510(k) Summary

The assigned 510(k) number is:

2.1 Subjectter's Identification:

Name: JOYTECH Healthcare Co., Ltd..
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2.2 Name of the Device:

Trade Name: Fully Automatic Digital Blood Pressure Monitor
Including:All models as table below

Type	Models
Arm-type	DBP-1314,DBP-1313,DBP-1303,DBP-1334,DBP-1305,DBP-1307,DBP-1209,DBP-1211, DBP-1312,DBP-1318,DBP-1319,DBP-1326,DBP-1231,DBP-1332,DBP-1333,DBP-1335, DBP-1346,BM40,DBP-1254,DBP-1330,DBP-1257,DBP-1358,DBP-1359,DBP-1204, DBP-1210,
Wrist-Type	DBP-2160,DBP-2261

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 Predicate device of Sejoy, **BP-1307** (K Number: **K120554**), with a reason that their cuff is of the same size (22-36cm).

The Wrist-type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the Predicate device of Sejoy, **BP-2208** (K Number: **K121355**).

2.5 Device Description:

The arm-type series use an inflatable cuff which wraps around the patient's upper arm. 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 minute. There is a maximum pressure safety setting at 300 mmHg. The device will not inflate the cuff higher than 300 mmHg.

2.5.1 The detail comparisons among arm-type series are listed in table below:

Table2.2- Characteristics of Arm-type blood pressure monitor

Features / Models	A	B	C	D	E	F	G	H	I（mm）	J（cm）	K(mm)	L	M	N	O
DBP-1211	Y	Y	120 Memories×1	Y	N	Y	N	N	131×102 ×65	22-36	45×30	N	N	N	N
DBP-1312	Y	Y	60 Memories×2	Y	N	Y	Y	Y	131×102 ×65	22-36	62.7×46.4	N	N	N	N

DBP-1318	Y	Y	60 Memories×2	Y	N	Y	Y	Y	139× 88× 43	22-36	66 ×43	N	N	N	N
DBP-1326	Y	Y	30 Memories×4	Y	N	Y	Y	Y	139×88×44	22-36	65.9×42.8	N	N	N	N
DBP-1305	Y	Y	60 Memories×2	Y	N	Y	Y	Y	166×114×72	22-36	84.1×55.1	O	O	O	N
DBP-1307	Y	Y	60 Memories×2	Y	Y	Y	N	Y	166×114× 72	22-36	102.1×68.9	O	O	O	N
DBP-1319	Y	Y	60 Memories×2	Y	N	Y	Y	Y	166×114× 72	22-36	102×68.9	O	O	O	N
DBP-1231	Y	Y	120 Memories×1	Y	N	Y	Y	Y	140 ×98× 48	22-36	62.3× 46	N	O	N	N
DBP-1332	Y	Y	60 Memories×2	Y	N	Y	Y	Y	148×100× 56	22-36	84.1×55.1	O	O	O	N
DBP-1333	Y	Y	60 Memories×2	Y	N	Y	Y	Y	164×111× 60	22-36	102.1×68.9	O	O	O	N
DBP-1314	Y	Y	30 Memories×4	Y	N	Y	Y	Y	110×155×70	22-36	84.1×55.1	N	N	N	N
DBP-1313	Y	Y	30 Memories×4	Y	N	N	N	N	110×155×70	22-36	84.1×55.1	N	N	N	N
DBP-1209	Y	Y	120 Memories×1	Y	N	N	N	N	134×99×66	22-36	62.7×46.4	N	N	N	N
DBP-1303	Y	Y	30Memories×4	Y	N	N	N	N	110×155×70	22-36	62.7×46.4	N	N	N	N
DBP-1334	Y	O	30Memories×4	Y	N	Y	Y	Y	110×155×70	22-36	62.7×46.4	N	N	N	N
DBP-1335	Y	N	60 Memories×2	Y	Y	Y	N	Y	135×105×53	22-36	59.9×50.9	N	N	N	N
DBP-1346	Y	Y	30Memories×4	Y	Y	Y	Y	Y	140×98×53	22-36	78 × 71	Y	N	N	N
BM40	Y	Y	30Memories×4	Y	Y	Y	N	Y	119×109×60	22-36	83.4×54.4	N	N	N	N
DBP-1254	Y	Y	60 Memories×2	Y	N	Y	N	Y	134×99×66	22-36	62.7×46.4	N	N	N	N
DBP-1257	Y	Y	120 Memories×1	Y	N	Y	N	N	131×102×44	22-36	45 × 30	N	N	N	N
DBP-1358	Y	Y	60 Memories×2	Y	N	Y	Y	Y	131×102×44	22-36	45.7×62	N	O	N	N
DBP-1359	Y	Y	60 Memories×2	Y	N	Y	Y	Y	131×102×44	22-36	67 × 67	O	O	N	N
DBP-1204	Y	Y	120 Memories×1	N	N	N	N	N	150×112×56	22-36	83 × 35	N	N	N	N
DBP-1210	Y	Y	120 Memories×1	N	N	N	N	N	132×100×63	22-36	45 × 30	N	N	N	N
DBP-1330	Y	Y	60 Memories×2	Y	N	Y	Y	Y	148×100×56	22-36	84.1×54.1	Y	Y		Y

