January 26, 2024

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

Re: K231303
Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor, Model: BM 92
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 26, 2023
Received: December 26, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 C. Browning -S

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)* K231303

Device Name
Arm-type Fully Automatic Digital Blood Pressure Monitor

Model: BM 92

Indications for Use *(Describe)*

The Arm-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 with circumference ranging from 22cm to 42cm.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: Arm-type Fully Automatic Digital Blood Pressure Monitor

Model: BM 92

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 is substantially equivalent to the following predicate device:

510(k) number	Predicate device model	Product code	Manufacturer

K192609	GUS622	DXN	Globalcare Medical Technology Co., Ltd

2.5 Device Description:

The Arm-type Fully Automatic Digital Blood Pressure Monitor (BPM) series, non-invasive, blood pressure measurement system for over-the-counter (OTC) use in home and clinical environment. The systolic and diastolic pressures are determined using the oscillometric method, where the cuff is inflated with an integral controllable piezoelectric pump and deflates via an electric automatic rapid deflation valve. During measurements, the electric pump within the main unit slowly inflates the arm cuff, generating cuff pressure which is monitored and from which pulse waveform data is extracted. This waveform data is analyzed by software algorithms within the microprocessor to determine pulse rate, systolic pressure, and diastolic pressure. The measure pressure range from 0 to 299mmHg, and the pulse rate range from 30 to 180 beats/min.

The pulse rate measurement compares the longest and the shortest time intervals of detected pulse waves to the mean time interval and displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

Meanwhile, this blood pressure monitor device can be used as a stand-alone unit to finish the blood pressure measurement or in conjunction with the APP through 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 measurement results from the blood pressure monitor device, which 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 functions for BM 92 are listed in table below:

Models Features	A	B	C	D	E	F	G	H	I	J	K	L	M	N
BM 92	Y	N	2*120 memories	Y	Y	Y	Y	125*95*44	22-42cm	71*76	Y	Y	Y	Y

A = Powered by alkaline battery
B= Powered by AC adaptor
C = Memory Size
D = Time & Date
E = WHO (World Health Organization) Classification Indicator
F = Average of all memories, AM/PM Average for the last 7 days
G = Irregular Heartbeat Detection
H = Outside Demission (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= Bluetooth Function
N= Cuff Loose Detection

Note:
Y= Yes
N = No

The device is designed and manufactured according to 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 Arm-type Fully Automatic Digital Blood Pressure Monitor is intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm.

2.7 Comparison of Technological Characteristics with predicate device:

The arm-type blood pressure monitor BM 92 manufactured by JOYTECH have the same arm cuff type, features and specifications with the Globalcare blood pressure monitor GUS622 which 510k number is K192609, therefore we choose the device act as

the predicate device. The detail comparison of technical characteristic as below:

Comparison item	Subject devices for BM 92	Predicate device GUS622 (K192609)	Comparison result / Explanation
The trade name	Arm-type Fully Automatic Digital Blood Pressure Monitor	Globalcare GUS622 Blood Pressure Monitor	/
Manufacturer	JOYTECH Healthcare Co., Ltd.	Globalcare Medical Technology Co., Ltd	/
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
Indication for use	The Arm-type Fully Automatic Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm.	The Globalcare GUS622 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.	Similar Note 1
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measurement type	Determined during inflation	Determined during inflation	Identical
Cuff location	Upper arm	Upper arm	Identical
Specification			
Measuring range	Systolic Pressure: 60mmHg ~ 260 mmHg; Diastolic Pressure: 40mmHg ~ 200 mmHg; Pulse: 30~180 Beats/Minute	Systolic Pressure: 50mmHg ~ 280 mmHg; Diastolic Pressure: 30mmHg ~ 220 mmHg; Pulse: 40~199 Beats/Minute	Similar. Note 2
Max cuff pressure	299 mmHg	300mmHg	Similar
Accuracy	Static Pressure:± 3mmHg Pulse: ± 5%	Pressure:±0.4kPa (3mmHg) Pulse value: ± 5%	Identical
Inflation	By air pump	By air pump	Identical
Pressure release	By solenoid valve	By solenoid valve	Identical
Operating Temp. &	Temp.: 10°C~40°C Humidity: 15~93%RH	Temp.:10°C~40°C Humidity:< 90% relative	Similar Note 3

humidity	Atmospheric: 800hPa~1060hPa	humidity (non-condensing) Pressure:800hPa~1050hPa	
Storage Temp. & humidity	Temp.: -25°C~55°C Humidity: ≤93% RH	Temp.:-20°C~55°C Humidity:< 90% relative humidity (non-condensing) Pressure:800hPa~1050hPa	Similar Note 4
Cuff circumference	22-42 cm	22-42 cm	Identical
Supply power source	4x1.5V AAA battery	4x1.5V AAA battery or AC adaptor	Similar Note 5
Bluetooth transmission function	Yes	Unclear	Different Note 6
Sterilization	Not applicable	Not applicable	Identical
Features			
Irregular heartbeat	Irregular heartbeat	Irregular heartbeat	Identical
Memory	2*120 Memories	2 x 60 memory spaces	Similar. Note 7
Cuff loose indicator	Yes	Yes	Identical

Note 1: The intended use of subject device and predicate device are similar. The clinical accuracy of subject device applied to adolescents over 12 years of age population have been verified and validated, which comply with the requirements of ISO 81060-2. And the clinical safety also have been validated as for without any AE or side-effect in clinical investigation.

Note 2: The measuring range of the subject device have been verified by IEC 60601-1 and 80601-2-30 standard test.

Note 3: The operation environment of the subject device have been verified by IEC 60601-1 and 80601-2-30 standard test.

Note 4: The storage environment of the subject device have been verified by IEC 60601-1 and 80601-2-30 standard test.

Note 5: The different power supply of the subject device have been verified by IEC 60601-1 and IEC 60601-1-2 standard test.

Note 6: The intended use of Bluetooth functionality is to transmit the measurement result from point A to point B only, not intended for active patient monitoring. It not only has been verified and validated through Software verified and validation report, but also passed the IEC 60601-1, IEC60601-1-2 standard test.

Note 7: The quantity of storage readings is different between the subject device and predicate device. The change in the specification is documented, and the change does not affect the intended use or the fundamental scientific technology.

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:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.
- AAMI ES60601-1:2005+AMD1:2012+AMD2:2021, 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+AMD1:2020 , 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+AMD1:2020 , 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

- 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"

The test results 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.

The key factors that affect clinical trials, such as the sensors, and the core algorithms are the same between BM92 and DBP-6279B. Therefore, the clinical investigation report for the model for DBP-6279B is applicable for BM92.

A total of 90 patients participated in the clinical study (2 were excluded because they were part of other clinical trials). Same arm sequential method was adopted during the clinical testing. A manual Mercury Sphygmomanometer was used as a reference device. All the subjects were volunteers 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.

See Attachment 2-1: ISO 81060-2 Clinical Trial Report

2.10. Conclusions:

Based on the information provided in this submission, the subject devices and predicate devices have very similar intended uses and fundamental technological characteristics. It has been tested, documented, and demonstrated that the differences between them do not raise any questions on safety or effectiveness.

This submitted arm-type for BM 92 manufactured by JOYTECH Healthcare Co., Ltd. Has been found to be substantially equivalent to the predicate device (Globalcare GUS622 Blood Pressure Monitor) manufactured by Globalcare Medical Technology Co., Ltd. (K192609).

--- End of this section---