April 6, 2020

Honsun (Nantong) Co., Ltd
Iris Du
RA manager
No.8, Tongxing Road, Nantong Economic & Technology
Development Area
Nantong, 226009
CHINA

Re: K192500
Trade/Device Name: Aneroid Sphygmomanometer Model HS-20A, HS-20D, HS-201W, HS-201Y, HS-201C1, HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C, HS-50B, HS-50D
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: March 6, 2020
Received: March 11, 2020

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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192500

Device Name
Aneroid Sphygmomanometer Model HS-20A, HS-20D, HS-201W, HS-201Y, HS-201C1, HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C, HS-50B, HS-50D

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.

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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Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

Chapter 6. 510(K) Summary

1.submitter

- Company name: HONSUN(NANTONG)Co.,Ltd
- Address:No.8, Tongxing Road, Nantong Economic & Technological development Area,Jiangsu, 226009, China
- Postal Code:226010
- TEL:86-0513-80580127
- Contact person: Xinhua Pan (General Manager)
  Iris Du(RA Manager)
- E-mail:dulh@lordmed.com

2.Subject Device Information

- Model HS-20A,HS-20D, HS-50C, HS-50B, HS-50D, HS-201Q3,HS-201C1,HS-201Y, HS-201W
- Common name: Blood Pressure Kit(Blood Pressure Cuff)
- Trade name: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3/ Aneroid sphygmomanometer with stethoscope, Model HS-50C,HS-50B,HS-50D
- Product Code： DXQ,LDE
- Regulation name: 21CFR 870.1120/21CFR 870.1875
- Regulation class: II
- Review Panel: Cardiovascular

3.Predicate device

- RH non-Automated Blood Pressure Meter, MODEL Max02 and RH non-Automated Blood Pressure Meter with stethoscope.MODEL

Max0201,Max0202,Max0203,(K190902)

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.

5.Device description

Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1, HS-201Q3/ Aneroid sphygmomanometer with stethoscope, Model HS-50C,HS-50B, HS-50D 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 HS-50C,HS-50D,HS-50B also include a stethoscope. It is conjunction with stethoscope when use.

The subject devices are same as the predicate device(K190902) in terms of PVC or latex inflation bulb and the PVC or latex bladder. Besides, the material of added the optional various size of cuff (nylon or cotton cuff for this application)and the aluminum manometer are identical to the predicate device (K190902).

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

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

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 sphymomanometer Model HS-20A, HS-20D, HS-201W, HS-201Y, HS-201C1, HS-201Q3/ Aneroid sphymomanometer with stethoscope, Model HS-50C, HS-50B, HS-50D.

Comparison item	Subject device: Aneroid sphymomanometer Model HS-20A, HS-20D,HS-201W, HS-201Y, HS-201C1, HS-201Q3/ Aneroid sphymomanometer with stethoscope, Model HS-50C, HS-50B, HS-50D	Predicate device : RH non-Automated Blood pressure meter Model Max 02,RH non-Automated Blood pressure meter with stethoscope, Max0201, Max0202,Max0203	Result of comparison
Applicant	HONSUN(NANTONG)Co.,Ltd	Wenzhou Renhua Instruments Co.,Ltd	
510(K) number	Applying	K190902	-
Regulation number	21 CFR 870.1120	21 CFR 870.1120	Same
Product code	DXQ.LDE	DXQ.LDE	Same
Classification	Class Ⅱ	Class Ⅱ	Same
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.	Same

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

Over-the-counter use	Yes	Yes	Same
Target population	New born, Infants, children, young adults,adults	New born, Infant, children, young adults, adults	Same
Where used	Hospital, home, office, and ambulance, etc.	Hospital, home, office, and ambulance, etc.	Same
Anatomical sites	Upper arm(leg for child)	Upper arm(leg for child)	Same
Measurement Method	Ausculatory Korotkoff sounds method	Ausculatory 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 300mmHg with a minimum interval of 2 mmHg	From 0 to 300mmHg with a minimum interval of 2 mmHg	Same

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

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.	Same
Design of stethoscope	Three types option: Single head Dual head Rappaport	Three types option: Single head Dual head Rappaport	Same
Materials	The manometer :aluminum and stainless steel materials. The tubing ,inflation bulb:PVC or 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 latex. Cuff:Nylon cloth or cotton cloth for outside layer. Cuff bladder:PVC or nature latex	Same
Accuracy	Pressure : ±3mmHg of reading	Pressure : ±3mmHg of reading	Same
Compatibility with environment	It can be used from 50℉to 104℉(10℃ to 40℃) and 15%~85% RH humidity .	It can be used from 50℉to 104℉(10℃ to 40℃) and 15%~85% RH humidity .	Same

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

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
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
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
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)	Same

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

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:

Same in details:

- Compared with the predicate device(K190902) RH non-Automated Blood pressure meter Model Max 02,RH non-Automated Blood pressure meter with stethoscope, Max0201, Max0202, Max0203, the subject device Aneroid sphymomanometer Model HS-20A, HS-20D, HS-201W, HS-201Y, HS-201C1, HS-201Q3/ Aneroid sphymomanometer with stethoscope, Model HS-50C, HS-50B, HS-50D are same as the predicate device(K190902) in terms of materials of the inflation bulb,tubing, cuff and manometer.
- Predicate device (K190902) and subject device HS-20A, HS-20D, HS-50C, HS-50B, HS-50D, HS-201Q3, HS-201C1, HS-201Y, HS-201W have same classification,indication for use, target population, measurement method, product physical design and operation, performance parameter ranges,mechanical safety, anatomical sites, operation principles and etc. The structure of the predicate device (K190902) are same as the subject device ,which all have manometer, bulb, tube, various size of cuff and stethoscope(optional).The predicate device and subject device all have dual head stethoscope, single head stethoscope and rappaport stethoscope.

Sponsor:HONSUN(NANTONG)Co.,Ltd

Subjective device: Aneroid sphygmomanometer Model HS-20A,HS-20D,HS-201W, HS-201Y,HS-201C1,HS-201Q3
Aneroid sphygmomanometer with stethoscope Model HS-50C,HS-50B,HS-50D

Difference in details:

- The different sizes of the cuffs and bladders,cuff circumstance are provided in order to accommodate target population. All performance have been tested in this submission and do not raised any safety or effectiveness issue.All performance specification was verified to comply with the ISO 81060-1 standard.

7. Non-clinical testing

Non-clinical testing included biocompatibility and bench testing. The tests listed in the ISO 10993 and ISO 81060-1, were included. Results of testing were acceptable.

8. Clinical testing

No clinical study is included in this submission.

Conclusion

RH non-automated blood pressure meter Model Max 02, non-automated blood pressure meter with stethoscope Model Max0201, Max 0202,Max0203(K190902) and subject device have the same intended use and similar technological characteristics. Moreover, information contained in this submission supplied demonstrates that any difference in their characteristic do not raise any new questions of safety or effectiveness. Thus, aneroid sphygmomanometer Model HS-20A, HS-20D, HS-201W, HS-201Y, HS-201C1, HS-201Q3/ aneroid sphygmomanometer with stethoscope, Model HS-50C, HS-50B, HS-50D are equivalent to the predicate device(K190902)..