November 28, 2022

Cardicare Company, Ltd.
% Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K222652
Trade/Device Name: Aneroid Sphygmomanometer; Single Patient Use Aneroid Sphygmomanometer
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: September 1, 2022
Received: September 1, 2022

Dear Charles Mack:

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,

Stephen C. Browning -S

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)*

K222652

Device Name
Aneroid Sphygmomanometer
Single Patient Use Aneroid Sphygmomanometer

Indications for Use *(Describe)*

The Aneroid Sphygmomanometer is intended to be used in a healthcare facility by medical professionals or in the home to measure systolic and diastolic pressure on children and adults. The device is intended to be manually attached to a patient and manually inflated, along with a manual method for detecting Korotkoff sounds.

The Single Patient Use Aneroid Sphygmomanometer is intended to be used in a healthcare facility by medical professionals or in the home to measure systolic and diastolic pressure on children and 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.

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K 510(k) SUMMARY

Preparation Date:	September 2, 2022
Manufacturer's Name and Address:	Cardicare Company, Ltd. 9 Yan An Road, Wu Shan Plaza Town, Unit 7003, Hangzhou City, Zhejiang Province, China 310002
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Aneroid Sphygmomanometer Single Patient Use Aneroid Sphygmomanometer
Common Name(s):	blood pressure cuff
Regulation Name(s):	Blood Pressure Cuff
Regulation Number(s):	21CFR870.1120
Product Code:	DXQ
Device Class:	Class II
Predicate Device: Reference Device:	Cardicare Company, Ltd.; K082542 Shanghai Caremate Medical Device Co. Ltd; K211084

Device Description:

Aneroid Sphygmomanometer

The Aneroid Sphygmomanometer is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This Non-automated Sphygmomanometer uses an occluding cuff and an aneroid sphygmomanometer to measure pressure. The proposed device is OTC, non-invasive, non-automated, and non-sterile.

The proposed device consists of an aneroid gauge, cuff, bladder, and inflation bulb. There are four models, including AS-ND-001, AS-ND-001LG, AS-ND-001CH, and AS-D-001. The differences between models are in the size, color, and material of the cuff.

Single Patient Use Aneroid Sphygmomanometer

The device is intended to be manually attached to a patient and manually inflated, along with a manual method for detecting Korotkoff sounds. The proposed device is OTC, non-invasive, non-automated, and non-sterile.

The proposed device consists of a manometer, cuff, and inflation bulb. There are four models: AS-SPU-W, AS-SPU-Y, AS-SPU-LG, and AS-SPU-CH. The differences between models are in the size and color of the cuff.

Both types of aneroid sphygmomanometers use the same measurement method of the Korotkoff sounds method; they are all reusable same measurement range and accuracy. The single-patient use type is for single-patient multiple uses only to avoid cross infection. Both types of aneroid sphygmomanometer can be sold with/without optioned stethoscopes which have been listed with the FDA.

The proposed device is Over-The-Counter use, non-sterile, reusable device.

Principles of Operation/Measurement Method:

Auscultatory Korotkoff sounds method

Comparison of Technological Characteristics with the Predicate Device

Characteristics	Subject Device	Primary Predicate Device	Reference Device	Discussion
Device	Aneroid Sphygmomanometer Single Patient Use Aneroid Sphygmomanometer	Aneroid Sphygmomanometer	Aneroid Sphygmomanometer	-
Submitter	Cardicare Company, Ltd.	Cardicare Company, Ltd.	Shanghai Caremate Medical Device Co. Ltd	-
510(K) Number	Pending	K082542	K211084	-
Classification	2	2	2	Same
Regulation Number	870.1120	870.1120	870.1120	Same
Product Code	DXQ	DXQ	DXQ	Same
Classification Name	Blood pressure cuff	Blood pressure cuff	Blood pressure cuff	Same

