March 1, 2022

Joytech Healthcare Co., Ltd
Dandan Huang
Regulatory Engineer
No.365, Wuzhou Road, Yuhang Economic Development Zone
Hangzhou, Zhejiang 311100
China

Re: K213189
Trade/Device Name: 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: January 20, 2022
Received: January 26, 2022

Dear Dandan Huang:

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,

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)*
K213189

Device Name
Wrist-type Fully Automatic Digital Blood Pressure Monitor
Including DBP-2101, DBP-2202, DBP-2116, DBP-2206, DBP-2208, DBP-2220, DBP-2242, DBP-2141, DBP-2152, DBP-2253, DBP-2228, DBP-2229, DBP-2127, DBP-2261, DBP-2160

Indications for Use *(Describe)*
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.

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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JOYTECH Healthcare Co., Ltd..

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: Wrist-type Fully Automatic Digital Blood Pressure Monitor

Including all models DBP-2101, DBP-2202, DBP-2116, DBP-2206, DBP-2208, DBP-2220, DBP-2242, DBP-2141, DBP-2152, DBP-2253, DBP-2228, DBP-2229, DBP-2127, DBP-2261, DBP-2160

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 Wrist-type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the Predicate device of Wrist-type blood pressure monitor DBP-2261(K173024)

manufactured by JOYTECH Healthcare Co., Ltd..

2.5 Device Description:

The Wrist-type Fully Automatic Digital Blood Pressure Monitor is consist of sphygmomanometer main body and cuff. The mainbody contains ABS housing, LCD, keys, measurement control module, pneumatic control module, power supply module.

The Wrist-type Fully Automatic Digital Blood Pressure Monitor is automatic, non-invasive, blood pressure measurement system for over-the-counter (OTC) use in home and clinical environment. The device with an inflatable cuff wrapping around the patient's wrist and the cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method and silicon integrate pressure sensor technology. The deflation rate is controlled by a preset mechanical valve at a constant rate. The pressure of the cuff is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for three minutes. The cuff can measure pressure range from 0 to 300mmHg, and the pulse rate range from 30 to 180 beats/min. The detail comparisons between Wrist-type series are listed in table below:

Table 2.1 Characteristics of Wrist-type Blood Pressure Monitor

Features / Models	A	B	C	D	E	F	G	H（mm）	I (cm)	J(mm)	K	L	M	N	O
DBP-2101	Y	120 Memories×1	N	N	N	N	N	76×67.5×29	13.5-21.5	30×36	N	N	N	Y	Y
DBP-2202	Y	30 Memories×4	Y	N	N	N	N	79×64×29	13.5-21.5	42×34	N	N	N	Y	Y
DBP-2116	Y	120 Memories×1	Y	Y	N	N	N	79×66×28	13.5-21.5	45×30	N	N	N	Y	Y
DBP-2229	Y	30 Memories×4	Y	Y	N	Y	Y	76×67.5×28.5	13.5-21.5	45×30	N	N	N	Y	Y
DBP-2228	Y	30 Memories×4	Y	N	N	N	N	76×67.5×28.5	13.5-21.5	45×30	N	N	N	Y	Y
DBP-2127	Y	120 Memories×1	N	N	N	N	N	76×67.5×28.5	13.5-21.5	45×30	N	N	N	Y	Y
DBP-2206	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32.5	13.5-21.5	45×30	N	O	N	Y	O
DBP-2208	Y	60 Memories×2	Y	Y	Y	Y	N	77×64×32.5	13.5-21.5	49×38	O	O	N	Y	O
DBP-2220	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32	13.5-21.5	49×38	O	O	N	Y	O
DBP-2141	Y	120 Memories×1	Y	Y	N	Y	Y	84×64×29	13.5-21.5	45×30	N	O	N	Y	O
DBP-2242	Y	60 Memories×2	Y	Y	N	Y	Y	84×64×29	13.5-21.5 or 12.5-23cm (Optional)	49×38	O	O	N	Y	O

DBP-2152	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32	13.5-21.5	45×30	N	O	N	Y	O
DBP-2253	Y	60 Memories×2	Y	Y	Y	Y	N	77×64×32.5	13.5-21.5	49×38	O	O	N	Y	O
DBP-2261	Y	60 Memories×2	Y	Y	N	Y	Y	85×62×25	13.5-21.5	43×40	O	O	N	Y	O
DBP-2160	Y	60 Memories×2	Y	Y	N	Y	Y	85×62×25	13.5-21.5	30.6×45	O	O	N	Y	O

Note:

A = Powered by AAA Batteries

B= Memory Size

C= Time & Date

D = WHO (World Health Organization) Classification Indicator

E = Results Average in Three way

F = Irregular Heartbeat Detection

G = Last 3 Results Average

H= Outside Dimension (L x W x H in unit mm)

I = Cuff Size

J = LCD Size (Viewing Area in unit mm)

K= Backlight

L= Voice function

M= PC Interface

N=Low voltage detection

O=Beep

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 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:

