



December 19, 2017

Suzhou Minhua Medical Apparatus Supplies Co., LTD
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

Re: K171889

Trade/Device Name: Reusable Blood Pressure Cuff, with list of 164 models attached
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: November 10, 2017
Received: November 15, 2017

Dear Diana Hong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

List of 164 models

Table 1 Specifications of Reusable Blood Pressure Cuff – with Internal Bladder

No.	Product code	Name	Tube	Arm size
1	MH002RCP10-1	Small adult	One	17-22cm
2	MH002RCP10-2	Small adult	two	17-22cm
3	MH002RCP11-1	Small adult long	One	22-30 cm
4	MH002RCP11-2	Small adult long	two	22-30 cm
5	MH002RCP12-1	Adult	One	22-30 cm
6	MH002RCP12-2	Adult	two	22-30 cm
7	MH002RCP14-1	Large Adult	One	30-42 cm
8	MH002RCP14-2	Large Adult	two	30-42 cm
9	MH002RCP15-1	Large Adult long	One	42-48 cm
10	MH002RCP15-2	Large Adult long	two	42-48 cm

Table 2 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (HP)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06HP1	Infant	One	9-14.8cm
2	MH002RCT06HP2	Infant	two	9-14.8cm
3	MH002RCT07HP1	Infant long	One	9-14.8cm
4	MH002RCT07HP2	Infant long	two	9-14.8cm
5	MH002RCT08HP1	Child	One	13.8-21.5cm
6	MH002RCT08HP2	Child	two	13.8-21.5cm
7	MH002RCT09HP1	Child long	One	13.8-21.5cm
8	MH002RCT09HP2	Child long	two	13.8-21.5cm
9	MH002RCT10HP1	Small adult	One	20.5-28.5cm
10	MH002RCT10HP2	Small adult	two	20.5-28.5cm
11	MH002RCT11HP1	Small adult long	One	20.5-28.5cm
12	MH002RCT11HP2	Small adult long	two	20.5-28.5cm
13	MH002RCT12HP1	Adult	One	27.5-36.5cm
14	MH002RCT12HP2	Adult	two	27.5-36.5cm
15	MH002RCT13HP1	Adult long	One	27.5-36.5cm
16	MH002RCT13HP2	Adult long	two	27.5-36.5cm

17	MH002RCT14HP1	Big adult	One	35.5-46cm
18	MH002RCT14HP2	Big adult	two	35.5-46cm
19	MH002RCT15HP1	Big adult long	One	35.5-46cm
20	MH002RCT15HP2	Big adult long	two	35.5-46cm
21	MH002RCT16HP1	Thigh	One	45-56.5cm
22	MH002RCT16HP2	Thigh	two	45-56.5cm

Table 3 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (SL)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06SL1	Infant	One	9-14.8cm
2	MH002RCT06SL2	Infant	two	9-14.8cm
3	MH002RCT07SL1	Infant long	One	9-14.8cm
4	MH002RCT07SL2	Infant long	two	9-14.8cm
5	MH002RCT08SL1	Child	One	13.8-21.5cm
6	MH002RCT08SL2	Child	two	13.8-21.5cm
7	MH002RCT09SL1	Child long	One	13.8-21.5cm
8	MH002RCT09SL2	Child long	two	13.8-21.5cm
9	MH002RCT10SL1	Small adult	One	20.5-28.5cm
10	MH002RCT10SL2	Small adult	two	20.5-28.5cm
11	MH002RCT11SL1	Small adult long	One	20.5-28.5cm
12	MH002RCT11SL2	Small adult long	two	20.5-28.5cm
13	MH002RCT12SL1	Adult	One	27.5-36.5cm
14	MH002RCT12SL2	Adult	two	27.5-36.5cm
15	MH002RCT13SL1	Adult long	One	27.5-36.5cm
16	MH002RCT13SL2	Adult long	two	27.5-36.5cm
17	MH002RCT14SL1	Big adult	One	35.5-46cm
18	MH002RCT14SL2	Big adult	two	35.5-46cm
19	MH002RCT15SL1	Big adult long	One	35.5-46cm
20	MH002RCT15SL2	Big adult long	two	35.5-46cm
21	MH002RCT16SL1	Thigh	One	45-56.5cm
22	MH002RCT16SL2	Thigh	two	45-56.5cm

