Jan 5, 2022

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

Re: K212115
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: November 27, 2021
Received: December 7, 2021

Dear Ren Yunhua:

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,

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)*
K212115

Device Name
Fully Automatic Digital Blood Pressure Monitor
Including
Arm-type: DBP-6279B, DBP-6179, DBP-6173, DBP-6273B, DBP-6275B, DBP-6175, DBP-6277B, DBP-6177, DBP-6181, DBP-6281B, DBP-6182, DBP-6282B, DBP-6185, DBP-6285B, DBP-6186, DBP-6286B, DBP-6191
Wrist-type: DBP-8276H, DBP-8176H, DBP-8278B, DBP-8178, DBP-8288B, DBP-8188, DBP-8189

Indications for Use *(Describe)*

The 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.

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: K212115

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

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2.2 Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor

Arm-type	DBP-6279B, DBP-6179, DBP-6173, DBP-6273B, DBP-6275B, DBP-6175, DBP-6277B, DBP-6177, DBP-6181, DBP-6281B, DBP-6182, DBP-6282B, DBP-6185, DBP-6285B, DBP-6186, DBP-6286B, DBP-6191
Wrist-type	DBP-8276H, DBP-8176H, DBP-8278B, DBP-8178, DBP-8288B, DBP-8188, DBP-8189

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
K161886	H-BP100SBP	DXN	Guangdong Transtek Medical Electronics 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
K182127	BP6100	DXN	OMRON HEALTHCARE Co., Ltd.
K182166	BP4350	DXN	OMRON 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 detail comparisons among the Arm-Type series are listed in table below:

Features / Models	A	B	C	D	E	F	G	H	I（mm）	J（cm）	K(mm)	L	M	N	O	P	Q	R	S	T
DBP-6179	Y	O	60 Memories×2	Y	N	Y	Y	Y	142.5*107.2*44	22-36	112*62	O	O	N	N	N	N	O	Y	Y
DBP-6279B	Y	O	60 Memories×2	Y	N	Y	Y	Y	142.5*107.2*44	22-36	112*62	O	O	N	N	Y	N	O	Y	Y
DBP-6173	Y	O	60 Memories×2	Y	N	Y	Y	Y	142.5*107.2*44	22-36	95.5*54.5	O	O	N	N	N	N	O	Y	Y
DBP-6273B	Y	O	60 Memories×2	Y	N	Y	Y	Y	142.5*107.2*44	22-36	95.5*54.5	O	O	N	N	Y	N	O	Y	Y
DBP-6175	Y	O	60 Memories×2	Y	N	Y	Y	Y	128*130*144	22-36	118*65	O	O	N	N	N	N	O	Y	Y
DBP-6275B	Y	O	60 Memories×2	Y	N	Y	Y	Y	128*130*144	22-36	118*65	O	O	N	N	Y	N	O	Y	Y
DBP-6177	Y	O	60 Memories×2	Y	N	Y	Y	Y	149.8*80.4*45.7	22-36	83.1*53.1	O	O	N	N	N	N	O	Y	Y
DBP-6277B	Y	O	60 Memories×2	Y	N	Y	Y	Y	149.8*80.4*45.7	22-36	83.1*53.1	O	O	N	N	Y	N	O	Y	Y
DBP-6181	Y	O	60 Memories×2	Y	N	Y	Y	Y	155.5*108.5*75	22-36	87.5*85	O	O	N	N	N	N	O	Y	Y
DBP-6281B	Y	O	60 Memories×2	Y	N	Y	Y	Y	155.5*108.5*75	22-36	87.5*85	O	O	N	N	Y	N	O	Y	Y
DBP-6182	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	N	N	O	Y	Y
DBP-6282B	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	Y	N	O	Y	Y
DBP-6185	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	N	N	O	Y	Y
DBP-6285B	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	Y	N	O	Y	Y
DBP-6186	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	N	N	O	Y	Y
DBP-6286B	Y	O	60 Memories×2	Y	N	Y	Y	Y	150*108*65	22-36	87.5*85	O	O	N	N	Y	N	O	Y	Y
DBP-6191	Y	O	60 Memories×2	Y	N	Y	Y	Y	136*94.5*57	22-36	50*62	O	O	N	N	N	N	O	Y	Y

