June 28, 2023

Wenzhou Kangshun Medical Devices Co.,Ltd
Eric Shi
QA&QC Manager
No. 706 Yanyun Road,Lingkun Street,Oujiangkou Industrial
Cluster District
Wenzhou City, Zhejiang 325011
China

Re: K230859
Trade/Device Name: Aneroid Sphygmomanometer
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: March 29, 2023
Received: March 29, 2023

Dear Eric Shi:

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,

Hetal B. Patel -S

for

Robert Kazmierski
Acting 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)*
K230859

Device Name
Non-Automated Blood Pressure Meter

Indications for Use *(Describe)*

The aneroid sphygmomanometer is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on children or adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.
There are a variety of stethoscopes can be an optioned accessory,depending on the model.

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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510(k) Summary

1.Submitter Information

Company Name:Wenzhou Kangshun Medical Devices Co.,Ltd.

Address:No.706 Yanyun Road,Lingkun Street,Oujiangkou Industrial Cluster District,Wenzhou City,Zhejiang 325011,China.

Phone:+86-13857771939

Contact Person (including title):Eric Shi (QA&QC Manager)

E-mail:eric-shi@isosh.com

Subject Device Information

Type of 510(k):	Traditional
Common Name:	Non-Automated Blood Pressure Meter
Trade Name:	Aneroid Sphygmomanometer
Regulation Name:	Blood Pressure Cuff
Product Code:	DXQ,LDE
Regulation Number:	21 CFR 870.1120
Regulation Class:	2

2.Predicate Device Information

Common Name:	WX non-Automated Blood Pressure Meter
Regulation Name:	Blood Pressure Cuff
510(k) number:	K212416
Product Code:	DXQ
Regulation Number:	21 CFR 870.1120
Regulation Class:	2

3.Device Description

The product is a manual non-invasive aneroid sphygmomanometer which respectively uses an inflation cuff wrapped around the upper arm.

The cuff is inflated and deflated by a manual inflation bulb. Besides a manometer (Aneroid gauge), the accessories of MODEL Ks-1222,Ks-1621,Ks-3201,Ks-2201,Ks-2203 also includes one selected cuff, one inflation bulb, instruction manual and a vinyl bag.

It is conjunction with Stethoscope when use.

4.Indications for Use

The product is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on children or adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

There are a variety of stethoscopes can be an optioned accessory,depending on the model.

5.Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comment**
Product Name	Non-Automated Blood Pressure Meter	WX non-Automated Blood Pressure Meter	--
General Comparison			
510(k) Number	K230859	K212416	N/A
Device Classification	Blood Pressure Cuff	Blood Pressure Cuff	Same
Regulation Number	21 CFR 870.1120	21 CFR 870.1120	Same
Product Code	DXQ,LDE	DXQ	Same
Indications for Use	The product is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on children or adults.The device is intended to be manually attached to a patient and manually inflated along with a	WX non-Automated Blood Pressure Meter is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on children or adults. The device is intended to be manually attached to a patient and manually inflated along with a	Same

Elements of Comparison	Subject Device	Predicate Device	Comment
	manual method for detecting Korotkoff sounds. There are a variety of stethoscopes can be an optioned accessory,depending on the model.	manual method for detecting Korotkoff sounds. There are a variety of stethoscopes can be an optioned accessory, depending on the model. The device is applicable to all patients at least 2 years of age.	
Model	Ks-1222,Ks-1621,Ks-3201, Ks-2201,Ks-2203	WX02,WX0201, WX0202, WX0203	
Over-TheCounter Use	Yes	Yes	
Where used	Home, Hospital, heathcare facility, ambulance etc.	Home, Hospital, heathcare facility, ambulance etc.	Same
Target population	Children or adults	Infants, children, young adults, and adults	Different 1
Anatomical sites	Upper Arm (leg for child)	Upper Arm (leg for child)	Same
Measurement Method	Auscultatory Korotkoff sounds Method	Auscultatory Korotkoff sounds Method	Same
Inflation	Manual	Manual	Same
Deflation	Manual	Manual	Same
Display	Aneroid Manometer	Aneroid Manometer	Same
The monitor scale	0 to 300 mmHg with a minimum interval of 2 mmHg	From 0 to 300 mmHg with a minimum interval of 2 mmHg	Same
Design of blood pressure meter	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped around the patient's limb	Same

