October 19, 2021

Shanghai Caremate Medical Device Co. Ltd
Mark Chu
General Manager
Building 4, No. 281, Hong An Road, Jinshan District,
Shanghai, 201503
China

Re: K211084
Trade/Device Name: Aneroid Sphygmomanometer, Aneroid Sphygmomanometer with stethoscope
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: August 28, 2021
Received: September 16, 2021

Dear Mark Chu:

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)*
K211084

Device Name
Aneroid sphygmomanometer, Aneroid sphygmomanometer with stethoscope

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 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.

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

Sponsor Identification and Designated Submission Correspondent

Company name	Shanghai Caremate Medical Device Co. Ltd
Address	Building 4, No. 281, Hong An Road, Zhujing Town, Jinshan District, Shanghai, 201503, China
Establishment Registration Number	3007699082
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Date of Preparation: 9/8/2021

Predicate Device Information

510(k) Number	K192500
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

Proposed Device Information

Trade Name	Aneroid sphygmomanometer, Aneroid sphygmomanometer with stethoscope
Classification Name	Blood pressure cuff
Regulatory Information	
Classification Product code	DXQ
Subsequent Product Code	LDE
Regulation Number	CFR 870.1120, CFR 870.1875
ReviewPanel	Cardiovascular

Indications for Use of Propose Device

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.

Device Description of Propose Device

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 non-invasive, non-automated, non-sterile, reusable device.

The proposed device is consisting of manometer, cuff, cuff bladder, inflation bulb and with/without stethoscope. There are eight models including CM-BPM, CM-BPM-S, CM-BPM-D, CM-BPM-R, CM-PBPM-1, CM-PBPM-2, CM-PBPM-3 and CM-PBPM-C. The differences of eight models are on the size and material of manometer, material of cuff bladder, material of inflation bulb and stethoscope type if the device has stethoscope.

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 [FDA recognition No.: 3-96].
ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity[FDA recognition No.: 2-245];
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization[FDA recognition No.: 2-174];

Biocompatibility testing:
The biocompatibility evaluation for the cuff and stethoscope 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:

- Cytotoxicity
- Sensitization
- Irritation

Performance testing:
Non-invasive sphygmomanometers performance testing per ISO 81060-1:2007;

Clinical Test Conclusion

No clinical study is included in this submission.

Comparison of Technology Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device Aneroid Sphygmomanometer	Predicate Device K192500	Remark
Product name	Aneroid sphygmomanometer, Aneroid sphygmomanometer with stethoscope	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	DXQ, LDE	Same
Regulation No.	21 CFR 870.1120 21 CFR 870.1875	21 CFR 870.1120 21 CFR 870.1875	Same
Class	Ⅱ	Ⅱ	Same
Indication for Use	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.	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.	Different 1
Over-The Counter Use	Yes	Yes	Same
Where used	Home, Hospital, healthcare facility, ambulance etc.	Home, Hospital, healthcare facility, ambulance etc.	Same
Target population	New borns, infants, children, young adults and adults	New borns, infants, children, young adults and adults	Same
Anatomical sites	Upper Arm (leg for child)	Upper Arm (leg for child)	Same
Measurement	Auscultatory Korotkoff sounds Method	Auscultatory Korotkoff sounds Method	Same

Method			
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 minimum interval of 2 mmHg.	From 0 to 300 mmHg with a minimum interval of 2 mmHg.	Same
Design of the device	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	Same
Materials	The manometer: aluminum or ABS The tubing, inflation bulb and cuff bladder: Neoprene or Silicon rubber or Nature latex or PVC Cuff: Nylon cloth for outside layer.	The manometer: aluminum and stainless steel materials. The tubing, inflation bulb and cuff bladder: PVC or nature latex. Cuff: Nylon cloth for outside layer.	Different 2
Accuracy	Pressure: +/- 3 mmHg of reading.	Pressure: +/- 3 mmHg of reading.	Same
Cuff sizes	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）	780mm*220mm 615mm*175mm 540mm*145mm 500mm*140mm 345mm*110mm 255mm*75mm 185mm*55mm	Different 3
Cuff circumference	Fits arm circumferences 100mm-620mm, the standard cuff should be available for use in measuring a New born, infant, child's leg blood pressure and for child, young adult, and adult with larger arms	Fits arm circumferences 100mm-660mm, the standard cuff should be available for use in measuring a New born, infant, child's leg blood pressure and for child, young adult, and adult with larger arms	Different 4
Cuff bladder size	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)	180mm*370mm 145mm*315mm 120mm*220mm 80mm*150mm 60mm*120mm 40mm*80mm	Different 5

Configuration	Manometer, cuff, cuff bladder, inflation bulb and with/without stethoscope.	Manometer, cuff, cuff bladder, inflation bulb and with/without stethoscope.	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

Different 1- Indications for use

The indications for use of proposed device include the target population, while the predicate device doesn't include this information. But they have the same target population, therefore, the proposed device and predicate device have the same indications for use.

Different 2- Material

The material of out shell of manometer, material of tubing and inflation bulb of proposed device is different from the predicate device. But these material is not the patient-contact material, therefore the difference on material does not raise new questions on safety and effectiveness of the proposed device.

Different 3 – 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 on cuff size does not raise new questions on safety and effectiveness of the proposed device.

Different 4 – Cuff circumference

The arm circumferences for the proposed cuff is 100mm-620mm, and the arm circumferences for the predicate cuff is 100mm-660mm. The range of arm circumferences for proposed device is covered by that of the predicate device, therefore, the difference on cuff circumference does not raise new questions on safety and effectiveness of the proposed device.

Different 5 – 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 on cuff bladder size does not raise new questions on safety and effectiveness of the proposed device.

Conclusion

Based on the comparison and analysis above, the proposed devices are as safe, as effective, and performs as well as the legally marketed predicate device K192500.