March 23, 2021

Wuxi Exanovo Medical Instrument Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, Shanghai 200120
China

Re: K203620
Trade/Device Name: Aneroid Sphygmomanometer
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: January 22, 2021
Received: January 22, 2021

Dear Diana Hong:

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,

for LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K203620

Device Name
Aneroid Sphygmomanometer

Indications for Use *(Describe)*
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.

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.

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Tab #6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K203620

1. Date of Preparation: 12/15/2020

2. Sponsor Identification

Wuxi Exanovo Medical Instrument Co., Ltd.
No.42, Xixin Road, Zhangjing, Xibei Town, Wuxi City, 214194, China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Aneroid Sphygmomanometer
Classification Name: Blood pressure cuff

Regulatory Information
Classification Name: Blood pressure cuff
Classification: II;
Product Code: DXQ
Regulation Number: 21CFR 870.1120
Review Panel: Cardiovascular

Regulatory Information
Classification Name: Stethoscope, manual
Classification: II;
Product Code: LDE
Regulation Number: 21 CFR 870.1875
Review Panel: Cardiovascular

Indications for Use
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.

Device Description
The proposed device is composed of manometer, cuff, cuff bladder, inflation bulb and optioned stethoscopes. It is available in four models, MC-20A, MC-20B, MC-30 and MC-50, which are different in cuff material, cuff bladder material and stethoscope option. The aneroid sphygmomanometer should be used in conjunction with a stethoscope. For model MC-50, there are three types of stethoscope for option: Single Head, Dual Head and Sprague Rappaport stethoscope, while the other models of the proposed device do not have stethoscope in configuration. There are also six sizes of cuff for each model device in order to fit varies arm circumference of user. The proposed device is Over-The-Counter use, non-sterile, reusable device.

5. Identification of Predicate Device

510(k) Number: K190902
Product Name: RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203

6. Non-Clinical Test Conclusion

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 81060-1:2007 Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type.
- 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;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device Aneroid Sphygmomanometer	Predicate Device K190902	Remark
Product Code	DXQ, LDE	DXQ, LDE	SE
Regulation No.	21 CFR 870.1120	21 CFR 870.1120	SE
Class	II	II	SE
Indication for Use	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.	RH 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.	SE
Over-The Counter Use	Yes	Yes	SE
Where used	Home, Hospital, healthcare facility, ambulance etc.	Home, Hospital, healthcare facility, ambulance etc.	SE
Target population	infants, children, young adults and adults	infants, children, young adults and adults	SE
Anatomical sites	Upper Arm (leg for child)	Upper Arm (leg for child)	SE
Measurement Method	Auscultatory Korotkoff sounds Method	Auscultatory Korotkoff sounds Method	SE
Inflation	Manual by inflation bulb	Manual by inflation bulb	SE

Deflation	Manual deflation via valve	Manual deflation via valve	SE
Display	Aneroid Manometer	Aneroid Manometer	SE
The monitor scale	From 0 to 300 mmHg with a minimum interval of 2 mmHg.	From 0 to 300 mmHg with a minimum interval of 2 mmHg.	SE
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.	SE
Design of Stethoscope	Three types option: Single head Dual head Sprague Rappaport	Three types option: Single head Dual head Sprague Rappaport	SE
Materials	The manometer: aluminum and stainless steel materials. The tubing, inflation bulb: PVC or nature latex. Cuff: Nylon cloth or cotton cloth for outside layer. Cuff bladder: PVC or nature latex	The manometer: aluminum and stainless steel materials. The tubing, inflation bulb: PVC or nature latex. Cuff: Nylon cloth or cotton cloth for outside layer. Cuff bladder: PVC or nature latex	SE
Accuracy	Pressure: +/- 3 mmHg of reading.	Pressure: +/- 3 mmHg of reading.	SE
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.	SE
Cuff Sizes	21" × 5.7"(540mm*145mm) 26" × 6.9" (660mm*175mm) 30.7" × 8.67" (780mm*220mm) 14.96" × 4.33" (380mm*110mm) 11.81" ×2.76" (300mm*70mm) 9.84" × 2.16"(250mm*55mm）	20" × 5.5" (510mm*140mm) 21.7" × 6.3" (550mm*160mm) 24.4" × 6.9" (620mm*175mm) 28.3" × 8.3" (720mm*210mm) 13.4" × 4.15" (340mm*105mm) 10.2" × 3" (260mm*75mm)	Analysis 1
Cuff Circumference	Fits arm circumferences 8.7" to 17.3" (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.	Fits arm circumferences 8.7" to 17.3" (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.	SE
Cuff bladder Size	8.7"×4.7" (220mm*120mm) 11.8"×5.9" (300mm*150mm) 14.76" × 7.28"(375mm*185mm) 6.9"×3.3"(175mm*85mm) 3.15" × 1.57"(80mm*40mm) 3.54" × 0.98"(90mm*25mm)	8.7" × 4.7"(220mm*120mm) 11.8" × 5.9"(300mm*150mm) 13.4" × 6.7"(340mm*170mm) 6.9" × 3.3"(175mm*85mm) 7.5" x 2"(190mm*50mm)	Analysis 2

Cuff Color	Black	Blue, Pink, Black	Analysis 3
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)	SE
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	SE
Performance	compatible as requirement of ISO 81060-1	compatible as requirement of ISO 81060-1	SE

Analysis 1 – Cuff Sizes

The cuff sizes of proposed device are different from predicate device. However, the cuff size of proposed device is similar to the predicate device and the Cuff Circumference of the two devices is the same. The Velcro on cuff is designed to fit varies arm circumference. This difference doesn't raise new problems on the safety and effectiveness of the proposed device. Therefore, this difference does not affect the substantially equivalence between the proposed device and predicate device.

Analysis 2 – Cuff bladder Size

The cuff bladder size of the proposed device is partly different from predicate device. However, the cuff bladder size of proposed device is similar to the predicate device. It could fit varies requirements of users. This difference doesn't raise new problems on the safety and effectiveness of the proposed device. Therefore, this difference does not affect the substantially equivalence between the proposed device and predicate device.

Analysis 3 – Cuff Color

The cuff color of the proposed device is different from the predicate device. However, the biocompatibility of the cuff of proposed device had been tested and the test results show no adverse effect of the material. Therefore, this difference does not affect the substantially equivalence between the proposed device and predicate device.

9. Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device are determined to be Substantially Equivalent (SE) to the predicate device.