February 19, 2025

Shenzhen BSX Technology Electronics Co., Ltd.
Xiyu Lu
RA Manager
Rm101&2/F~4/F, Building No.13, Ailian Industrial park,
Wulian Community, Longgang Distric
Shenzhen, GuangDong 518116
China

Re: K241578
Trade/Device Name: Wrist Digital Blood Pressure Monitor (BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 13, 2025
Received: January 13, 2025

Dear Xiyu Lu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Robert T. Kazmierski -S

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241578

Device Name

Wrist Digital Blood Pressure Monitor (BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355)

Indications for Use *(Describe)*

The Wrist Digital Blood Pressure Monitor (Model: BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355) is a digital and non-invasive monitor intended to measure the diastolic, systolic blood pressure and pulse rate in adult with an inflatable wrist cuff circumference ranging from 13.5 to 19.5cm. It is intended for clinical and home use.

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.

510(K) Summary

1. Prepared Date: 2024/05/15

2. Submitter Information

Name	Shenzhen BSX Technology Electronics Co., Ltd.
Address	Rm101&2/F~4/F, Building No.13, Ailian Industrial park, Wulian Community, Longgang Distric, ShenZhen, GuangDong, 518116, CHINA
Contact person	Kai Fang
Tel	86 - 755 - 28719103
E-mail	kaifang186@126.com

3. Submission Correspondent

Contact person	Xiyu Lu
E-mail	Xiyu.Luke@outlook.com
Tel	+86-13713938991

4. Subject Device Information

Proprietary Name	Wrist Digital Blood Pressure Monitor
Common Name	Noninvasive blood pressure measurement system
Model	BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355
Classification	System, Measurement, Blood-Pressure, Non-Invasive
Review Panel	Cardiovascular
Product Code	DXN
Regulation Number	870.1130
Regulatory Class	II

5. Predicate Device

K182127, Omron Healthcare, Inc.	
Trade/Device Name	Wrist Blood Pressure Monitor
Model	BP6100
Regulation Name	Noninvasive Blood Pressure Measurement System
Regulatory Class	Class II
Product Code	DXN

6. Indications for Use

The Wrist Digital Blood Pressure Monitor (Model: BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355) is a digital and non-invasive monitor intended to measure the diastolic, systolic blood pressure and pulse rate in adult with an inflatable wrist cuff circumference ranging from 13.5 to 19.5cm. It is intended for clinical and home use.

7. Summary of technological characteristics of device compared to the predicate devices, see the table

A comparison of similarities and differences between the proposed devices (Wrist Digital Blood Pressure Monitor, BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355) and the predicate device (K182127) is provided below:

	Propose Device	**Predicated Device**	**Comparison**
Product Name	Wrist Digital Blood Pressure Monitor	Wrist Blood Pressure Monitor	/
Manufacturer	Shenzhen BSX Technology Electronics Co., Ltd.	Omron Healthcare, Inc.	/
Model	BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355	BP6100 (K182127)	/
Classification	21 CFR§870.1130, Noninvasive blood pressure measurement system	21 CFR§870.1130, Noninvasive blood pressure measurement system	SE
Product Code	DXN - Noninvasive blood pressure measurement	DXN - Noninvasive blood pressure measurement	SE
Indications for Use	The Wrist Digital Blood Pressure Monitor (Model: BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355) is a digital and non-invasive monitor intended to measure the diastolic, systolic blood pressure and pulse rate in adult with an inflatable wrist cuff circumference ranging from 13.5 to 19.5cm. It is intended for clinical and home use.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm).	Different Note1
Environment of Use	Clinical/Home Use	Home Use	Different Note1
Patient Population	Adults	Adults	Same
Over-The-Counter (OTC)	Yes	Yes	SE
Measurement method	Cuff oscillometric method	Cuff oscillometric method	SE
Measurement Range	Cuff pressure range 0 to 295mmHg Pulse Rate: 40 to 180 beats/min.	Cuff pressure range 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min.	Different Note2