A = Powered by 4 AA 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 Dimension (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
Y= Yes
N = No
O= Optional function depending on clients' needs

2.5.2 The detail comparisons between Wrist-type series are listed in table below:

Table2.3- 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
DBP-2160	Y	Y	60 Memories×2	Y	N	Y	Y	85×62×25	13.5×21.5	30.6×45	N	O	N
DBP-2261	Y	Y	60 Memories×2	Y	N	Y	Y	85×62×25	13.5×21.5	43×40	O	O	N

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= LCD Backlight
L= Voice
M= PC connecter
Y= Yes
N = No
O= Optional function depending on clients' needs

The devices are all designed and manufactured according to AAMI/ANSI/IEC80601-2-30:2009/ A1:2013, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

2.6 Intended Use:

The Fully Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents age 12 through 21 years of age.

2.7 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards including AAMI/ANSI/IEC80601-2-30:2009/ A1:2013, medical electrical equipment - part 2-30 as well as AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012, AAMI/ANSI/IEC 60601-1-2:2014, ISO 10993-5: 2009 Biological evaluation of medical devices —Part 5:Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

Guidance documents include the "FDA Non-invasive Blood Pressure (NIBP) Monitor Guidance" and "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "FDA guidance Use of International Standard ISO 10993."

2.8 Non-clinical Tests:

Electromagnetic Compatibility Test according to IEC/EN 60601-1-2:2014

General Safety Provisions Test according to AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012

Performance Test according to AAMI/ANSI/IEC80601-2-30:2009/ A1:2013, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers The test result all meet or exceed the requirement of the standards.

Biocompatibility Test according to FDA Use of International Standard ISO 10993, ISO 10993-5: 2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

2.9 Discussion of Clinical Tests Performed:

Clinical tests were performed and complied the accuracy requirements of ISO 81060-2 Second edition 2013-05-01, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type.

2.9.1 Arm-type blood pressure monitor

1) Subjects:

Eighty-five subjects in the hospital were participated in clinical study.

2) Method:

A standard mercury sphygmomanometer was used as a reference standard. Simultaneous and blinded blood pressure determinations were performed by two doctors.

3) Criteria:

The ISO81060-2 Standard recommended :

A. a mean difference of x5mmHg, with standard deviation of differences of x8 mmHg between test device and reference method.

B.For the systolic and diastolic blood pressures for each of the m subjects, the standard deviation, of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer shall meet the criteria listed in Tab 1 when calculated according to Equation(3).

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.										

4) Result

Through clinical research, we can convinced that the clinical device is safe and effective.The results of the clinical data refer the follow two tables.

	Average(mmHg)	Standard deviation(mmHg)
Criterion 1		
Systolic blood pressure	-0.57	4.63
Diastolic blood pressure	-1.61	5.30
Criterion 2		
Systolic blood pressure	-0.57	3.71
Diastolic blood pressure	-1.61	4.94

According to table, the statistical results are as follows:

Method 1:

Average of systolic blood pressure is -0.57 mmHg (< ± 5 mmHg), standard deviation of systolic blood

pressure is 4.63 mmHg (<8 mmHg)
Average of diastolic blood pressure is -1.61 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 5.30 mmHg (<8 mmHg)

Method 2:

Average of systolic blood pressure is -0.57 mmHg (<±5 mmHg), standard deviation of systolic blood pressure is 3.71 mmHg (<6.91mmHg)
Average of diastolic blood pressure is -1.61 mmHg (<±5 mmHg), standard deviation of diastolic blood pressure is 4.94 mmHg (<6.73 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 Wrist-type blood pressure monitor

1) Subjects:
Eighty-five subjects in the hospital were participated in clinical study.

2) Method:
A standard mercury sphygmomanometer was used as a reference standard. Simultaneous and blinded blood pressure determinations were performed by two doctors.

3) Criteria:
The ISO81060-2 Standard recommended :
A. a mean difference of x5mmHg, with standard deviation of differences of x8 mmHg between test device and reference method.
B.For the systolic and diastolic blood pressures for each of the m subjects, the standard deviation, of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer shall meet the criteria listed in Tab 1 when calculated according to Equation(3).

