June 18, 2019

Dongguan Mars Medical Products Co., Ltd
% Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, 511660
CHINA

Re: K191209
Trade/Device Name: Aneroid Type Blood Pressure Kit
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: May 6, 2019
Received: May 6, 2019

Dear Jinghua Zhou:

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 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)*
K1912O9

Device Name
Aneroid Type Blood Pressure Kit

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 models MS-200, MS-200D and MS-200M are intended to be manually attached to a patient and manually inflated along with a manual method.

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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Section 5 - 510(k) Summary

Date of Summary Preparation: April 30, 2019

1. Submitter's Identifications

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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Blood Pressure Cuff
Product Name: Blood Pressure Cuff
Trade Name: Aneroid Type Blood Pressure Kit
Model: MS-200, MS-200D, MS-200M
Classification Panel: Cardiovascular
Product Code: DXQ
Device Classification: Class II

4. The Predicate Devices

K780715 Aneroid Type Blood Pressure Kit

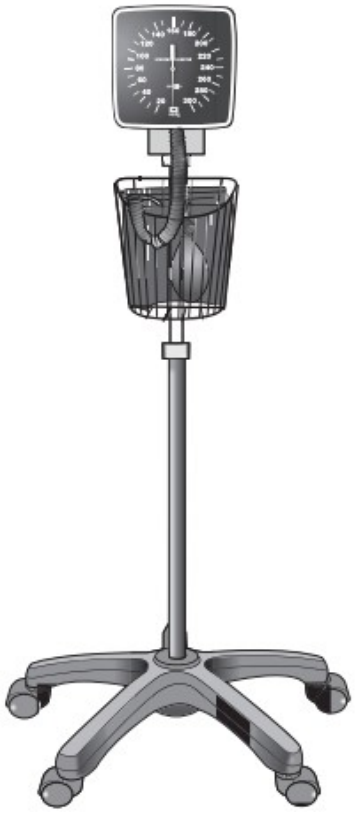
5. Device Description

Aneroid Type Blood Pressure Kit, models MS-200, MS-200D and MS-200M 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.

The proposed device has three models, MS-200/MS-200D/MS-200M. The three models have same intended use, same design and measuring principle, same measuring range and same main components. The only differences among the three

models are assembly accessories for fixation and installation of the aneroid sphygmomanometer.

Table 1 Model Differences Comparison

Model	Type	Main components	Assembly accessories	Picture
MS-200	Wall mounted type	●Aneroid gauge ●Wall clock mount bracket ●Adult size cuff with bladder and inflation bulb ●Metal leur connector set ●Black plastic double-ended male connector ●Coil tubing ●Mini screwdriver	Same parts: ●Four (4) 1” Screws ●Four (4) drywall anchors ●Two (2) ¼” lock screws Different parts only used for Desk type: one lower bracket M6 screw & washer one base and base pad	
MS-200D	Desk type			
MS-200M	Mobile type		●Floor Stand ●Five(5)Caster Wheels ●Metal Basket ●3-piece Pole Assembly(black pole, silver pole, spring) ●Height Adjustment Knob **Floor Stand Hardware** ●One (1) 4.8/M8 Screw Bolt with 2 Washers ●Two (2) 3/8” Screws with Integrated Washers + Two (2) ●Washers ●Two (2) ½” Screws **Wall Mount Hardware** Same as the “Same parts”	

Main components:
Aneroid gauge: indicate the measurement result
Wall clock mount bracket: fix the aneroid gauge
Adult size cuff with bladder and inflation bulb: the cuff is inflated and deflated by the manual inflation bulb
Metal leur connector set: connect the black plastic double-ended male connector and the rubber tube
Black plastic double-ended male connector: connect the metal leur connector set and the coil tubing
Coil tubing: connect the aneroid gauge and the black plastic double-ended male connector
Mini screwdriver: adjust and set to zero when the needle of the aneroid gauge is not within the zero square position

Assembly accessories: fix and install the aneroid sphygmomanometer as wall type, or desk type, or mobile type

Cuff types and dimensions:
The device includes an Adult sized nylon cuff. Additional cuff sizes are available through your dealer. The types and dimensions of the optional cuff are as below:

Size	Dimensions (inches)	Arm Girth (inches)	Dimensions (Centimeters)	Arm Girth (Centimeters)
Infant	3.54”W x 11.8”L	5.12” –7.48”	9.00cm W x 30.0cm L	13.0cm –19.0cm
Child	4.33”W x 14.2”L	7.64” –10.5”	11.00cm W x 36.0cm L	19.4cm –26.7cm
Adult	5.71”W x 21.3”L	10.0” –16.0”	14.50cm W x 54.0cm L	25.4cm –40.6cm
Large Adult	6.89”W x 24.6”L	13.5” –20.0”	17.50cm W x 62.5cm L	34.4cm –50.8cm
Thigh	8.46”W x 30.5”L	16.0” –26.0”	21.50cm W x 77.5cm L	40.6cm –66.0cm