The PCB and Main chip of blood pressure monitor device inside were changed based on the marketed products which applied to K170666 including models DBP-2101, DBP-2202, DBP-2116, DBP-2206, DBP-2208, DBP-2220, DBP-2242, DBP-2141, DBP-2152, DBP-2253, DBP-2228, DBP-2229, DBP-2127 and marketed products which applied to K173024 including models

DBP-2261, DBP-2160 manufacturing by JOYTECH Healthcare Co., Ltd. , which is considered to be significant change affecting effectiveness and safety. Therefore it had to resubmitted 510(k) application. As for intended use, operation principle, features and specification have been keep the same, the device DBP-2261(K173024) was selected as predicate device. The detail comparison of technical characteristic as table below:

Table 2.2 The comparison of subject device and Predicate device

Comparison item	**Subject device in present application**	**Predicate device K173024 (Model:DBP-2261)**	**Comparison result / Explanation**
The trade name	Wrist-type Fully Automatic Digital Blood Pressure Monitor	Wrist-type Fully Automatic Digital Blood Pressure Monitor	Identical
Manufacturer	JOYTECH Healthcare Co., Ltd.	JOYTECH Healthcare Co., Ltd.	Identical
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
Indications 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 intended for used by adults and adolescents age 12 through 21 years of age to measure the systolic and diastolic blood pressure and pulse rate.	Identical
Environment of Use	Home and Clinical environment (OTC)	Home and Clinical environment (OTC)	
Technical characteristic/Specification			
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during deflation	Determined during deflation	Identical
Cuff location	Wrist	Wrist	Identical
Measuring range	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 30mmHg～200 mmHg Pulse:30~180 Beats/min	Systolic Pressure: 60mmHg～260 mmHg Diastolic Pressure: 30 mmHg～200 mmHg Pulse:30~180 Beats/min	Identical
Max cuff pressure	300 mmHg	300 mmHg	Identical
Cuff circumference	Other models: Fits wrist circumference 13.5-21.5cm DBP-2242 Fits wrist circumference 13.5-21.5cm and 12.5-23cm (optional)	Fits wrist circumference 13.5-21.5cm	Similar Note1
Accuracy	Static Pressure:± 3mmHg	Static Pressure:± 3mmHg	Identical

	Pulse: ± 5%	Pulse: ± 5%	
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: 700hPa~1060hPa	Similar Note 2
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤93% RH	Temp.: -25℃~70℃ Humidity: ≤93% RH	Similar Note 3
Pressure sensor	Silicon integrate pressure sensor	Silicon integrate pressure sensor	Identical
Air Pump	DC3V Micro air pump	DC3V Micro air pump	Identical
Solenoid valve	DC3V solenoid-controlled valve	DC3V solenoid-controlled valve	Identical
Main Chip	SZC900	uPD78F0485w	Different Note 4
Display component	Device LCD	Device LCD	Identical
PCB	DBP-2101: BP01SNPCB	BP61PCB	Similar Note 5
	DBP-2202: BP02SNPCB		
	DBP-2206: BP06SNPCB		
	DBP-2208, DBP-2220: BP08SNPCB		
	DBP-2116: BP16SNPCB		
	DBP-2228, DBP-2229, DBP-2220: BP20SNPCB		
	DBP-2261, DBP-2160: BP61SNPCB		
	DBP-2242, DBP-2141, DBP-2152, DBP-2253: BSP22SNPCB		
Supply power source	2*1.5V AAA batteries	2*1.5V AAA batteries	Identical
PC Interface	No	No	Identical
Ingress Protection Rating	IP22	IP22	Identical
Material	ABS housing and Nylon Fleece cuff	ABS housing and Nylon Fleece cuff	Identical
Sterilization	Not applicable	Not applicable	Identical
Device Functions			
Irregular heart beat	Irregular heart beat is displayed on the LCD (some models see table 2.1)	Irregular heat beat is displayed on the LCD.	Same There is no new risks for deleting the function.
WHO classification indicator	None: DBP-2101, DBP-2202, DBP-2228, DBP-2127	Yes	Same There is no

	Yes: other models		new risks for deleting the function.
Memory function	DBP-2101, DBP-2127, DBP-2116, DBP-2141: 120 Memories×1	2*60 Memories	Similar Note6
	DBP-2202, DBP-2228, DBP-2229: 30 Memories×4		
	Other models: 60 Memories×2		
Results Average in Three way	DBP-2208 own this function, while other models none.	None	Similar Note 7
Last 3 Results Average	Yes: DBP-2229, DBP-2206, DBP-2220, DBP-2141, DBP-2242, DBP-2152, DBP-2261, DBP-2160	Yes	Identical
	Other models none		
Backlight	Optional: DBP-2208, DBP-2220, DBP-2242, DBP-2253, DBP-2261, DBP-2160	Optional	Identical
	Other model none		
Voice	Optional: DBP-2206, DBP-2208, DBP-2220, DBP-2141, DBP-2242, DBP-2152, DBP-2253, DBP-2261, DBP-2160	Optional	Identical
	Other models none		

Note 1: The device DBP-2242 adding the fit wrist circumstance 12.5cm-23cm is not change the cuff material and device specification and feature. The accuracy and new cuff size have been verified and validated by safety and clinical test report. It cannot be bring new risks.

