May 18, 2022

Wenzhou Xikang Medical Instruments Co., Ltd
℅ Sandy Liu, Consultant
Jin Services Co.
9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North District
Tainan City, 70447
Taiwan

Re: K212416
Trade/Device Name: WX non-Automated Blood Pressure Meter, MODEL WX02, WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: April 6, 2022
Received: April 22, 2022

Dear Sandy Liu:

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,

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)*
K212416

Device Name
WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203

Indications for Use *(Describe)*
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 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.

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

Company Name:	WENZHOU XIKANG MEDICAL INSTRUMENTS CO., LTD
Company Address:	NO.1478 Haining Road, Haibin Street, Longwan District, Wenzhou, Zhejiang 325024, China
Telephone:	86-577-86876969
Fax:	N/A
Contact Person:	WANG TIANCE
Summary Preparation Date:	May 11, 2022
Device Trade Name:	WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203
Classification Name:	Blood pressure cuff
Regulation Number:	21 CFR 870.1120
Product Code:	DXQ
Device Class:	Class 2
Panel:	Cardiovascular

PREDICATE DEVICE:

RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)

INDICATIONS FOR USE

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 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.

DEVICE DESCRIPTION

WX non-Automated Blood Pressure Meter 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 WX02, WX0201, WX0202, WX0203 also includes one selected cuff, one inflation bulb, instruction manual and a vinyl bag. Model WX0201, WX0202, WX0203 include additional stethoscope (Single head, Dual head, and Sprague Rappaport). It is conjunction with Stethoscope when use.

The PVC or nature latex inflation bulb and optional various size of cuffs which cuffs outside layer is made of Nylon Cloth or Cotton Cloth can be selected according to user's need.

Substantial Equivalence Comparison

It is substantially equivalent to the predicate device (K190902), RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 with respect to indications for use, device description, and technical characteristics.

All comparison table for applied devices are as following, and the substantial equivalence determination is based on the 510(k) Substantial Equivalence Decision-Making Process Flowchart which includes the comparison and discussion of indications for use, technology, and performance specifications.

comparison item	**New device** **WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203**	**Predicate device** **RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)**	**Result of Comparison**
Applicant	WENZHOU XIKANG MEDICAL INSTRUMENTS CO., LTD	Wenzhou Renhua Instruments Co., Ltd	Different
Classification	Class II	Class II	SAME
Regulation number	21CFR 870.1120	21CFR 870.1120	SAME
Product code	DXQ	DXQ	SAME
Indications for	The device is intended to be	The device is intended to be	SAME

comparison item	New device WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203	Predicate device RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)	Result of Comparison
use	used by medical professionals or at home for the measurement of systonic and diastonic pressure by detecting Korotkoff sounds.	used by medical professionals or at home for the measurement of systonic and diastonic pressure by detecting Korotkoff sounds.	
Over-The-Counter Use	Yes	Yes	SAME
Where used	Home, Hospital, heathcare facility, ambulance etc.	Home, Hospital, heathcare facility, ambulance etc.	SAME
Target population	infants, children, young adults, and adults	infants, children, young adults, and adults	SAME
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 by inflation bulb	Manual by inflation bulb	SAME
Deflation	Manual deflation via valve	Manual deflation via valve	SAME
Display	Aneroid Manometer	Aneroid Manometer	SAME
The monitor scale	From 0 to 300 mmHg with a	From 0 to 300 mmHg with a	SAME

comparison item	New device WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203	Predicate device RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)	Result of Comparison
	minimum interval of 2 mmHg.	minimum interval of 2 mmHg.	
Design of blood pressure meter	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure.	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure.	SAME
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 or nature latex. Cuff: Nylon cloth or cotton	The manometer: Zinc Alloy or Aluminum materials. The tubing, inflation bulb: PVC or nature latex. Cuff: Nylon cloth or cotton	SAME

comparison item	New device WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203	Predicate device RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)	Result of Comparison
	cloth for outside layer. Cuff bladder: PVC or nature latex	cloth for outside layer. Cuff bladder: PVC or nature latex	
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	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)	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)	SAME
Cuff Circumference	Fits arm circumferences 8.7” to 17.3” (220mm to 440 mm), The standard cuff should be available for use	Fits arm circumferences 8.7” to 17.3” (220mm to 440 mm), The standard cuff should be available for use	SAME

comparison item	New device WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203	Predicate device RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902)	Result of Comparison
	in measuring a child's leg blood pressure and for children with larger arms.	in measuring a child's leg blood pressure and for children with larger arms.	
Cuff bladder Size	8.7"x 4.7"(220mm*120mm) 11.8"x 5.9"(300mm*150mm) 13.4"x 6.7"(340mm*170mm) 6.9"x 3.3"(175mm*85mm)	8.7"x 4.7"(220mm*120mm) 11.8"x 5.9"(300mm*150mm) 13.4"x 6.7"(340mm*170mm) 6.9"x 3.3"(175mm*85mm)	SAME
Cuff Color	Blue, Pink, Black	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	biocompatible as requirement of ISO 10993-1 ISO 10993-5 ISO 10993-10	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

Discussion

Comparing with the predicate device, RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203 (K190902), WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203 have same product name, classification and product code, product physical design and operation, same Aneroid gauge, packaging materials, performance parameter ranges, physical properties, mechanical properties, biocompatibility. The differences between those two devices are as following,

- Package brand name, layout design, trade name and model name.

Non-Clinical Testing
Non-clinical testing included biocompatibility and bench testing. The tests listed in the ISO10993 and ISO81060-1, were included. Results of testing were acceptable.

Clinical Study
No clinical study is included in this submission.

CONCLUSION
WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203 have the same intended use and same technological characteristics as the above predicate devices. Thus, WX non-Automated Blood Pressure Meter, MODEL WX02 and WX non-Automated Blood Pressure Meter with Stethoscope, MODEL WX0201, WX0202, WX0203 are substantially equivalent to the predicate devices.