



December 21, 2023

Suzhou Minhua Medical Apparatus Supplies Co., LTD  
% Alex Wang  
Regulatory Affairs Specialist  
Suzhou Minhua Medical Apparatus Supplies Co., Ltd.  
No.789, Wu Fang Road, Friendship Industrial Zone,  
Song Ling Town, Wu Jiang  
Suzhou, Jiangsu 215222  
China

Re: K233276  
Trade/Device Name: Reusable Blood Pressure Cuff  
Regulation Number: 21 CFR 870.1120  
Regulation Name: Blood Pressure Cuff  
Regulatory Class: Class II  
Product Code: DXQ  
Dated: August 28, 2023  
Received: September 29, 2023

Dear Alex Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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,  
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Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K233276

Device Name  
Reusable Blood Pressure Cuff

### Indications for Use (Describe)

The Reusable Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in adult size.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Tab #6 510(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: \_\_\_\_\_

1. Date of Preparation: 08/28/2023
2. Sponsor Identification

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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 non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in adult size.

##### Device Description

The proposed device is an accessory used in conjunction with non-invasive 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: K171889

Product Name: Reusable Blood Pressure Cuff

#### 6. Non-Clinical Test Conclusion

6.1 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: 2018, Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.
- ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
- 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.

## 6.2 Human Factors / Usability Testing

Usability testing is not required per the risk profile of this product.

## 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 non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in adult size.	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 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 Universal: 22-42 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 two differences for the proposed cuff and predicate device 1.

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 Internal Bladder

Item	Proposed Device Cuff with Internal Bladder	Predicate Device 2 K171889
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 non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in adult size.	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.
Patient populations	adult	infant, pediatric but not neonatal, and adult sizes
Tube configuration	One tube	One or Two tube
Bladder	Internal Bladder	Internal Bladder or 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	Small adult: 17-22cm Small adult long / Adult: 22-30 cm Large Adult: 30-42 cm Large Adult long: 42-48 cm Universal: 22-42 cm	Small adult: 17-22cm Small adult long / Adult: 22-30 cm Large Adult: 30-42 cm Large Adult long: 42-48 cm 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
Reusable	Yes	Yes
Sterile	No	No
Pressure range	0-300mmHg	0-300mmHg
Material	Polyester	Polyester or TPU leather with nylon
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10.	Comply with ISO 10993-5 and ISO 10993-10.

There are six differences for the proposed cuff and predicate device 2.

For intended use:

The difference of intended use between proposed device and predicate device 2 is the patient population. and the patient populations of proposed devices is included in the range of the predicate device 2. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

For patient populations:

The patient populations of proposed devices is included in the range of the predicate device 2. And the patient populations are indicated in user manual clearly for identification. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

For tube configuration:

The tube configuration range of proposed devices is included in the range of the predicate device 2. And the configuration 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 bladder:

The bladder type of proposed devices is included in the types of the predicate device 2. And the type 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 size:

The cuff size range of proposed devices is included in the range of the predicate device 2. 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 materials of proposed devices is identical to the materials of predicate device 2 with internal bladder type. 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.