Characteristics	Subject Device	Primary Predicate Device	Reference Device	*Discussion*
Indication for Use	The Aneroid Sphygmomanometer is intended to be used in a healthcare facility by medical professionals or in the home to measure systolic and diastolic pressure on children and adults. The device is intended to be manually attached to a patient and manually inflated, along with a manual method for detecting Korotkoff sounds. The Single Patient Use Aneroid Sphygmomanometer is intended to be used in a healthcare facility by medical professionals or in the home to measure systolic and diastolic pressure on children and adults. The device is intended to be manually attached to a patient and manually inflated, along with a manual method for detecting Korotkoff sounds.	The Aneroid Sphygmomanometer with Stethoscope, Model HBPK-A, is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospitals or at home to monitor both systolic and diastolic pressure. This device is sold with an adult D size cuff and suitable for use on adults.	The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on new borns, infants, children, young adults and adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.	*Note 1*
Usage	Reusable	Reusable	Reusable	*Same*
Measurement Method	Korotkoff sounds method	Korotkoff sounds method	Korotkoff sounds method	Same

Characteristics	Subject Device	Primary Predicate Device	Reference Device	*Discussion*
Patient Population	Children, young adults and adults	Adult	New borns, infants, children, young adults and adults	*Note 2*
OTC or Rx	OTC	OTC	OTC	Same
Material	Manometer: Aluminum or Zinc+ABS Cuff: Nylon or cotton or PVC Bladder: PVC Tubing: PVC Hook: Nylon Loop: Nylon	Manometer: Zinc Cuff: Cotton or nylon Latex bladder: Latex or PVC The head of the stethoscope: Aluminum alloy The membrane of the stethoscope: PVC The tube of the stethoscope: PVC	Manometer: aluminum or ABS Tubing, inflation bulb, and cuff bladder: Neoprene or Silicon rubber or Nature latex or PVC Cuff: Nylon cloth for the outside layer	*Note 3*
Tube Quantity	2	2	2	Same
Cuff Circumference (Range in mm)	Conforms to AHA bladder sizes recommendations: Fits arm circumferences 120 mm-508 mm. The standard cuff should be available to measure a child, adult, and adult with large arms.	Adult (with D ring): 24-32cm	Fits arm circumferences 100mm-620mm, the standard cuff should be available for use in measuring a Newborn, infant, or child's leg blood pressure and for a child, young adult, and adult with larger arms	*Note 4*

Characteristics	Subject Device	Primary Predicate Device	Reference Device	*Discussion*
Cuff Sizes	For Aneroid Sphygmomanometer cuff Adult: 53 x 14.5cm Large adult: 62 x 17.5cm Child: 34 x 11cm Adult (with D ring): 50 x 14cm For Single Patients, Use the Aneroid Sphygmomanometer cuff Adult: 53 x 15cm Large Adult: 63 x 17.5cm Child: 31 x 8.5 cm	Adult (with D ring): 50 x 14cm	31.49" × 8.66"（800mm*220mm） 24.41" × 6.89"（620mm*175mm） 20.47" × 5.51"（520mm*140mm） 13.4" × 4.33"（340mm*110mm） 9.84" ×3.15"（250mm*80mm） 8.27" × 2.36"（210mm*60mm）	*Note 5*
Cuff Bladder Size	For Aneroid Sphygmomanometer Adult:22 x 12 cm Large adult: 31 x 13.5 cm Child: 17.5 x 8.5 cm Adult (with D ring): 22 x 12cm For Single Patient Use Aneroid Sphygmomanometer The cuff bladder is integrated with the cuff. The device has no separate bladder.	Adult (with D ring): 22 x 12cm	13.39" × 6.69" (340mm*170mm) 12.2"×5.51" (310mm*140mm) 8.66"×4.72' '(220mm*120mm) 6.69"×3.15" (170mm*80mm) 4.33" × 2.36" (110mm*60mm) 3.15" × 1.57" (80mm*40mm)	*Note 6*
Pressure Limits	0-300mmHg	0-300mmHg	0-300mmHg	Same

