October 13, 2022

Zhejiang LuDe Technology Development Co., Ltd.
Iris Du
RA Manager
NO. 298 Jichang North Road, Longwan District
Wenzhou, Zhejiang 325024
China

Re: K221857
Trade/Device Name: Aneroid sphygmomanometer Model QL-20, QL-201, Aneroid sphygmomanometer with stethoscope, Model QL-50
Aneroid sphygmomanometer, QL-20,
Aneroid sphygmomanometer, QL-201
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: September 23, 2022
Received: September 23, 2022

Dear Iris Du:

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)*
K221857

Device Name
Aneroid sphygmomanometer Model QL-20, QL-201, Aneroid sphygmomanometer with stethoscope, Model QL-50

Indications for Use *(Describe)*
The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds. This product can measure the blood pressure of people aged 3 years and above.

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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Chapter 6. 510(K) Summary

1.submitter

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2.Subject Device Information

Model: QL-20, QL-201, QL-50

Common name: Blood Pressure Kit(Blood Pressure Cuff)

Trade name: Aneroid sphygmomanometer Model QL-20, QL-201/ Aneroid sphygmomanometer with stethoscope, Model QL-50

Product Code：DXQ,LDE

Regulation name: 21CFR 870.1120 (Blood pressure cuff)/21CFR 870.1875(Stethoscope)

Regulation class: Ⅱ

Review Panel: Cardiovascular

3.Predicate device

Sponsor:Wenzhou Renhua Instruments Co.,Ltd

Device Name: RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with Stethoscope, MODEL Max0201, Max0202, Max0203

510(K) number: K190902

Product Code:DXQ,LDE

Regulation class: Ⅱ

Review Panel: Cardiovascular

4.Intended use

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.This product can measure the blood pressure of people aged 3 years and above.

5.Device description

Aneroid sphygmomanometer Model QL-20, QL-201/ Aneroid sphygmomanometer with stethoscope, Model QL-50 are 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 include cuff, inflation bulb, instruction manual and carrying case. Model QL-50 also includes a stethoscope. It is conjunction with stethoscope when use.

6. Substantial equivalence comparison

It is substantially equivalence 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 indication for use, device description, and technical description.

All comparison table for applied device 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 indication for use, technology, and performance specifications.

The new device column includes the following device: Aneroid sphygmomanometer Model QL-20, QL-201/ Aneroid sphygmomanometer with stethoscope, Model QL-50

Item	Subject Device	Predicate Device	Remark
Applicant	Zhejiang LuDe Technology Development Co., Ltd.	Wenzhou Renhua Instruments Co.,Ltd	/
510(K)number	Applying	K190902	/
Regulation number	21 CFR 870.1120	21 CFR 870.1120	SE
Product code	DXQ.LDE	DXQ.LDE	SE
Classification	Class II	Class II	SE
Intended use	The device is intended to be used by medical professional or at home for the measurement of systolic and diastolic pressure by detecting korotkoff sounds.	The device is intended to be used by medical professional or at home for the measurement of systolic and diastolic pressure by detecting korotkoff sounds.	SE
Over-the-counter use	Yes	Yes	SE
Target population	Aged 3 years and above	New born, Infants, children,youngadults,adults	Similar Note 1
Where used	Hospital, home, office,and ambulance, etc.	Hospital, home, office,and ambulance, etc.	SE
Anatomical sites	Upper arm(leg for child)	Upper arm(leg for child)	SE
Measurement method	Ausculatory Korotkoff sounds method	Ausculatory 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 300mmHg with a minimum interval of 2mmHg	From 0 to 300mmHg with a minimum interval of 2mmHg	SE
Design	The device comprised tubing attached to a cuff with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure.	The device comprised tubing attached to a 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	One type option: Single head	Three types option: Single head Dual head Rappaport	Similar Note2
Materials	The manometer : aluminum and stainless steel materials. Cuff:Nylon cloth or cotton cloth for outside layer.	The manometer :aluminum and stainless steel materials. Cuff:Nylon cloth or cotton cloth for outside layer.	SE
Accuracy	Pressure : ±3mmHg of reading	Pressure : ±3mmHg of reading	SE
Compatibility	It can be used from 50℉to	It can be used from 50℉to	SE

with environment	104℉(10℃ to 40℃) and 15%~85% RH humidity .	104℉(10℃ to 40℃) and 15%~85% RH humidity .	
Cuff size	185mm*55mm 255mm*75mm 345mm*110mm 500mm*140mm 540mm*145mm 615mm*175mm 780mm*220mm	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)	Similar Note3
Cuff circumference	Fits arm circumferences 100mm-660mm,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-440cm),the standard cuff should be available for use in measuring a child’s leg blood pressure and for children with larger arms.	Similar Note4
Cuff bladder size	40mm*80mm 60mm*120mm 80mm*150mm 120mm*220mm 145mm*315mm 180mm*370mm	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”×2”(190mm*50mm)	Similar Note5
Contents(with accessories)	Aneroid gauge,Arm cuff, inflation bulb, and instruction manual, stethoscope(option)	Aneroid gauge,Arm cuff, inflation bulb, 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

Discussion of difference:

Note ID	Justification
Note 1	The population range of subject device is smaller than predicate device. The different population range don’t raise any safety or effectiveness issue and the performance of subject device was tested in accordance with ISO 81060-1 and no safety issue was found.
Note 2	The subject device only has one kind of the stethoscope (Single head stethoscope), while the predicate has three kinds of stethoscope(Single head stethoscope, Dual head stethoscope, Rappaport stethoscope). The

	different type of stethoscopes don't raise any safety or effectiveness issue.
Note 3, Note 4 and Note 5	The different sizes of the cuffs and bladders,cuff circumstance are provided in order to accommodate varies target population. All performance have been tested in this submission in accordance with ISO 81060-1 standard and do not raised any safety or effectiveness issue. Therefore, these differences do not raise any new issues on safety and effectiveness of the subject device.

Discussion:

Compared with predicate device, the subject device has same intended use, component, patient of population, accuracy and etc. The only difference is the cuff and bladder size, cuff circumference. This difference is discussed and evaluated in the above table and it shows that there is no new issues of safety and effectiveness raised. So subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

7. Non-clinical testing

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject 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;

8. Clinical testing

No clinical study is included in this submission.

9.Conclusion

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