A = Powered by 3 AAA size batteries
B= Powered by AC adaptor
C = Memory Size
D = Time & Date
E = Results Average in Three way
F = WHO (World Health Organization) Classification Indicator
G = Last 3 Results Average

H = Irregular Heartbeat Detection
I = Outside Demission (L x W x H in unit mm)
J = Cuff Size
K = LCD Size (Viewing Area in unit mm)
L = LCD Backlight
M= Voice
N= PC connecter
O=Music
P=Bluetooth Function
Q=mmHg/kPa Switchable
R=Beep buzzer
S= Cuff Loose Detection
T= Arm Shake Detection

Note:
Y= Yes
N = No
O= Optional function depending on clients' needs

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

Features / Models	A	B	C	D	E	F	G	H（mm）	I (cm)	J(mm)	K	L	M	N	O	P	Q	R	S	T
DBP-8176H	Y	60 Memories×2	Y	Y	Y	Y	Y	62*55.2*19	13.5-21.5	34*34.6	Y	N	N	N	N	Y	O	Y	N	O
DBP-8276H	Y	60 Memories×2	Y	Y	Y	Y	Y	62*55.2*19	13.5-21.5	34*34.6	Y	N	N	Y	N	Y	O	Y	N	O
DBP-8178	Y	60 Memories×2	Y	Y	Y	Y	Y	73*66*27.5	13.5-21.5	44*42	O	O	N	N	N	O	O	Y	N	N
DBP-8278B	Y	60 Memories×2	Y	Y	Y	N	Y	73*66*27.5	13.5-21.5	44*42	O	O	N	Y	N	O	O	Y	N	N
DBP-8188	Y	60 Memories×2	Y	Y	Y	Y	Y	84*62*25	13.5-21.5	43.7*40	O	O	N	N	N	O	O	Y	N	N
DBP-8288B	Y	60 Memories×2	Y	Y	Y	Y	Y	84*62*25	13.5-21.5	43.7*40	O	O	N	Y	N	O	O	Y	N	N
DBP-8189	Y	60 Memories×2	Y	Y	Y	Y	Y	84*62*23.6	13.5-21.5	32*40.5	O	N	N	N	N	Y	O	Y	N	N

Note: DBP-8276H, DBP-8176H are equipped with lithium battery. Other models equipped with alkaline battery.

A = Powered by AAA Batteries / Lithium battery
(DBP-8276H, DBP-8176H equipped with rechargeable lithium battery)
B= Memory Size
C= Time & Date
D = WHO (World Health Organization) Classification Indicator
E = Last 3 Results Average
F = Irregular Heartbeat Detection
G = Low Voltage detection
H= Outside Dimension (L x W x H in unit mm)
I = Cuff Size
J = LCD Size (Viewing Area in unit mm)
K= LCD Backlight
L= Voice
M= PC connecter
N=Bluetooth function
O=mmHg/kPa Switchable
P=Beep buzzer
Q=Heart Zone indicator

R= Arm Shake indicator
S= Cuff Loose indicator
T=Powered by AC adaptor
Note:
Y= Yes
N = No
O= Optional function depending on clients' needs

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 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.

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.

2.7 Comparison of Technological Characteristics with predicate device:

2.7.1 Arm-type

The arm-type blood pressure monitor manufactured by JOYTECH have the same arm cuff type, features and specifications with the Welch Allyn blood pressure monitor H-BP100SBP which 510k number is K161886, 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 K161886 (model:H-BP100SBP)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Welch Allyn Blood Pressure Device	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	Guangdong Transtek Medical Electronics 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	Welch Allyn Blood Pressure	Similar

	Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age.	Device H-BP100SBP is digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 15 cm to 54 cm (about 6-21 inches). These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.	Note1
Measuring principle	Oscillometric method	Oscillometric method	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: 30mmHg～200 mmHg Pulse:30~180 Beats/Minute	Systolic Pressure: 50mmHg ～ 260 mmHg Diastolic Pressure: 25mmHg～220 mmHg Pulse:40~199 Beats/Minute	Similar. Note2
Max cuff pressure	299 mmHg	300mmHg	Similar
Accuracy	Static Pressure:± 3mmHg Pulse: ± 5%	Pressure:±0.4kPa (3mmHg) Pulse value: ± 5%	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.:5℃~40℃ Relative humidity 85%RH Atmospheric pressure:86kPa to 106kPa	Similar Note 3
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.:-20℃~60℃ Relative Humidity: 10% RH－93% RH Atmospheric Pressure: 50kPa to 106 kPa	Similar Note 4
Cuff circumference	Fits arm circumference 22-36 cm	The three preformed cuff units, which are applicable to arm circumference between 15-24cm, 22-42cm and 40-54cm to meet different Population's need.	Similar. Note 5
Supply power source	3x1.5V AAA battery or 2MOPP Medical AC adaptor (DC 5V, 1A, recommend but not provide)	powered by four AA alkaline batteries or by a AC adapter (DC 6V,1A)(not include)	Similar The different in the specification is documented and tested
PCB or Electrical scheme	BP73PCB BP75PCB	Unknown	Similar The different in the

	BP77PCB BP81PCB BP91PCB		specification 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	V4.0	Similar. Note6
System requirement	Bluetooth 4.0 or later/ Android 5.0 or later/ IOS 9.0 or later	Platform which support Bluetooth 4.0 technology	Similar Note 7
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	Unknown	Different. Note8
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0.5dBi	Frequency range: 2.4 GHz (2402 - 2480 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	Irregular heart beat is displayed on the LCD.	Irregular heart beat is displayed on the LCD.	Identical
Blood Pressure categories	WHO classification	Blood pressure high and low distinguish	Similar Note9
Arm shake indicator	Yes	Yes	Identical
Cuff loose indicator	Yes	None	Different. Note10
Memory	2*60 Memories in Two Groups with Date and Time	Have memory function	Similar. Note11
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 is used to outer housing of the main unit.	Similar. Note12

Note1: The intended use of subject device and predicate device are the same. The clinical accuracy of subject device applied to adolescents over 12 years of age population have been verified and validation , which comply with the requirements of ISO 81060-2. And the clinical safety also have been validated as for without any AE or side-effect in clinical investigation.

Note2: The measuring range of the subject device have been verified by IEC60601-1 and IEC 80601-2-30 standard test.

Note3: The operation environment of the subject device have been verified by IEC 60601-1 and IEC 80601-2-30 standard test.

Note4: The storage environment of the subject device have been verified by IEC 60601-1 and IEC 80601-2-30 standard test.

Note5: The safety and effective for fits arm circumference 22-36cm of subject device have been verified and validation by bench test according to IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30. Meanwhile, the clinical accuracy of cuff size 22-36cm have been validation according to the ISO 81060-2:2018, which cannot raise new safety and effective issue.

Note 6: The subject device adopt new BT version and it could compatible for BT 4.0. The cybersecurity risk has been considered and the overall residual risk is acceptable.

Note7: All over of subject models have passed FCC, EN301489-1, EN301489-17, EN 300328 and wireless coexistence test.

Note8: The change in the specification is documented, and the cybersecurity risk has been considered and the overall residual risk is acceptable. The change does not affect the intended use or the fundamental scientific technology.

Note9: The blood pressure WHO classification function have been verified by software verified and validation report.

Note10: The cuff loose indicator function of subject device have been verified and validation through Software verified and validation report. And this function adding cannot bring new risks.

Note 11: 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.

Note12:The materials of cuff from subject device have been tested and found to comply with requirements of ISO 10993-5: 2009 and ISO 10993-10:2010, which cannot result in cytotoxicity, sensitization and Irritation or intracutaneous reacticity.

