



February 8, 2017

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Sejoy Electronics & Instruments Co., Ltd.
Mr. Ren Yunhua, General Manager
Building 2, No. 202, Zhenzhong Road
West Lake Economy & Technology Zone
Hang Zhou, 310030
CHINA

Re: K161577

Trade/Device Name: Arm-type Fully Automatic Digital Blood Pressure Monitor
models BP-46 and BP-1304

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II

Product Code: DXN

Dated: August 27, 2016

Received: January 10, 2017

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

A handwritten signature in black ink, appearing to read "Bram Zuckerman", is written over a large, semi-transparent blue logo of the Food and Drug Administration (FDA). The logo consists of the letters "FDA" in a bold, sans-serif font. Below the signature, the word "for" is written in a small, lowercase font.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161577

Device Name

The Arm-type Fully Automatic Digital Blood Pressure Monitors for BP-1304 and BP-46

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.

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

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SECTION 2

510 (k) Summary

510(k) Summary

The assigned 510(k) number is: _____

2.1. Date Prepared:

2016.03.29

2.2. Subjectter's Identification:

Name: Sejoy Electronics & Instruments Co., Ltd.

Addr.: Building 2, No.202, Zhenzhong Road, West Lake Economy & Technology Zone,
Hangzhou, China 310030

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 Arm-type Fully Automatic Digital Blood Pressure Monitor

Including the following models: BP-46, BP-1304

Common Name: Blood Pressure Monitor

Classification name: Non-invasive blood pressure measurement System

21 CFR 870-1130, Class II, 74-DXN.

2.4. Classification Information:

Regulation Number: 870.1130

Product Code: DXN Device

Class: II


Panel: 74 Cardiovascular

2.5. Predicate Device Information:

The Arm-Type Fully Automatic Digital Blood Pressure Monitor BP-1304 is substantially equivalent to the following device: Blood Pressure Monitor BP-1304, and BP-46 substantially equivalent to BM-40, FDA 510(k) number: K120554, manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD..

2.6. Device Description:

The Arm-Type Fully Automatic Digital Blood Pressure Monitor uses 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.

For BP-46 and BP-1304, the blood pressure results are compared with WHO (World Health Organization) Blood Pressure classification, which are severe Hypertension, Moderate Hypertension, Mild Hypertension, High-normal, Normal, and Optimal. The corresponding LCD segment will be turned on along with the systolic, diastolic, and pulse rate information. They will display an irregular heartbeat symbol “” if an irregular heartbeat was detected during the measurement process. BP-46 can display average results in three ways.

The device is designed and manufactured according to AAMI / ANSI / IEC 80601-2-30:2009, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

2.7. Intended Use:

The Arm-Type Fully Automatic Digital Blood Pressure Monitors BP-1304 and BP-46 are intended to use for adults and adolescents age 12 through 21 years of age to measure the systolic and diastolic blood pressure and pulse rate.

2.8. Difference of comparison with predicate device:

The difference between the predicate device BP-1304 and the subject Arm-type fully automatic blood pressure monitor BP-1304 is one new arm-cuff (Size: 22.0cm-42cm) added as optional for users. The difference between BM-40 and BP-46 is technological characteristics as described below.

2.9. Non-clinical Tests:

Electromagnetic Compatibility Test according to IEC/EN 60601-1-2:2007;

General Safety Provisions Test according to AAMI/ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R)2012 and A2:2010/(R)2012;

Performance Test according to IEC 80601-2-30:2009, 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 G95-1 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.

2.10. Discussion of Clinical Tests Performed:

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.

2.11. Conclusions:

The subject Arm-type Fully Automatic Blood Pressure Monitor BP-1304 is itself of the predicate device BP-1304 manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD. (FDA 510(k) number: K120554). The addition of new arm-cuff (Size: 22cm-42cm) will not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

The subject Arm-type Fully Automatic Blood Pressure Monitor BP-46 is substantially equivalent to the predicate device BM-40 manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD. (FDA 510(k) number: K120554). The difference between them will not (1) affect the intended use or (2) alter the fundamental scientific technology of the device.