Accuracy	Blood Pressure: Within ±3mmHg Pulse Rate: Within ±5 % of reading	Blood Pressure: Within ±3mmHg Pulse Rate: Within ±5 % of reading	SE
Pressure Sensor	Piezo resistance sensor	Piezo resistance sensor	SE
Inflation Method	Automatic inflation with electric pump	Automatic inflation with electric pump	SE
Deflation Method	Automatic rapid deflation valve	Automatic rapid deflation valve	SE
Display Type	LCD digital display	LCD digital display	SE
Power Source	Two "AAA" batteries	Two "AAA" batteries	SE
Operating Conditions	5 to 40 °C (41 to 104 °F) 15 to 85 %RH (non-condensing)	10 to 40 °C (50 to 104 °F) 15 to 90 %RH (non-condensing)	Different Note3
Storage/Transport Conditions	-20 to 55 °C (-4 to 131 °F) 10 to 93 %RH (non-condensing)	-20 to 60 °C (-4 to 140 °F) 10 to 90 %RH (non-condensing)	Different Note3
Dimensions (W*D*H)	BSX312: 78.5 × 30.2 × 68mm BSX313: 78.5 x 30.2 x 68mm BSX315: 85.5 x 28.5 x 78mm BSX322: 86 x 28.3 x 66mm BSX323: 94 x 29.2 x 74.9mm BSX353: 78.5 x30.2 x 68mm BSX355: 85.5 x 28.5 x 78mm	93× 20× 62mm	Different Note3
Weight	Approx. 150g (containing WRIST CUFF)	Approx. 86g (3.0 oz) (not including battery)	Different Note3

Analysis

From the comparison table, the propose device and predicate device have the same measurement method, measurement accuracy, patient population, pressure sensor and display type etc. There are slightly differences between the devices as follow:

	Difference clause	Discussion
Note1	Wrist circumference range Environment of Use	Proposed device: wrist circumference ranging from 13.5cm to 19.5 cm. Predicated device: wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm). Both devices achieved ISO 80601-2-30 Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers and have the same measurement accuracy though they have slightly wrist circumference and the subjected device would be used in clinic which would not change the intended use of the device.
Note2	Cuff pressure range	Proposed device: Cuff pressure range 0 to 295mmHg Predicated device: Cuff pressure range 0 to 299 mmHg There is slightly range difference and the device passed the test of ISO 80601-2-30 Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers, this difference would not affect the performance and safety of the propose device.
Note3	Operating Conditions, Storage/Transport Conditions, Dimensions, Weight	Minor differences in the dimensions, weight features relate mostly to convenience considerations do not impact the safety or performance of blood pressure or pulse rate measurements. These differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The proposed devices and the predicate device have similar technological characteristics. Both devices are battery-operated wrist blood pressure monitors intended for home use and employ the oscillometric method for measuring blood pressure and pulse rate. Both devices have the same pulse rate range of 40 to 180 beats/min though slightly difference of cuff pressure range (Note2). The devices share the same accuracy range of pressure reading of ±3 mmHg and the same accuracy range for pulse rate reading of ± 5%.

SUBSTANTIAL EQUIVALENCE

The proposed Indications for Use for the Wrist Digital Blood Pressure Monitor is similar to the Indications for Use for the predicate device.

They both intended for use in homecare for blood pressure and pulse rate measurement of adults. The different cuff circumference would not change the intended use. (Note1), and

different use environment has been tested by IEC 60601-1 & ISO 80601-2-30 and showed positive result.
Comparison testing demonstrated that the proposed device is equivalent to the predicate device with regard to measurement of blood pressure in a pulse wave generator test.

Minor differences in the technological features relate mostly to convenience considerations or routine performance updates and do not impact the safety or performance of blood pressure or pulse rate measurements (Note3). Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the proposed device is substantially equivalent to the predicate device.

Wrist Digital Blood Pressure Monitor has been evaluated the safety and performance by lab bench testing as following:

- ✓ Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30 standards
- ✓ Electromagnetic compatibility test according to IEC 60601-1-2 standard
- ✓ Performance according to AAMI / ANSI / ISO 81060-2 standard
- ✓ Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- ✓ Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

Clinical data

The proposed device (BSX335) was tested to ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. The study enrolled 130 subjects, and 85 subjects (44 males and 41 females) met the inclusion requirements were selected with an age range of 12 to 81 years. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018. No adverse effect and/or complication is found in the validation study.

CONCLUSIONS [807.92(b)(3)]

The conclusions drawn from the nonclinical and clinical tests performed in support of that the proposed device is safe and effective and performs at least as safely and effectively as the legally marketed K182127 predicate device.

SUMMARY

The Wrist Blood Pressure Monitor (Model BSX312, BSX313, BSX315, BSX322, BSX323, BSX353, BSX355) is substantially equivalent to the Omron Model BP6100 predicate device(K182127).