Materials:
Aneroid gauge: the enclosure of gauge is made of Aluminum (bottom) and ABS (panel)
Wall clock mount bracket: steel
Adult size cuff with bladder and inflation bulb: the cuff outside layer is made of nylon cloth or cotton cloth (optional), and inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene) (optional), and the inflation bulb is made of PVC or Latex (Rubber), the tubes connecting to the inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene)
Metal leur connector set: chrome plated aluminum
Black plastic double-ended male connector: PVC
Coil tubing: TPU
Mini screwdriver: metal

6. Intended Use of Device

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The models MS-200, MS-200D and MS-200M are intended to be manually attached to a patient and manually inflated along with a manual method.

7. Summary of Substantial Equivalence

Table 2 Comparison to Predicate Device

	Proposed Device	Predicate device	Comparison
510k Number	------	K780715	------
Product Code	DXQ	DXQ	Same
Proprietary Name	Aneroid Type Blood Pressure Kit	Aneroid Type Blood Pressure Kit	Same
Model	MS-200, MS-200D, MS-200M	MS-115, MS-116, MS-117, MS-200, MS-200D, MS-200M	------
Manufacturer	Dongguan Mars Medical Products Co., Ltd	Dongguan Mars Medical Products Co., Ltd	------
Indications for Use	The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The models MS-200, MS-200D and MS-200M are intended to be manually attached to a patient and manually inflated along with a manual method.	The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The models MS-115, MS-116, MS-117 are intended to be manually attached to a patient and manually inflated along with a manual method and Auscultatory Korotkoff sounds method. The models MS-200, MS-200D and MS-200M are intended to be manually attached to a patient and manually inflated along with a manual method.	Same The proposed device models are contained in those of the predicate device. And the measurement method of models MS-200/200D/200M is same.
Type of Use	Prescription Use	Over-The-Counter Use	Different The difference does not raise safety and effectiveness of the

			proposed device
Operating Principle	Aneroid Type Blood Pressure Kit, models MS-200, MS-200D and MS-200M 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.	Aneroid Type Blood Pressure Kit, models MS-115, MS-116, MS-117, MS-200, MS-200D and MS-200M 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.	Same
Basic Design	The Aneroid Type Blood Pressure Kit is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This non-automated sphygmomanometer uses an occluding cuff, an aneroid sphygmomanometer to measure pressure.	The Aneroid Type Blood Pressure Kit is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This non-automated sphygmomanometer uses an occluding cuff, an aneroid sphygmomanometer to measure pressure (applied for models MS-115/116/117/200/200D/200M) and a stethoscope for detecting Korotkoff sounds (applied for models MS-115/116/117).	Same The basic design of the proposed device is same as the predicate device models MS-200/200D/200M.
Measuring Method	Aneroid	MS-115/116/117: Aneroid / Auscultatory MS-200/200D/200M: Aneroid	Same The measuring method of the proposed device is same as the predicate device models MS-200/200D/200M.
Inflation system	Manual inflation with air pump bulb	Manual inflation with air pump bulb	Same

Deflation system	Manual deflation	Manual deflation	Same
Main Components	Aneroid gauge Wall clock mount bracket Adult size cuff with bladder and inflation bulb Metal leur connector set Black plastic double-ended male connector Coil tubing Mini screwdriver	MS-115/116/117: Aneroid gauge Inflation bulb Binaural Y-Tubing Adult size cuff Stethoscope MS-200/200D/200M: Aneroid gauge Wall clock mount bracket Adult size cuff with bladder and inflation bulb Metal leur connector set Black plastic double-ended male connector Coil tubing Mini screwdriver	Same The main components of proposed device models are same as those models MS-200/200D/200M of predicate device.
Materials	Aneroid gauge: the enclosure of gauge is made of Aluminum (bottom) and ABS (panel) Wall clock mount bracket: steel Adult size cuff with bladder and inflation bulb: the cuff outside layer is made of nylon cloth or cotton cloth (optional), and inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene) (optional), and the inflation bulb is made of PVC or Latex (Rubber), the tubes connecting to the inside bladder is made of PVC, or Latex (Rubber), or Latex Free	MS-115/116/117: Aneroid gauge: the enclosure of gauge is made of steel Binaural: stainless steel and nature latex Y-Tubing: PVC Adult size cuff: the cuff outside layer is made of nylon cloth or cotton cloth (optional), and inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene) (optional), and the inflation bulb is made of PVC or Latex (Rubber) Stethoscope: stainless steel MS-200/200D/200M: Aneroid gauge: the	Same The materials of the proposed device are same as those of the predicate device models MS-200/200D/200M.