Table 4 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (MQ)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06MQ1	Infant	One	9-14.8cm
2	MH002RCT06MQ2	Infant	two	9-14.8cm
3	MH002RCT07MQ1	Infant long	One	9-14.8cm
4	MH002RCT07MQ2	Infant long	two	9-14.8cm
5	MH002RCT08MQ1	Child	One	13.8-21.5cm
6	MH002RCT08MQ2	Child	two	13.8-21.5cm
7	MH002RCT09MQ1	Child long	One	13.8-21.5cm
8	MH002RCT09MQ2	Child long	two	13.8-21.5cm
9	MH002RCT10MQ1	Small adult	One	20.5-28.5cm
10	MH002RCT10MQ2	Small adult	two	20.5-28.5cm
11	MH002RCT11MQ1	Small adult long	One	20.5-28.5cm
12	MH002RCT11MQ2	Small adult long	two	20.5-28.5cm
13	MH002RCT12MQ1	Adult	One	27.5-36.5cm
14	MH002RCT12MQ2	Adult	two	27.5-36.5cm
15	MH002RCT13MQ1	Adult long	One	27.5-36.5cm
16	MH002RCT13MQ2	Adult long	two	27.5-36.5cm
17	MH002RCT14MQ1	Big adult	One	35.5-46cm
18	MH002RCT14MQ2	Big adult	two	35.5-46cm
19	MH002RCT15MQ1	Big adult long	One	35.5-46cm
20	MH002RCT15MQ2	Big adult long	two	35.5-46cm
21	MH002RCT16MQ1	Thigh	One	45-56.5cm
22	MH002RCT16MQ2	Thigh	two	45-56.5cm

Table 5 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (DM)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06DM1	Infant	One	9-14.8cm
2	MH002RCT06DM2	Infant	two	9-14.8cm
3	MH002RCT07DM1	Infant long	One	9-14.8cm
4	MH002RCT07DM2	Infant long	two	9-14.8cm
5	MH002RCT08DM1	Child	One	13.8-21.5cm
6	MH002RCT08DM2	Child	two	13.8-21.5cm
7	MH002RCT09DM1	Child long	One	13.8-21.5cm
8	MH002RCT09DM2	Child long	two	13.8-21.5cm

9	MH002RCT10DM1	Small adult	One	20.5-28.5cm
10	MH002RCT10DM2	Small adult	two	20.5-28.5cm
11	MH002RCT11DM1	Small adult long	One	20.5-28.5cm
12	MH002RCT11DM2	Small adult long	two	20.5-28.5cm
13	MH002RCT12DM1	Adult	One	27.5-36.5cm
14	MH002RCT12DM2	Adult	two	27.5-36.5cm
15	MH002RCT13DM1	Adult long	One	27.5-36.5cm
16	MH002RCT13DM2	Adult long	two	27.5-36.5cm
17	MH002RCT14DM1	Big adult	One	35.5-46cm
18	MH002RCT14DM2	Big adult	two	35.5-46cm
19	MH002RCT15DM1	Big adult long	One	35.5-46cm
20	MH002RCT15DM2	Big adult long	two	35.5-46cm
21	MH002RCT16DM1	Thigh	One	45-56.5cm
22	MH002RCT16DM2	Thigh	two	45-56.5cm

Table 6 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (NA)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06NA1	Infant	One	9-14.8cm
2	MH002RCT06NA2	Infant	two	9-14.8cm
3	MH002RCT07NA1	Infant long	One	9-14.8cm
4	MH002RCT07NA2	Infant long	two	9-14.8cm
5	MH002RCT08NA1	Child	One	13.8-21.5cm
6	MH002RCT08NA2	Child	two	13.8-21.5cm
7	MH002RCT09NA1	Child long	One	13.8-21.5cm
8	MH002RCT09NA2	Child long	two	13.8-21.5cm
9	MH002RCT10NA1	Small adult	One	20.5-28.5cm
10	MH002RCT10NA2	Small adult	two	20.5-28.5cm
11	MH002RCT11NA1	Small adult long	One	20.5-28.5cm
12	MH002RCT11NA2	Small adult long	two	20.5-28.5cm
13	MH002RCT12NA1	Adult	One	27.5-36.5cm
14	MH002RCT12NA2	Adult	two	27.5-36.5cm
15	MH002RCT13NA1	Adult long	One	27.5-36.5cm
16	MH002RCT13NA2	Adult long	two	27.5-36.5cm

