



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

November 9, 2015

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

Re: K152426
Trade/Device Name: Wrist - Type Fully Automatic Digital Blood Pressure Monitor (BP-2116, BP-2220, BSP-21, BSP-22)
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 15, 2014
Received: September 8, 2015

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 yours,

Bram D. Zuckerman -S

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)

K152426

Device Name

Wrist - Type Fully Automatic Digital Blood Pressure Monitor
(BP-2116, BP-2220, BSP-21, BSP-22)

Indications for Use (Describe)

Measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents age 12 through 21 years of age with cuff circumference of 13.5 – 21.5 cm.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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. Date Prepared:

2015.07.27

2.2. Submitter's Identification:

Name: Sejoy Electronics & Instruments Co., Ltd.

Add.: 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 Wrist-type Fully Automatic Digital Blood Pressure Monitor

Including the following models: BP-2116, BP-2220, BSP-21, BSP-22

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 Wrist-Type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the following device: Blood Pressure Monitor (Model BP-2206) , FDA 510(k) number: K121355 , manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD..

2.6. Device Description:

The wrist-type Fully Automatic Digital Blood Pressure Monitor uses an inflatable cuff which is wrapped 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 in 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 minutes. There is a maximum pressure safety setting at 300 mmHg, the device will not inflate the pressure of cuff higher than 300 mmHg.

For BP-2220, BSP-22, 120 memories are divided into two groups as the predicate device BP-2206, with 60 memories each group. For BP-2116, BSP-21, 120 memories are for one group. For BP-2116, BP-2220, BSP-21, BSP-22, 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. BP-2220 , BSP-21 , BSP-22 can calculate the average of the last three measurements as the predicate device BP-2206. BP-2220, BSP-21, BSP-22 will display an irregular heartbeat symbol "❤️" if an irregular heartbeat was detected during the measurement process. BP-2116 cancels Irregular Heartbeat Detection and "Last 3 results average". For BP-2220, BSP-22, there are 3 optional functions and there is 2 optional functions for BSP-21 as BP-2206, and there is no optional function for BP-2116.

The devices are all 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. Indications for Use:

Measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents age 12 through 21 years of age with cuff circumference of 13.5 – 21.5 cm.

2.8. Summary comparing technological characteristics with predicate device:

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical Safety	Identical

The difference of technological characteristics between the predicate device and the submit wrist-type fully automatic blood pressure monitors is the appearance and the function.

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 Wrist-type Fully Automatic Blood Pressure Monitors BP-2116, BP-2220, BSP-21, BSP-22 have the same intended use and similar technological characteristics as the Blood Pressure Monitor manufactured by SEJOY ELECTRONICS & INSTRUMENTS CO., LTD. (Model BP-2106, FDA 510(k) number: K121355).

Moreover, verification and validation tests as part of this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared devices.

In the other words, those engineering differences do 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.