2.7.2 Wrist-type

The wrist-type blood pressure monitor manufactured by JOYTECH have the same wrist cuff type, features and specifications with the Omron wrist blood pressure monitor BP6100 which 510k number is K182127, therefore we choose the device act as the predicate device. While BP6100 model has no bluetooth function, Omron wrist blood pressure monitor BP4350 (K182166) was chosen to be predicate device 2 with bluetooth function. The detail comparison of technical characteristic as below:

Comparison item	Subject device in present application	Predicate device 1 K182127	Predicate device 2 K182166	Comparison result /

		(Model:BP6100)	(Model: BP4350)	Explanation
The trade name	Wrist-type Fully Automatic Digital Blood Pressure Monitor	Wrist Blood Pressure Monitor Model BP6100	Wrist Blood Pressure Monitor Model BP4350	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	OMRON HEALTHCARE Co., Ltd	OMRON 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	The Fully Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 year of age.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Similar Note1
Measuring principle	Oscillometric method	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during inflation	Determined during inflation	Determined during inflation	Identical
Cuff location	Wrist	Wrist	Wrist	Identical
Specification				
Measuring range	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 30mmHg～200 mmHg Pulse:30~180 Beats/min	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 40 mmHg～215 mmHg Pulse:40~180 Beats/min	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 40 mmHg～215 mmHg Pulse:40~180 Beats/min	Similar. Note 2
Max cuff pressure	299 mmHg	299 mmHg	299 mmHg	Identical
Cuff	Fits wrist	Fits wrist circumference	Fits wrist circumference	Identical

circumference	circumference 13.5-21.5cm	13.5-21.5cm	13.5-21.5cm	
Accuracy	Static Pressure:± 3mmHg Pulse: ± 5%	Static Pressure:± 3mmHg Pulse: ± 5% of display reading	Static Pressure:± 3mmHg Pulse: ± 5% of display reading	Identical
Inflation	By air pump	By air pump	By air pump	Identical
Pressure release	By solenoid valve	By solenoid valve	By solenoid valve	Identical
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric: 800hPa~1060hPa	Temp.: 10℃~40℃ Humidity: 15~90%RH Atmospheric: 800hPa~1060hPa	Temp.: 10℃~40℃ Humidity: 15~90%RH Atmospheric: 800hPa~1060hPa	Similar Note 3
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.:-20℃~60℃ Relative Humidity: 10% RH – 90% RH Atmospheric	Temp.:-20℃~60℃ Relative Humidity: 10% RH – 90% RH Atmospheric	Similar Note 4
Supply power source	For models DBP-8178, DBP-8278B, DBP-8188, DBP-8288B, DBP-8189: 2x1.5V AAA battery DBP-8276H and DBP-8176H are powered by 3.7 V rechargeable lithium battery or 2MOPP Medical AC adaptor (DC 5V,1A, recommend but not provide)	Two “AAA” batteries 1.5v	Two “AAA” batteries 1.5v	Similar. Note 5
Display component	1.Device LCD; 2.iOS device or Android device	Device LCD	1.Device LCD; 2.iOS device or Android device	Identical to predicate device 2.
Bluetooth Module version	V5.0	None	Unknown	Note 6
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation type: GFSK Antenna gain: 0.5dBi	None	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: < 20 dBm	Equivalent The difference have been verified by FCC test.
Bluetooth features	Transmit data to smart phone via Bluetooth	None	Transmit data to smart phone via Bluetooth	Identical to the predicate device 2.
Function on APP	Storage test result/ Announce test result/ Read memories in App/ Empty memories in App/	None	Storage test result/Read memories in App/ Empty memories in App/etc.	Similar Note 7

	Draw curve/ Set the personal information in app			
Sterilization	Not applicable	Not applicable	Not applicable	Identical
Features				
Irregular heart beat	Irregular heart beat is displayed on the LCD.	Irregular heart beat is displayed on the LCD.	Irregular heart beat is displayed on the LCD.	Identical
Body movement detection	Yes	Yes	Yes	Identical
Cuff loose detection	No	Yes	Yes	Different Note 8
Heart zone indicator	Prompt the user whether the cuff is located in correct height when measurement.	Yes	Yes	Identical
WHO /ACC AHA classification indicator	Yes	Yes	Yes	Identical
Memory	2*60 Memories in Two Groups with Date and Time	60 memories in one groups	2*100 Memories in Two Groups with Date and Time	Similar Note 9

