March 3, 2023

Qingdao Yasee Medical Device Co., Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222394
Trade/Device Name: Electronic Sphygmomanometers
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 8, 2022
Received: August 8, 2022

Dear Prithul Bom:

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/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.

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222394

Device Name
Electronic Sphygmomanometer

Indications for Use *(Describe)*
Electronic Sphygmomanometer (Model JN-163EW) is a home use digital monitor intended for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm.
The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

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
PRAStaff@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

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter & Foreign Manufacture Identification

Qingdao Yasee Medical Device Co., Ltd.
No.9 Xiuyuan Road, High-tech Industrial Development Zone, Qingdao City, 266112
Shandong Province, P.R. China
Tel：+86 532 68012805
Submitter's FDA Registration Number：N/A

Contact Person

Name：Xiangqun Ye
Company：JL Management and Consulting LLC
Address：755 Watershed Ct., Ann Arbor, MI 48105
Tel: +1.650.265.8159
Email: jlmcllc.info@gmail.com

Date of Summary: April 10, 2022

Device Name

Trade name	Electronic Sphygmomanometer
Common Name	Electronic Sphygmomanometer
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Device Classification	II
Regulation Number	21 CFR 870.1130
Panel	Cardiovascular
General Product Code	DXN

Predicate Device Information:

(1) K150908, "XM-01 Automatic Electronic Blood Pressure Monitor", manufactured by "Sky Innovation Technology (Shanghai) Limited."

Trade/Device Name	XM-01 Electronic Automatic Blood Pressure Monitor
Regulation Number	21 CFR 870.1130
Regulation Name	Noninvasive Blood Pressure Measurement System
Regulatory Class	Class II
Product Code	DXN

Device Description:

Electronic Sphygmomanometer is designed to measure the systolic and diastolic blood pressure of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. This is a home use device.

Measurement method to define systolic and diastolic pressure is similar to the Oscillometric method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. With a sensor, the microprocessor converts tiny alterations in cuff pressure to electrical signals and analyzes those signals to define the systolic and diastolic blood pressure and calculates heartbeat rate, which is a well-known technique in the market called the "Oscillometric method".

The electronic sphygmomanometer achieves its function by a software. As the hardware includes an LCD, it can show the results of the blood pressure measurements and store 99 groups of data which can be checked and deleted.

The device is composed of a main unit and a cuff unit. The cuff unit, which is applicable to wrist circumference approximately between 13.5 and 19.5 cm, includes the inflatable bladder and shell. The main unit consists of the microprocessor, pressure sensor, pump, the electromagnetic deflation control valve and the battery**.** The subject device is powered by 2X AAA Lithium battery.

Indications for Use:

Electronic Sphygmomanometer (Model JN-163EW) is a home use digital monitor intended for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm.

The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Testing Summary:

To prove the safety and effectiveness of Electronic Sphygmomanometer, the device was tested according to corresponding standards.

Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 80601-2-30, Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated noninvasive sphygmomanometers

IEC60601-1, Electrical safety

IEC60601-1-2, Electromagnetic compatibility

IEC 60601-1-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance

ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

ISO 10993-5:2009 Biological Evaluation of Medical Devices--Part 5: Tests For In Vitro Cytotoxicity

ISO 10993-10:2010 Biological Evaluation of Medical Devices--Part 10: Tests For Irritation and Skin Sensitization

Clinical Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use.

The clinical trials for the Electronic Sphygmomanometers were performed according to the standard ISO 81060-2:2019+A1:2020, Non-Invasive Sphygmomanometers – Part 2: Clinical Validation of Automated Measurement Type, and relevant volunteers were collected to conduct actual clinical trial of blood pressure measurement.

Comparison with Predicate Device

The following table shows similarities and differences between our device and the predicate devices.

Table 1: Comparison of Intended Use, Mechanism, Labeling, and Design

Description	Subject Device	Predicate Device (K150908)	Comparison
Indication for Use	Electronic Sphygmomanometer (Model JN-163EW) is a home use digital monitor intended for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm. The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.	XM-01 Automatic Electronic Blood Pressure Monitor is a home use digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm. The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.	Same
Component	Main Unit, Cuff, Battery	Main Unit, Cuff, Battery	Same
Measurement Method	Oscillographic	Oscillographic	Same

User Control	User can manually control measurement	User controls measurement from mobile devices through mobile application software	Minor difference
Labelling	Company Name and Address, Specifications, Product Descriptions, Indications for Use, Contraindication for Use, Precautions, Warnings, Safety Terms and Conditions, Safety Alert Description, Safety and Performance Standards, etc.	Company Name and Address, Specifications, Product Descriptions, Indications for Use, Contraindication for Use, Precautions, Warnings, Safety Terms and Conditions, Safety Alert Description, Safety and Performance Standards, etc.	Same
Power Source	AAA Lithium Battery	Rechargeable Lithium Battery	Similar
Cuff	Wrist warp around	Wrist warp around	Same
Display	LCD Display	Remote display on mobile devices	See discussion
Wireless Mode	None	Bluetooth	See discussion
Data Storage	Local	On mobile devices and on server	See discussion

Our device is essentially identical to the predicate device in terms of indications for use, design, mechanism, and labeling between subject device and the predicate device. The several minor differences do not affect the safety and effectiveness of the device.

Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Electronic Sphygmomanometers (Model JN-163EW)" and its predicate devices have identical indications for use, design, mechanism, labeling, and similar performance, clinical tests.

The difference between the "Electronic Sphygmomanometers (Model JN-163EW)"and its predicate device do not raise any question regarding its safety and effectiveness.

"Electronic Sphygmomanometers (Model JN-163EW)", as designed and manufactured, are as safe and effective as its predicate device, and therefore is substantially equivalent as its predicate device.

The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device according to 807.92(b)(3).