July 29, 2019

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

Re: K190886
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor – DBP-1204, DBP-1307, DBP-1332, DBP-1305, DBP-1334, DBP-1231, DBP-1314, DBP-1209, DBP-1303, DBP-1335
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 20, 2019
Received: July 1, 2019

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,

Stephen Browning
Assistant Director
Division of CardiacElectrophysiology, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190886

Device Name
Arm-type Fully Automatic Digital Blood Pressure Monitor - DBP-1204, DBP-1307, DBP-1332, DBP-1305, DBP-1334, DBP-1231, DBP-1314, DBP-1209, DBP-1303, DBP-1335

Indications for Use *(Describe)*
Measure blood pressure (systolic and diastolic) 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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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,311100, 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: Arm-type Fully Automatic Digital Blood Pressure Monitor

Including: DBP-1204,DBP-1307,DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,

DBP-1209,DBP-1303,DBP-1335

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 Monitor DBP-1204,DBP-1307, DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,DBP-1209,DBP-1303,DBP-1335 are corresponding substantially equivalent to the following device: Blood Pressure Monitor DBP-1204,DBP-1307,DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,DBP-1209,DBP-1303, DBP-1335, FDA 510(k) number: K173024, manufactured by JOYTECH Healthcare Co., Ltd..

2.5 Device Description:

The Arm-Type Fully Automatic Digital Blood Pressure Monitor (Models: DBP-1204,DBP-1307,DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,DBP-1209,DBP-1303,DBP-1335) uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff circumference is limited to 22cm-48cm (be comprised of 3 cuffs, 22cm-36cm,22cm-42cm,32cm-48cm,select one. And the model DBP-1335 is comprised of 4 cuffs,22cm-36cm,22cm-42cm,32cm-48cm,33-43cm, select one.) which 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 among the Arm-Type Fully Automatic Digital Blood Pressure Monitors are list in table below:

Features / Models	A	B	C	D	E	F	G	H	I（mm）	J（cm）	K(mm)	L	M	N
DBP-1204	Y	Y	120Memories×1	N	N	N	N	N	150×112×56	22-48	83×35	N	N	N
DBP-1307	Y	Y	60 Memories×2	Y	Y	Y	N	Y	166×114× 72	22-48	102.1×68.9	O	O	N
DBP-1332	Y	Y	60 Memories×2	Y	N	Y	Y	Y	148×100× 56	22-48	84.1×55.1	O	O	N
DBP-1305	Y	Y	60 Memories×2	Y	N	Y	Y	Y	166×114×72	22-48	84.1×55.1	O	O	N
DBP-1334	Y	O	30Memories×4	Y	N	Y	Y	Y	110×155×70	22-48	62.7×46.4	N	N	N
DBP-1231	Y	Y	120 Memories×1	Y	N	Y	Y	Y	140 ×98× 48	22-48	62.3× 46	N	O	N
DBP-1314	Y	Y	30 Memories×4	Y	N	Y	Y	Y	110×155×70	22-48	84.1×55.1	N	N	N
DBP-1209	Y	Y	120 Memories×1	Y	N	N	N	N	134×99×66	22-48	62.7×46.4	N	N	N
DBP-1303	Y	Y	30Memories×4	Y	N	N	N	N	110×155×70	22-48	62.7×46.4	N	N	N
DBP-1335	Y	N	60 Memories×2	Y	Y	Y	N	Y	135×105×53	22-48 *	59.9×50.9	N	N	N

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 Demission (L x W x H in unit mm)
J = Cuff Size 22cm-48cm (be comprised of 3 cuffs, 22cm-36cm,22cm-42cm,32cm-48cm,select

one.
Note:'*'And the model DBP-1335 is comprised of 4 cuffs,22cm-36cm,22cm-42cm,32cm-48cm,33-43cm, select one.)
K = LCD Size (Viewing Area in unit mm)
L = LCD Backlight
M= Voice
N=Music
Y= Yes
N= No
O= Optional function depending on clients' needs

The device are all designed and manufactured according to AAMI / ANSI / IEC 80601-2-30:2009/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 Difference of comparison with predicate device:

The subject Arm-type fully automatic blood pressure monitor (Model: DBP-1204,DBP-1307,DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,DBP-1209,DBP-1303,DBP-1335) has the same functions and principle with predicated device which utilizes Oscilliometric measurement method to determine the blood pressure and the result can be shown on the LCD.

The modification that was occurred is only cuff size from 22cm-36cm change to range within 22cm-48cm (be comprised of 3 cuffs, 22cm-36cm,22cm-42cm,32cm-48cm,select one. And the model DBP-1335 is comprised of 4 cuffs,22cm-36cm,22cm-42cm,32cm-48cm,33-43cm,select one.).

2.8. Non-clinical Tests:

Electromagnetic Compatibility Test according to IEC 60601-1-2:2014, EN 60601-1-2:2015;

General Safety Provisions Test according to AAMI/ANSI ES 60601-1:2005/(R) 2012

and A1:2012 and C1:2009/(R)2012 and A2:2010/(R)2012;

Performance Test according to IEC 80601-2-30:2009(First Edition) and 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 Bluebook Memorandum G95-1Use 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.

2.10. Discussion of Clinical Tests Performed:

Blood pressure monitor with its accessory which the fit arm circumference cuff sizes are 22-42cm and 32-48cm, these clinical tests were performed and comply with the accuracy requirements of ISO 81060-2 Second edition 2013-05-01, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type.

Due to the cuff size of 33-43cm which is falling into the scope of 32-48cm, and both the double size cuffs (33-43cm and 32-48cm) are constructed with the same size internal bladder. So the clinical test result of the cuff size 32-48cm can represent and validate the another cuff which cuff size is 33-43cm meanwhile.

2.11. Conclusions:

The subject Arm-type Fully Automatic Blood Pressure Monitor (Model: DBP-1204,DBP-1307,DBP-1332,DBP-1305,DBP-1334,DBP-1231,DBP-1314,DBP-1209,DBP-1303,DBP-1335) is itself of the corresponding predicate device manufactured by JOYTECH Healthcare Co., Ltd. (FDA 510(k) number: K173024). The addition of new arm-cuff range 22cm-48cm (be comprised of 3 cuffs, 22cm-36cm,22cm-42cm,32cm-48cm,select one.And the model DBP-1335 is comprised of 4 cuffs,22cm-36cm,22cm-42cm,32cm-48cm,33-43cm,select one.) will not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.