	(Neoprene) Metal leur connector set: chrome plated aluminum Black plastic double-ended male connector: PVC Coil tubing: TPU Mini screwdriver: metal	enclosure of gauge is made of Aluminum (bottom) and ABS (panel) Wall clock mount bracket: steel Adult size cuff with bladder and inflation bulb: the cuff outside layer is made of nylon cloth or cotton cloth (optional), and inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene) (optional), and the inflation bulb is made of PVC or Latex (Rubber), the tubes connecting to the inside bladder is made of PVC, or Latex (Rubber), or Latex Free (Neoprene) Metal leur connector set: chrome plated aluminum Black plastic double-ended male connector: PVC Coil tubing: TPU Mini screwdriver: metal	
Measuring range	Pressure: 0 - 300 mmHg	Pressure: 0 - 300 mmHg	Same
Accuracy	Pressure: ±3 mmHg	Pressure: ±3 mmHg	Same
Storage condition	-10°C ~ +60°C, 10% ~ 95% RH	-10°C ~ +60°C, 10% ~ 95% RH	Same
Operating condition	+10°C ~ +40°C, 15% ~ 85% RH	+10°C ~ +40°C, 15% ~ 85% RH	Same
Cuff dimension	Size: Infant — Dimension: 3.54”W x 11.8”L / 9.00cm W x 30.0cm L Size: Child — Dimension: 4.33”W x 14.2”L / 11.00cm W x 36.0cm L	Size: Infant — Dimension: 3.54”W x 11.8”L / 9.00cm W x 30.0cm L Size: Child — Dimension: 4.33”W x 14.2”L / 11.00cm W x 36.0cm L	Same

	Adult	5.71”W x 21.3”L 14.50cm W x 54.0cm L		Adult	5.71”W x 21.3”L 14.50cm W x 54.0cm L	
	Large Adult	6.89”W x 24.6”L 17.50cm W x 62.5cm L		Large Adult	6.89”W x 24.6”L 17.50cm W x 62.5cm L	
	Thigh	8.46”W x 30.5”L 21.50cm W x 77.5cm L		Thigh	8.46”W x 30.5”L 21.50cm W x 77.5cm L	
Arm Girth	Size	Arm Girth		Size	Arm Girth	Same
	Infant	5.12” –7.48” 13.0cm –19.0cm		Infant	5.12” –7.48” 13.0cm –19.0cm	
	Child	7.64” –10.5” 19.4cm –26.7cm		Child	7.64” –10.5” 19.4cm –26.7cm	
	Adult	10.0” –16.0” 25.4cm –40.6cm		Adult	10.0” –16.0” 25.4cm –40.6cm	
	Large Adult	13.5” –20.0” 34.4cm –50.8cm		Large Adult	13.5” –20.0” 34.4cm –50.8cm	
	Thigh	16.0” –26.0” 40.6cm –66.0cm		Thigh	16.0” –26.0” 40.6cm –66.0cm	
Standard	ISO 81060-1 ISO 10993-1 ISO 10993-5 ISO 10993-10			ANSI/AAMI SP9 ISO 10993-1 ISO 10993-5 ISO 10993-10		Similar Standards have been updated and replaced

8. Substantial Equivalence discussion:

Comparing with the predicate device (K780715), Aneroid Type Blood Pressure Kit Model MS-115, MS-116, MS-117, MS-200, MS-200D and MS-200M, modified Aneroid Type Blood Pressure Kit Model MS-200, MS-200D and MS-200M have same product name, classification and product code, product physical design and operation, same aneroid gauge, packaging materials, performance parameter ranges, physical properties, mechanical properties, biocompatibility. The differences between those two devices are as following:

- Type of use for the proposed device is Prescription Use, and the predicate device is OTC. The difference does not raise safety and effectiveness of the proposed device.
- Performance standard complied with the proposed device is ISO 81060-1:2007, and the predicate device is ANSI/AAMI SP9. Standards have been updated and replaced, the proposed device have performed test complying with ISO 81060-1:2007.

9. Non-Clinical Testing

Non-clinical testing included biocompatibility and bench testing. The tests listed in the ISO10993 and ISO81060-1, were included. Results of testing were acceptable.

10. Clinical Study

No clinical study is included in this submission.

11. Conclusion:

Aneroid Type Blood Pressure Kit, models MS-200, MS-200D and MS-200M have the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, Aneroid Type Blood Pressure Kit, models MS-200, MS-200D and MS-200M are substantially equivalent to the predicate devices.