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.										

4) Result
Through clinical research, we can convinced that the clinical device is safe and effective.The results of the clinical data refer the follow two tables.

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

According to table, 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.

2.10 Summary comparing technological characteristics with predicate devices:

2.10.1 Summary of subject models on comparison with BP-1307 (K120554)

Item	Predicate Device BP-1307(K120554)	All models of arm-type blood pressure monitor		Result
Indication for Use	The Fully Automatic Blood Pressure Monitors are intended to measure the systolic and diastolic blood pressure and pulse rate of adults and adolescents age 12 through 21 years of age.			Identical
Measurement Method	Oscillometric Method			Identical
Materials	ABS housing and Nylon Fleece cuff			Identical
Power Source	4 AA batteries or Medical AC Adapter (DC6.0V, 600mA)	DBP-1314, DBP-1313, DBP-1303, DBP-1334, DBP-1305, DBP-1307, DBP-1209, DBP-1211, DBP-1312, DBP-1318, DBP-1319, DBP-1326, DBP-1231, DBP-1332, DBP-1333, BM40, DBP-1254, DBP-1330, DBP-1257, DBP-1358, DBP-1359, DBP-1204, DBP-1210,	4 AA batteries or Medical AC Adapter (DC6.0V, 600mA)	Similar
		DBP-1346	1.5V AA×4	
		DBP-1335	1.5V AAA×4	
Cuff	22-36cm			Identical
PCB	BP07PCB	DBP-1204	BP04PCB	Similar
		DBP-1210	BP10PCB	
		DBP-1313, DBP-1314, DBP-1209, DBP-1254, DBP-1334, DBP-1231, DBP-1303,	SBM22PCB	
		DBP-1307, DBP-1305, DBP-1318, DBP-1319, DBP-1332, DBP-1333, DBP-1257, DBP-1358, DBP-1359	BP07PCB	
		DBP-1330	BP07YPCB	
		DBP-1211, DBP-1312,	BP11PCB	
		DBP-1346	BP46PCB	
		DBP-1326	BP07SPCB	
		BM40	BM40PCB	
		DBP-1335	BP35PCB	
USB port	No	DBP-1305, DBP-1307, DBP-1319, DBP-1332, DBP-1333	Yes	Similar

		DBP-1314, DBP-1313, DBP-1303, DBP-1334, DBP-1209, DBP-1211, DBP-1312, DBP-1318, DBP-1326, DBP-1231, DBP-1346, BM40, DBP-1254, DBP-1330, DBP-1257, DBP-1358, DBP-1359, DBP-1204, DBP-1210, DBP-1335	No	
Ingress Protection Rating	IP20			Identical
Accuracy Pressure	±3mmHg			Identical
Accuracy Pulse	±5%			Identical
Measurement Pressure Range	0mmHg~300mmHg			Identical
Measurement Pulse Range	30~180 beats/minute			Identical
Electrical Safety	According to IEC60601-1-2 According to IEC60601-1			Identical

2.10.2 Summary of subject models on comparison with BP-2208 (K121355)

Item	Predicate Device BP-2208(K121355)	Subject Device DBP-2160	Subject Device DBP-2261	Result
Indication for Use	The Fully Automatic Blood Pressure Monitors are intended to measure the systolic and diastolic blood pressure and pulse rate of adults and adolescents age 12 through 21 years of age.			Identical
Measurement Method	Oscillometric Method			Identical
Materials	ABS housing and Nylon Fleece cuff			Identical
Power Source	1.5V AAA×2			Identical
Cuff	13.5-21.5cm			Identical
PCB	BP08sPCB	BP61PCB	BP61PCB	Identical
Ingress Protection Rating	IP22			Identical
Accuracy Pressure	±3mmHg			Identical
Accuracy Pulse	±5%			Identical
Measurement Pressure Range	0mmHg~300mmHg			Identical
Measurement Pulse Range	30~180 beats/minute			Identical
Electrical Safety	According to IEC60601-1-2 According to IEC60601-1			Identical

There are no difference of technological characteristics between the predicate devices and the subject devices fully automatic blood pressure monitors.

2.12 Conclusions:

The Automatic Blood Pressure Monitors arm-type series have the same intended use and similar technological characteristics as the Predicate Device: **BP-1307** (K Number: **K120554**);

The Wrist-type Blood Pressure Monitors DBP-2160,DBP-2261 have the same intended use and similar technological characteristics as the Predicate Device:**BP-2208**(K Number:**K121355**)

BP-1307(K Number:**K120554**) and **BP-2208**(K Number:**K121355**) are manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

Moreover, verification and validation tests contained in this submission demonstrate that the difference in the subject models could maintain the same safety and effectiveness as that of predicate devices.

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.