November 22, 2017

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

Re: K170666
Trade/Device Name: Wrist-type Fully Automatic Digital Blood Pressure Monitor, Models DBP-2101, DBP-2202, DBP-2229, DBP-2228, DBP-2127, DBP-2206, DBP-2208, DBP-2116, DBP-2220, DBP-2141, DBP-2242, DBP-2156, DBP-2152, DBP-2253
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 23, 2017
Received: October 23, 2017

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170666

Device Name
The Wrist-type Fully Automatic Digital Blood Pressure Monitors, Models DBP-2101, DBP-2202, DBP-2229, DBP-2228, DBP-2127, DBP-2206, DBP-2208, DBP-2116, DBP-2220, DBP-2141, DBP-2242, DBP-2156, DBP-2152, DBP-2253

Indications for Use *(Describe)*

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.

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 健拓

JOYTECH Healthcare Co., Ltd..

510(k) Summary

The assigned 510(k) number is: K170666

2.1. Date Prepared:

2017.02.10

2.2. Subjectter's Identification:

Name: JOYTECH Healthcare Co., Ltd..
Add.: No. 365. Wuzhou Road, Yuhang Economic Development Zone, Hangzhou, China.
Contact Person: Yunhua Ren
Phone: +86-571-81957767
Fax: +86-571-81957750
Email: renyh@sejoy.com

2.3. Name of the Device:

Trade Name: The Wrist-type Fully Automatic Digital Blood Pressure Monitor
Including all models DBP-2101,DBP-2202,DBP-2229,DBP-2228,DBP-2127,DBP-2206,DBP-2208, DBP-2116,DBP-2220,DBP-2141, DBP-2242, DBP-2156,DBP-2152,DBP-2253.
Common Name: Blood Pressure Monitor
Classification name: Non-invasive blood pressure measurement System
21 CFR 870-1130, Class II, DXN.

2.4. Classification Information:

Regulation Number: 870.1130
Product Code: DXN
Device Class: II
Panel: 74 Cardiovascular

2.5. Predicate Device Information:

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

2.6. Device Description:

The wrist-type Fully Automatic Digital Blood Pressure Monitors with an inflatable cuff wrapping around the patient's wrist. 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.

The detail comparisons between 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
DBP-2101	Y	120 Memories×1	N	N	N	N	N	76×67.5×29	13.5-21.5	30×36	N	N
DBP-2202	Y	30 Memories×4	Y	N	N	N	N	79×64×29	13.5-21.5	42×34	N	N
DBP-2229	Y	30 Memories×4	Y	Y	N	Y	Y	76×67.5×28.5	13.5-21.5	45×30	N	N
DBP-2228	Y	30 Memories×4	Y	N	N	N	N	76×67.5×28.5	13.5-21.5	45×30	N	N
DBP-2127	Y	120 Memories×1	N	N	N	N	N	76×67.5×28.5	13.5-21.5	45×30	N	N

Features / Models	A	B	C	D	E	F	G	H（mm）	I (cm)	J(mm)	K	L
DBP-2206	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32.5	13.5-21.5	45×30	N	O
DBP-2208	Y	60 Memories×2	Y	Y	Y	Y	N	77×64×32.5	13.5-21.5	49×38	O	O
DBP-2116	Y	120 Memories×1	Y	Y	N	N	N	79×66×28	13.5-21.5	45×30	N	N
DBP-2220	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32	13.5-21.5	49×38	O	O
DBP-2141	Y	120 Memories×1	Y	Y	N	Y	Y	84×64×29	13.5-21.5	45×30	N	O
DBP-2242	Y	60 Memories×2	Y	Y	N	Y	Y	84×64×29	13.5-21.5	49×38	O	O
DBP-2152	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32	13.5-21.5	45×30	N	O
DBP-2253	Y	60 Memories×2	Y	Y	Y	Y	N	77×64×32.5	13.5-21.5	49×38	O	O
DBP-2156	Y	60 Memories×2	Y	Y	N	Y	Y	77×64×32	13.5-21.5	45×30	N	O

Table2.3- Characteristics of Wrist-type Blood Pressure Monitor

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
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.

2.7. Intended 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.

2.8.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."

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. Summary 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.

1) Subjects:

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

Table 2.2.1.1 The distribution of test objects(13.5~21.5cm)

Project		Frequency	Percentage	Effective Percentage
Gender	Female	41	48.2%	30%
	Male	44	51.8%	30%
Age	>12(the elderly)	85	100%	100%
Systolic blood pressure	≤100	24	9.4%	5%
	≥140	100	39.2%	20%
	≥160	23	9.0%	5%
Diastolic blood pressure	≤60	23	9.0%	5%
	≥85	154	60.4%	20%
	≥100	50	19.6%	5%

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)
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, 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-2208 (K121355)

Item / Model	BP-2208 (K121355)	DBP-2101	DBP-2229	DBP-2202	DBP-2228	DBP-2127	DBP-2206	DBP-2208	DBP-2116	DBP-2220	DBP-2141	DBP-2242	DBP-2152	DBP-2253	DBP-2156	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	Battery:1.5V(AAA)×2															Identical
Cuff	No change ,all same According to ISO-10993															Identical
PCB	BP08PCB	BP01PCB	BP20PCB	BP02PCB	BP20PCB	BP20PCB	BP08PCB	BP08PCB	BP16PCB	BP08PCB	BSP22PCB	BSP22PCB	BSP22PCB	BSP22PCB	BP08PCB	Similar
USB port	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	different
Ingress Protection Rating	IP22															Identical
display size(mm)	49×38	30×36	45×30	42×34	45×30	45×30	45×30	49×38	45×30	49×38	45×30	49×38	45×30	49×38	45×30	Similar
Accuracy Pressure	±3mmHg															Identical
Accuracy Pulse	±5%															Identical
Measurement Pressure Range	Systolic pressure:60mmHg～280mmHg; Diastolic pressure:30mmHg～200mmHg															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.

2.11. Conclusions:

Our Fully Automatic Blood Pressure Monitors wrist-type series as the Predicate Device: **BP-2208** (K Number: **K121355**), which is 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 cleared 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.