Characteristics	Subject Device	Primary Predicate Device	Reference Device	Discussion
Accuracy	Pressure +/-3mmHg of reading	Pressure +/-3mmHg of reading	Pressure +/-3mmHg of reading	Same
Anatomical Sites	Upper Arm	Upper Arm	Upper Arm (leg for child)	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Inflation	Manual by inflation bulb	Manual by inflation bulb	Manual by inflation bulb	Same
Deflation	Manual deflation via valve	Manual deflation via valve	Manual deflation via valve	Same
Display	Aneroid Manometer	Aneroid Manometer	Aneroid Manometer	Same
Performance	Conforms to ISO 81060-1	Conforms to ISO 81060-1 *(previous ANSI/AAMI SP10)*	Conforms to ISO 81060-1	Same
Biocompatibility	Conforms to ISO10993-1	Conforms to ISO10993-1	Conforms to ISO10993-1	Same

Discussion:

Note 1: Indications for use

The subject devices, including the conventional type and single patient use type, are both reusable. The measurement method and intended use for both types are the same as our previously cleared predicate device and reference device, except the single-patients use type is for single-patient use only. Both conform to the same applicable performance standards.

The indication for use statement for the subject devices has been standardized to meet the requirements of most recently cleared devices under product code-DXQ and similar reference devices. The difference doesn't raise new questions of safety or effectiveness compared to the predicate.

Note 2: Patient Population

The target population of the subject devices is larger than the predicate device but still covered by the reference devices, the same as most recently cleared aneroid sphygmomanometer devices.

They conform to the same performance standards (ISO81060-1). Therefore, the difference in the target population does not raise new questions on the safety and effectiveness of the subject device.

Note 3: Material

Although minor material differences exist among subject devices, predicate devices, and reference devices, they all conform to the same ISO10993-1 biocompatibility standards.

Note 4: Cuff circumference

The arm circumference for the proposed cuff is 120 mm-508 mm, and the arm circumference for the predicate cuff is 240-320 mm, the arm circumference for the reference cuff is 100 mm - 620 mm. The range of arm circumferences for the subject device is covered by the reference device, and they conform to the same performance standards; therefore, the difference in cuff circumference does not raise new questions on the safety and effectiveness of the subject device.

Note 5: Cuff sizes

The subject device's cuff sizes differ from the predicate and reference devices. However, the cuff size of the subject device is similar to the predicate device and the reference device. The Velcro on the cuff is designed to fit various arm circumferences. This difference doesn't raise new problems regarding the safety and effectiveness of the subject device. Therefore, this difference in cuff size does not introduce new questions on the safety and efficacy of the subject device.

Note 6: Cuff bladder size

The cuff bladder size is similar to the predicate device and reference device for Aneroid Sphygmomanometer. It could fit various requirements of users.
For Single Patient Use of an Aneroid Sphygmomanometer, the cuff bladder is integrated with the cuff and has no separate bladder.
However, the subject devices conform to ISO 81060-1. Therefore, this difference in cuff bladder size does not raise new questions on the safety and effectiveness of the subject device.

Performance Testing

Performance testing was provided to support the substantial equivalence determination and to validate & verify that the subject devices met all requirements of related applicable standards. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-Clinical Testing

Non-clinical testing was performed to verify substantial equivalence to the predicate device.

Performance:

Non-invasive sphygmomanometers performance testing per ISO 81060-1:2007; ISO 81060-1 First edition 2007-12-01 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

Biocompatibility:

The biocompatibility evaluation for the patient contact reusable cuff was conducted in accordance with the FDA Guidance ”Use of International Standard ISO-10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing with a risk management process, September 4, 2020, and International Standard ISO 10993-1 Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA. The testing items included:
ISO 10993-5: 2009 In Vitro Cytotoxicity
ISO 10993-10: 2010 Skin Irritation
ISO 10993-10: 2010 Skin Sensitization

Clinical Performance Data

No clinical data were required to demonstrate substantial equivalence.

Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Aneroid Sphygmomanometer and Single Patient Use Aneroid Sphygmomanometer is substantially equivalent to the Cardicare Company, Ltd., Aneroid Sphygmomanometer With Stethoscope Model HBPK-A cleared under K082542 and the Aneroid Sphygmomanometer, Aneroid Sphygmomanometer with stethoscope, manufactured by Shanghai Caremate Medical Device Co. Ltd, cleared under K211084 concerning the indications for use, target populations, treatment method, and technological characteristics.

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