17	MH002RCT14NA1	Big adult	One	35.5-46cm
18	MH002RCT14NA2	Big adult	two	35.5-46cm
19	MH002RCT15NA1	Big adult long	One	35.5-46cm
20	MH002RCT15NA2	Big adult long	two	35.5-46cm
21	MH002RCT16NA1	Thigh	One	45-56.5cm
22	MH002RCT16NA2	Thigh	two	45-56.5cm

Table 7 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (FL)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06FL1	Infant	One	9-14.8cm
2	MH002RCT06FL2	Infant	two	9-14.8cm
3	MH002RCT07FL1	Infant long	One	9-14.8cm
4	MH002RCT07FL2	Infant long	two	9-14.8cm
5	MH002RCT08FL1	Child	One	13.8-21.5cm
6	MH002RCT08FL2	Child	two	13.8-21.5cm
7	MH002RCT09FL1	Child long	One	13.8-21.5cm
8	MH002RCT09FL2	Child long	two	13.8-21.5cm
9	MH002RCT10FL1	Small adult	One	20.5-28.5cm
10	MH002RCT10FL2	Small adult	two	20.5-28.5cm
11	MH002RCT11FL1	Small adult long	One	20.5-28.5cm
12	MH002RCT11FL2	Small adult long	two	20.5-28.5cm
13	MH002RCT12FL1	Adult	One	27.5-36.5cm
14	MH002RCT12FL2	Adult	two	27.5-36.5cm
15	MH002RCT13FL1	Adult long	One	27.5-36.5cm
16	MH002RCT13FL2	Adult long	two	27.5-36.5cm
17	MH002RCT14FL1	Big adult	One	35.5-46cm
18	MH002RCT14FL2	Big adult	two	35.5-46cm
19	MH002RCT15FL1	Big adult long	One	35.5-46cm
20	MH002RCT15FL2	Big adult long	two	35.5-46cm
21	MH002RCT16FL1	Thigh	One	45-56.5cm
22	MH002RCT16FL2	Thigh	two	45-56.5cm

Table 8 Specifications of Reusable Blood Pressure Cuff – with Integrated Bladder (MF)

No.	Product code	Name	Tube	Arm size
1	MH002RCT06MF1	Infant	One	9-14.8cm
2	MH002RCT06MF2	Infant	two	9-14.8cm
3	MH002RCT07MF1	Infant long	One	9-14.8cm
4	MH002RCT07MF2	Infant long	two	9-14.8cm
5	MH002RCT08MF1	Child	One	13.8-21.5cm
6	MH002RCT08MF2	Child	two	13.8-21.5cm
7	MH002RCT09MF1	Child long	One	13.8-21.5cm
8	MH002RCT09MF2	Child long	two	13.8-21.5cm
9	MH002RCT10MF1	Small adult	One	20.5-28.5cm
10	MH002RCT10MF2	Small adult	two	20.5-28.5cm
11	MH002RCT11MF1	Small adult long	One	20.5-28.5cm
12	MH002RCT11MF2	Small adult long	two	20.5-28.5cm
13	MH002RCT12MF1	Adult	One	27.5-36.5cm
14	MH002RCT12MF2	Adult	two	27.5-36.5cm
15	MH002RCT13MF1	Adult long	One	27.5-36.5cm
16	MH002RCT13MF2	Adult long	two	27.5-36.5cm
17	MH002RCT14MF1	Big adult	One	35.5-46cm
18	MH002RCT14MF2	Big adult	two	35.5-46cm
19	MH002RCT15MF1	Big adult long	One	35.5-46cm
20	MH002RCT15MF2	Big adult long	two	35.5-46cm
21	MH002RCT16MF1	Thigh	One	45-56.5cm
22	MH002RCT16MF2	Thigh	two	45-56.5cm

Indications for Use

510(k) Number (if known)
K171889

Device Name
Reusable Blood Pressure Cuff

Indications for Use (Describe)

The Reusable Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in infant, pediatric but not neonatal, and adult sizes.

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

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K171889

1. Date of Preparation: 12/18/2017
2. Sponsor Identification

Suzhou Minhua Medical Apparatus Supplies Co., LTD

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Reusable Blood Pressure Cuff

Common Name: Blood Pressure Cuff

Regulatory Information

Classification Name: Blood Pressure Cuff

Classification: 2

Product Code: DXQ

Regulation Number:870.1120

Review Panel: Cardiovascular

Intended Use Statement:

The Reusable Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in infant, pediatric but not neonatal, and adult sizes.

Device Description

The proposed device is an accessory used in conjunction with noninvasive blood pressure measurement systems, and wrap around the patient's limb. The cuff is non-sterile and reusable.

