August 3, 2020

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

Re: K200649
Trade/Device Name: Arm-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: June 28, 2020
Received: July 6, 2020

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,

LT 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

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

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2.2 Name of the Device:

Trade Name: Arm-type Fully Automatic Digital Blood Pressure Monitor

Including: DBP-1307b,DBP-1305b,DBP-1318b,DBP-1319b,DBP-1332b,DBP-1333b,DBP-1257b, DBP-1358b,DBP-1359b

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 devices:

510(k) number	model	Product code	Manufacturer
K173024	DBP-1307	DXN	JOYTECH HEALTHCARE CO., LTD.
K161886	H-BP100SBP	DXN	Guangdong Transtek Medical Electronics Co.,Ltd

2.5 Device Description:

The Arm-Type series use an inflatable cuff which is wrapped 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.

An irregular heartbeats rhythm is defined as a rhythm that varies by 25% less or more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.

AND, these subject device can be used as a stand-alone unit to finish the blood pressure measurement or in conjunction with the "JOYTECH healthcare" 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, 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
DBP-1307b	Y	Y	60 Memories×2	Y	Y	Y	N	Y	166×114× 72	22-36	102.1×68.9	O	O	N	Y
DBP-1305b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	166×114×72	22-36	84.1×55.1	O	O	N	Y
DBP-1318b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	139× 88× 43	22-36	66 ×43	N	N	N	Y
DBP-1319b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	166×114× 72	22-36	102×68.9	O	O	N	Y
DBP-1332b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	148×100× 56	22-36	84.1×55.1	O	O	N	Y
DBP-1333b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	164×111× 60	22-36	102.1×68.9	O	O	N	Y
DBP-1257b	Y	Y	120Memories×1	Y	N	Y	N	N	131×102×44	22-36	45 × 30	N	N	N	Y
DBP-1358b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	131×102×44	22-36	45.7 × 62	N	O	N	Y
DBP-1359b	Y	Y	60 Memories×2	Y	N	Y	Y	Y	131×102×44	22-36	69 × 67	O	O	N	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 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=Music
O=Bluetooth Function
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 Comparison of Technological Characteristics with predicate device:

Comparison item	Subject device in present application	Predicate device 1 K173024 (model:DBP-1307)	Predicate device 2 K161886 (model:H-BP100SBP)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Arm-type Fully Automatic Digital Blood Pressure Monitor	Welch Allyn Blood Pressure Device	/
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
Intended	The Fully	The Fully Automatic	Welch Allyn Blood	Similar

use	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.	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.	Pressure 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.	
Measuring principle	Oscillometric method	Oscillometric method	Oscillometric method	Identical
Cuff location	Upper arm	Upper arm	Upper arm	Identical
Performance Attributes				
Measuring range	Systolic Pressure: 60mmHg ～ 280 mmHg Diastolic Pressure: 30mmHg ～ 200 mmHg Pulse:30~180 Beats/Minute	Systolic Pressure: 60mmHg ～ 280 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	Identical as predicate device 1
Max cuff pressure	300mmHg	300mmHg	300mmHg	Identical
Accuracy	Static Pressure: ± 3mmHg Pulse: ± 5%	Static Pressure: ± 3mmHg Pulse: ± 5%	Pressure: ± 0.4kPa (3mmHg) Pulse value: ± 5%	Identical
Physical Attributes				
Blood Pressure categories	WHO classification	WHO classification	None	Identical
Display componen t	1.Device LCD; 2.iOS device or Android device	Device LCD	1.Device LCD; 2.iOS device or Android device	Identical as predicate device 2
Inflation	By air pump	By air pump	By air pump	Identical
Pressure release	By solenoid valve	By solenoid valve	By solenoid valve	Identical
Cuff circumfere nce	Fits arm circumference 22-36 cm	Fits arm circumference 22-36 cm	The three preformed cuff units, which are applicable to arm	Identical as predicate device 1

			circumference between 15-24cm, 22-42cm and 40-54cm to meet different Population's need.	
Bluetooth Module version	v5.0	None	V4.0	Different
System requirement	Bluetooth 4.0 or later/ Android 5.0 or later/ IOS 9.0 or later	None	Platform which support Bluetooth 4.0 technology	Similar
Bluetooth features	Transmit data to smart phone via Bluetooth	None	Transmit data to smart phone via Bluetooth	Identical as predicate device 2
PCB or Electrical scheme	BP07BT PCB	BP07 PCB	Unknow	Similar
Apps on smart device				
Funtion on APP	Storage test result/ Announce test result/ Read memories in App/ Empty memories in app/ Draw curve/ Set the personal information in app	None	Unknow	Different, The change in the specification is documented, 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.
Environmental				
Operating Temp. & humidity	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric:	Temp.: 10℃~40℃ Humidity: 15~93%RH Atmospheric:	Temp.:5℃~40℃ Relative humidity 85%RH Atmospheric	Identical as predicate device 1

	700hPa~1060hPa	700hPa~1060hPa	pressure:86kPa to 106kPa	
Storage Temp. & humidity	Temp.: -25℃~55℃ Humidity: ≤90% RH	Temp.: -25℃~70℃ Humidity: ≤90% RH	Temp.:-20℃~60℃ Relative Humidity: 10% RH – 93% RH Atmospheric Pressure: 50kPa to 106 kPa	Similar
Electrical Power				
Supply power source	For models DBP-1318b,DBP-1257b, DBP-1358b,DBP-1359b: 4x1.5V AAA battery or Medical AC adapter (DC 6V, 600mA)(recommended, not provided)	4x1.5V AA battery or Medical AC adapter (DC 6V, 600mA)(recommended, not provided)	powered by four AA alkaline batteries or by a AC adapter(DC 6V,1A)(not include)	Equivalent The different in the specification is documented and tested
	For other models: 4x1.5V AA battery or Medical AC adapter (DC 6V, 600mA)(recommended, not provided)			
Other Attributes				
Sterilization	Not applicable	Not applicable	Not applicable	Identical
Material	PC and ABS for the case and plastic foil for the labels of the device. Biocompatible materials are used for the applied parts (Cuff containing a interal bladder)	PC and ABS for the case and plastic foil for the labels of the device. Biocompatible materials are used for the applied parts (Cuff containing a interal bladder)	ABS is used to outer housing of the main unit.	Identical as predicate device 1

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 80601-2-30:2009(First Edition) and A1:2013, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

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
- ISO10993-10:2010 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:

- ISO81060-2:2013 Non-invasive sphygmomanometers — Part 2: Clinical validation of automated measurement type.

Based on the core algorithm and same cuff circumference are completely equivalent to the Predicate device of Joytech, DBP-1307 (K Number: K173024), clinical testing was not required to establish equivalency of the device.

2.11. Conclusions:

This submitted Arm-type series have been found to be substantially equivalent to the predicate device. 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.

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.

--- End of this section---