Note1: The intended use of subject device and predicate device are the same. The clinical accuracy of subject device applied to adolescents over 12 years of age population have been verified and validation , which comply with the requirements of ISO 81060-2. And the clinical safety also have been validated as for without any AE or side-effect in clinical investigation.

Note 2: The measuring range of the subject device have been verified by IEC 60601-1 and IEC 80601-2-30 standard test.

Note 3: The operation environment of the subject device have been verified by IEC 60601-1 and IEC80601-2-30 standard test.

Note 4: The storage environment of the subject device have been verified by IEC 60601-1 and IEC80601-2-30 standard test.

Note 5: The supplied power of subject device model DBP-8278B, DBP-8178, DBP-8288B, DBP-8188, DBP-8189 are the same as the predicate device 1 and 2. The model DBP-8276H and DBP-8176H equipped with rechargeable lithium battery or powered by 2MOPP medical AC adaptor (Recommend but not provide). The lithium battery have pass the IEC 62133-2:2017 test. The Adaptor interface have been verified through safety and EMC test. The risk from lithium battery have been analysis and evaluation in risk management report , and the overall residual risk is acceptable.

Note 6: Although the Bluetooth module version of predicate device BP4350 was unknown, The subject device adopt new BT version 5.0 and it could compatible for BT 4.0. The cybersecurity risk has been considered and the overall residual risk is acceptable.

Note 7: The change in the specification is documented, and the cybersecurity risk has been considered and the overall residual risk is acceptable. The change does not affect the intended use or the fundamental scientific technology.

Note 8: Comparing with the predicate device, cuff loose indicate function deleting does not affect the the intended use or the fundamental scientific technology. And this function have been verified in software verification and validation report. This function adding cannot bring new risks.

Note 9: 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:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 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 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 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN300328:Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;
- ETSI EN 301489-1: Electromagnetic compatibilityand Radio spectrum Matters(ERM);ElectroMagnetic Compatibility (EMC)standard for radio equipment and services;Part 1:Common technical requirements;
- ETSI EN 301489-17: Electromagnetic compatibility and Radio spectrum Matters (ERM);

ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions or Broadband Data Transmission Systems;

Bio-compatibility Evaluation for patient contacting components:

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 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," dated May 11, 2005.

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.

Arm-type:

In the Arm-type fully automatic digital blood pressure clinical investigation, 85 patients (46 females and 39 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:

Even through the wrist circumference size of cuff is the same (13.5-21.5cm)among these subject wrist-type blood pressure monitors, but the the air bag size inside the wrist cuff have tiny difference, therefore we have conduct two clinical accuracy investigation which choose two

different representative models.

In the Wrist-type fully automatic digital blood pressure clinical investigation, Model DBP-8278B was selected as representative for testing. 85 patients (43 females and 42 males) participated in the clinical study. Same wrist 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.

In the Wrist-type fully automatic digital blood pressure clinical investigation, Model DBP-8276H was selected as representative for testing. 85 patients (41 females and 44 males) participated in the clinical study. Same wrist 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.

2.11. Conclusions:

This submitted arm-type series manufactured by JOYTECH Healthcare Co., Ltd. have been found to be respectively substantially equivalent to the predicate device (Welch Allyn Blood Pressure device H-BP100SBP) manufactured by Guangdong Transtek Medical Electronics Co., Ltd .(K161886). 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 1 (Omron wrist blood pressure monitor BP6100) manufactured by OMRON HEALTHCARE Co., Ltd (K182127) and the predicate device 2 (Omron wrist blood pressure monitor BP4350) manufactured by OMRON HEALTHCARE Co., Ltd (K182166) . 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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