The model difference of the proposed device includes bladder type, tube, color, joint model and size.

5. Identification of Predicate Device(s)

Predicate Device 1

510(k) Number: K133117

Product Name: Andon Blood Pressure Cuff

Predicate Device 2

510(k) Number: K152468

Product Name: Reusable Blood Pressure Cuff

6. 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:

- IEC 80601-2-30: 2013, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.
- 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.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for Cuff with Internal Bladder

Item	Proposed Device Cuff with Internal Bladder	Predicate Device 1 K133117
Device class	2	2
Product code	DXQ	DXQ
Regulation Number	21 CFR 870.1120	21 CFR 870.1120
Intended use	The Reusable Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in infant, pediatric but not neonatal, and adult sizes.	Blood Pressure Cuffs are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.
Patient populations	adult	adult
Tube configuration	One or two tube	One tube
Bladder	Internal Bladder	Internal Bladder
Principles of Operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure. Air hose is connected to the noninvasive blood pressure measurement systems.	Bladder is wrapped around the patient's limb and secured by hook and loop closure. Air hose is connected to the noninvasive blood pressure measurement systems.
Size	Small adult: 17-22cm Small adult long / Adult: 22-30 cm Large Adult: 30-42 cm Large Adult long: 42-48 cm	KD-525-P34: 15-24cm KD-525-P31: 20-34 cm KD-525-P32: 30-44 cm KD-525-P33: 40-48 cm

Reusable	yes	Yes
Sterile	No	No
Pressure range	0-300mmHg	0-300mmHg
Material	Polyester	Not available
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10.	Comply with ISO 10993-5 and ISO 10993-10.

There are four differences for the proposed cuff with internal bladder and predicate device 1.

For intended use,

The proposed devices include two types of bladder. The cuffs with integrated bladder include with sizes of infant, child and adult. But the cuffs with internal bladder only include adult size. The patient population of proposed cuffs with internal bladder include adult only. The intended use of proposed cuffs with internal bladder and predicate device 1 is same actually.

For tube configuration,

The proposed devices include one tube or two tubes, while the predicate device only includes one tube. More tube configuration can be applicable for more types of noninvasive blood pressure measurement system. And the two tubes configuration is very common for blood pressure cuff. The predicate device 2, Reusable Blood Pressure Cuff, includes two tubes configuration. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

For size:

The cuff size range of proposed devices is included in the range of the predicate device 1. And the size is indicated in user manual clearly for selection. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

For material:

The material of proposed device and predicate device 1 may be different, but both of them comply with ISO 10993-5 and ISO 10993-10. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Table 2 Comparison for Cuff with Integrated Bladder

ITEM	Proposed Device Cuff with Integrated Bladder	Predicate Device 2 K152468
Device class	2	2
Product code	DXQ	DXQ
Regulation Number	21 CFR 870.1120	21 CFR 870.1120

Intended use	The Reusable Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in infant, pediatric but not neonatal, and adult sizes.	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes
Patient populations	Infant / pediatric / adult	Infant / pediatric / adult
Tube configuration	One or two tube	One or two tube
Bladder	Integrated Bladder	Integrated Bladder
Principles of Operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure. Air hose is connected to the noninvasive blood pressure measurement systems.	Bladder is wrapped around the patient's limb and secured by hook and loop closure. Air hose is connected to the noninvasive blood pressure measurement systems.
Size	Infant / infant long: 9-14.8cm Child /child long: 13.8-21.5cm Small adult / small adult long: 20.5-28.5cm Small adult long / Adult: 27.5-36.5cm Big adult / big adult long: 35.5-46cm Thigh: 45-56.5cm	Infant: 8-13 cm Child: 12-19 cm Small adult: 17-25cm Adult: 23-33cm Large adult / large adult long: 31-40cm Thigh: 38-50cm
Reusable	yes	Yes
Sterile	No	No
Pressure range	0-300mmHg	0-300mmHg
Material	TPU leather with nylon	210D Nylon TPU and PVC
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10.	Comply with ISO 10993-5 and ISO 10993-10.

There are two differences for the proposed cuff with integrated bladder and predicate device 2.

For size,

The cuff size range of proposed devices is different to that of predicate device 2. But the different is slight. And the size is indicated in user manual clearly for selection. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

For material:

The material of proposed device and predicate device 2 is different, but both of them comply with ISO 10993-5 and ISO 10993-10. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.