Elements of Comparison	Subject Device	Predicate Device	Comment
	around the patient's limb and secured by hook and loop closure.	and secured by hook and loop closure.	
Design of Stethoscope	Three types of option: Single head Dual head Sprague Rappaport	Three types of option: Single head Dual head Sprague Rappaport	Same
Materials	The manometer: Zinc Alloy or Aluminum materials. The tubing, inflation bulb: PVC. Cuff:Nylon cloth.	The manometer: Zinc Alloy or Aluminum materials. The tubing,inflation bulb: PVC or nature latex Cuff: Nylon cloth or cotton cloth for outside layer. Cuff bladder: PVC or nature latex	Same
Accuracy	Pressure: +/- 3 mmHg of reading	Pressure: +/- 3 mmHg of reading	Same
Compatibility with environment	It can be used from 50°F to 104°F (10℃ to 40℃) and 15% ~ 85%RH humidity	It can be used from 50°F to 104°F(10℃ to 40℃) and 15% ~ 85%RH humidity	Same
Cuff Size	Ks-1222:500mm*140mm Ks-1621:520mm*140mm Ks-2201:630mm*175mm Ks-2203:720mm*210mm Ks-3201:380mm*110mm	20"x 5.5" (510mm*140mm) 21.7"x 6.3" (550mm*160mm) 24.4"x 6.9" (620mm*175mm) 28.3"x 8.3" (720mm*210mm) 13.4"x 4.15" (340mm*105mm)	Different 2
Cuff Circumference	Fits arm circumferences	Fits arm circumferences 220mm to	Same

Elements of Comparison	Subject Device	Predicate Device	Comment
	220mm to 440 mm.The standard cuff should be available for use in measuring a child's leg blood pressure and for children with larger arms	440 mm.The standard cuff should be available for use in measuring a child's leg blood pressure and for children with larger arms	
Cuff Color	Blue	Blue, Pink, Black	Same
Contents (with accessories)	Aneroid gauge, Arm Cuff, Inflation Bulb, Vinyl storage pouch and Instruction Manual, Stethoscope (option)	Aneroid gauge, Arm Cuff, Inflation Bulb, Vinyl storage pouch and Instruction Manual, Stethoscope (option)	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Biocompatible as requirement of ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Performance	compatible as requirement of ISO 81060-1	compatible as requirement of ISO 81060-1	Same

Different 1: The target population of the product is for children or adults and the target population of the predicate device is for Infants, children, young adults, and adults.

Different 2: The cuff size of Ks-1222,Ks-1621,Ks-2201 is shorter than predicate device.The cuff size of Ks-2203 is equivalent that predicate device.The cuff size of Ks-3201 is more than predicate device

6.Non-clinical Tests Performed on the Proposed Device

The company has performed non-clinical performance testing based on its risk assessment utilizing Failure Mode Effect Analysis (FMEA).

Following Quality System processes,required testing was conducted to validate the cumulative modifications made to the subject devices.

Substantial Equivalence is being supported with full performance testing representing the current devices currently marketed.

Performance test

• ISO 81060-1:2007 Non-invasive sphygmomanometersPart 1: Requirements and test methods for non-automated measurement type

Biocompatibility test

Testing was conducted according to relevant sections of ISO 10993:2019 Biological evaluation of medical devices.

Biocompatibility testing included:

• MTT cytotoxicity test

• Skin Sensitization Test

• Skin Irritation Test

• ISO 10993-1:2018 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 10993-10:2021 Biological evaluation of medical devices-Part 10: Tests for skin sensitization

• ISO 10993-23:2021 Biological evaluation of medical devices-Part 23: Tests for irritation

7.Clinical Testing

Not Applicable

8.Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K212416,the product is as safe,as effective.

9.Summary Prepared Date

22 June 2023