



July 3, 2019

Shenzhen BSX Technology Electronics Co., Ltd.
Zhijian Zhao
Sales Director
Rm301.3F&4F, 8th Building, LiHao Industrial Area
No.78 AiNan Road, Longgang
Shenzhen, 518116
CHINA

Re: K183058

Trade/Device Name: Arm-type Electronic Blood Pressure Monitor, Models BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II

Product Code: DXN

Dated: May 13, 2019

Received: May 29, 2019

Dear Zhijian Zhao:

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/pmnm.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 Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183058

Device Name

Arm-type Electronic Blood Pressure Monitor, Models BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595

Indications for Use (Describe)

The blood pressure monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Applicant

Shenzhen BSX Technology Electronics Co., Ltd.

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Contact Person

Zhijian Zhao

Prepare date

2019-05-10

2. Device name and classification

Device Name: Arm-type Electronic Blood Pressure Monitor

Models: BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595

Classification Name:

21 CFR 870.1130

Noninvasive Blood Pressure Measurement System

Product code: DXN

Regulatory Class: Class II

3. Predicate Device(s)

Shenzhen Pango Electronic Co., Ltd., PG-800B36 Electronic Blood Pressure
Monitor / K170151

4. Device Description

The Arm-type Electronic Blood Pressure Monitor is a battery powered automatic non-invasive blood pressure monitor, of which BSX516, BSX525, BSX583, BSX593 and BSX595 are powered by 4x1.5V AAA Alkaline Battery, and BSX523 is powered by 3.7V 400mAh Li-ion Battery. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure and pulse rate of the adult person at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa.

The difference between the six models include the battery type and the backlight indicator. BSX516, BSX525, BSX583, BSX593 and BSX595 are powered by 4x1.5V AAA Alkaline Battery, while BSX523 is powered by 3.7V 400mAh Li-ion Battery. Moreover, the subject device is equipped with backlight indicator except models BSX516 and BSX525.

The device has the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time. The proposed Arm-type Electronic Blood Pressure Monitor share the similar software, measurement principle and NIBP algorithm.

The proposed device is intended to be used in medical facilities or at home. And the effectiveness of this sphygmomanometer has not been established in pregnant (including pre-eclamptic) patients.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

5. Indications for Use

The blood pressure monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.

6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find differences between the subject device and predicate device.

Table 1 Comparison between the predicate PG-800B36 and the subject device

ITEM	Proposed Device BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595	Predicate Device PG-800B36/ K170151	Comparison Result
Manufacture	Shenzhen BSX Technology Electronics Co., Ltd.	Shenzhen Pango Electronic Co., Ltd.	---
Indications for Use	The blood pressure monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.	The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended arm circumference includes 22 cm~32 cm and 32 cm~42 cm.	Different
Contraindications	Not Known	Not Known	Same
Clinical Use	Medical Facilities and Home Use	Medical Facilities and Home Use	Same
Patient Population	Adult	Adult	Same
Measurement Type	Upper arm	Upper arm	Same
Measurement Principle	Oscillometric	Oscillometric	Same
Components	LCD / Key / Cuff / MCU / Pump / Batteries	LCD / Key / Cuff / MCU / Pump / Batteries	Same
Power Source	4x1.5V AAA Alkaline Battery (BSX516, BSX525, BSX583, BSX593 and BSX595)	4x1.5V AAA Alkaline Battery	Same
	3.7V 400mAh Li-ion Battery(BSX523)		Different
Physical Dimensions(mm)(Length*Width*Height)	Approx: 516: 110 x130 x 58 523: 106 x 145 x 68.5 525: 110 x130 x 58 583: 112 x 132 x 70.5 593: 112 x 132 x 70.5 595: 112 x 132 x 70.5	Approx: 140 x100 x50	Different
Weight	Approx: 370g, containing dry battery, CUFF	Approx: 420 g, excluding battery	

Measurement Range	Blood Pressure	0 ~ 299 mmHg	Blood Pressure	30 ~ 280 mmHg	Different
	Pulse Rate	40 -180 bpm	Pulse Rate	40-199 bpm	
Accuracy	Static Pressure	±3 mmHg	Static Pressure	±3 mmHg	Same
	Pulse	±5%	Pulse	±5%	
Arm Circumference	22 cm~32 cm		22 cm~42 cm		Different
Patient Contact Material	Cuff – Polyester		Cuff –Nylon		Different
Applied Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 80601-2-30:2009 81060-2:2013		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 80601-2-30:2009 81060-2:2013		Same
Operation Environments	+ 5℃~ + 40℃, 15%RH~85%RH Atmospheric Pressure: 80 kPa~106 kPa		+ 5℃~ + 40℃, 15%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa		Different
Storage Environments	- 20℃~ + 55℃, 10%RH~93%RH Atmospheric Pressure: 70 kPa~106 kPa		- 20℃~ + 55℃, 0%RH~93%RH Atmospheric Pressure: 50 kPa~106 kPa		

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the system.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Arm-type Electronic Blood Pressure Monitor and the NIBP CUFF were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- ☐ Cytotoxicity
- ☐ Skin Sensitization
- ☐ Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Arm-type Electronic Blood Pressure Monitor, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the 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* standard for EMC.

Bench Testing

Bench testing was conducted on the Arm-type Electronic Blood Pressure Monitor, consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2010 *MEDICAL ELECTRICAL EQUIPMENT –Part 1-11: 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*, ISO 80601-2-30: 2009 *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers* standards for performance effectiveness.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

Clinical testing is conducted per ISO 81060-2: 2013 *Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type*.

Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the BSX Arm-type Electronic Blood Pressure Monitor is substantially equivalent to the predicate devices.