found to be respectively substantially equivalent to the predicate device (DBP-8278B) manufactured by JOYTECH Healthcare Co., Ltd. (K212115). Based on the information provided in this submission, differences between the subject device and predicate devices have been tested and documented, it has been demonstrated that the subject devices are as safe and effective as the predicate device.

In the other words, the difference between the subject and the predicate devices does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device, and the new models as mentioned on this submission are considered substantial equivalent to the predicate devices。

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