Note 2: The operation atmospheric pressure is relate to the altitude. An increase in altitude is accompanied by a decrease in atmospheric pressure. The storage environment of the subject device modified have been verified by IEC 60601-1 and IEC80601-2-30 standard test.

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

Note 4: The main chip affect the accuracy and safety of the blood pressure monitor device.The safety and accuracy of the subject device have been verified by IEC 60601 series , IEC 80601-2-30 and IEC81060-2 standard test.

Note 5: The PCB affect the accuracy and safety of the blood pressure monitor device. The safety and accuracy of the subject device have been verified by IEC 60601 series , IEC 80601-2-30 and IEC81060-2 standard test.

Note 6: Memory group setting does not influence the accuracy, and the memory function have been verified by

software verification and validation report.

Note 7: Results average in three way function indicate three ways to evaluate blood pressure monitor average value. This function have been validated by Software verification and validation report.

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

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

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" and "FDA guidance Use of International Standard ISO 10993."

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.

2.9.1 Fit cuff circumstance 13.5-21.2cm for all all models

In the Wrist-type fully automatic digital blood pressure clinical investigation, Model DBP- 2208 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.

The clinical investigate statistic results in detail as below:

1) Statistic Methods:

Eligibility criteria 1: The mean value of difference is equal or within to ± 5mmHg and the standard deviation of no greater than 8 mmHg between subject device and reference device.

Eligibility criteria 2： According the known mean value of difference to determine the standard deviation required on the basis of table below. If the standard deviation is less than the corresponding standard deviation limit, the data set is judged as acceptable.

Table 1 — Averaged subject data acceptance (criterion 2) in mmHg

$\bar{x}_n$	Maximum permissible standard deviation, s_m, as function of, $\bar{x}_n$ mmHg									
	0,0	0,1	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,9
± 0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
± 1,	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
± 2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
± 3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
± 4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
± 5,	4,79	—	—	—	—	—	—	—	—	—
EXAMPLE For mean of ± 4,2 mmHg, the maximum permissible standard deviation is 5,49 mmHg.										

2) Statistic results

	Average(mmHg)	Standard deviation(mmHg)
Method 1		
Systolic blood pressure	0.84	5.25
Diastolic blood pressure	0.21	4.92
Method 2		
Systolic blood pressure	0.84	4.52
Diastolic blood pressure	0.21	4.36

According to Table above, the statistical results are as follows:

Method 1:

Average of systolic blood pressure is 0.84 mmHg (<±5 mmHg), standard deviation of systolic blood pressure is 5.25 mmHg (<8 mmHg)

Average of diastolic blood pressure is 0.21 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 4.92 mmHg (<8 mmHg)

Method 2:

Average of systolic blood pressure is 0.84mmHg (<±5 mmHg), standard deviation of systolic blood pressure is 4.52 mmHg (<6.95mmHg)

Average of diastolic blood pressure is 0.21 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 4.36 mmHg (<6.879 mmHg)

After comparing, the conclusion is that the averages difference in systolic and diastolic pressure and the corresponding standard deviation fall are within the range of the standard. It meets the requirements of clinical program.

2.9.2 Fit cuff circumstance 12.5-23cm for DBP-2242

In the Wrist-type fully automatic digital blood pressure clinical investigation, Model DBP-2242 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.

The clinical investigate statistic result as below:

1) The Statistic Methods are the same as the clause 2.9.1;

2) The Statistic Results presented as below:

	Average(mmHg)	Standard deviation(mmHg)
Method 1		
Systolic blood pressure	0.87	5.22
Diastolic blood pressure	0.20	4.93
Method 2		
Systolic blood pressure	0.87	4.48
Diastolic blood pressure	0.20	4.38

According to Table above, the statistical results are as follows:

Method 1:

Average of systolic blood pressure is 0.87 mmHg (<±5 mmHg), standard deviation of systolic blood pressure is 5.22 mmHg (<8 mmHg)

Average of diastolic blood pressure is 0.20 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 4.93 mmHg (<8 mmHg)

Method 2:

Average of systolic blood pressure is 0.87 mmHg (<±5 mmHg), standard deviation of systolic blood pressure is 4.48 mmHg (<6.887mmHg)

Average of diastolic blood pressure is 0.20 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 4.38 mmHg (<6.95 mmHg)

After comparing, the conclusion is that the averages difference in systolic and diastolic pressure and the corresponding standard deviation fall are within the range of the standard.It meets the requirements of clinical program.

2.10 Conclusions

This submitted wrist-type series manufactured by JOYTECH Healthcare Co., Ltd. have been found to be respectively substantially equivalent to the predicate device (Wrist-type Fully Automatic Digital Blood Pressure Monitor DBP-2261, K173024) manufactured by JOYTECH Healthcare Co., Ltd. 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 device