November 21, 2022

Wenzhou Xikang Medical Instruments Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K222420
Trade/Device Name: Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: October 25, 2022
Received: October 25, 2022

Dear Boyle 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 (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,
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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)*
K222420

Device Name
Disposable Blood Pressure Cuff

Indications for Use *(Describe)*
The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Wenzhou Xikang Medical Instruments Co., Ltd.
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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Email: Info@truthful.com.cn

Date Submitted: Aug.4th,2022

2.0 Device Information

Trade/Device name: Disposable Blood Pressure Cuff
Common name: Non-invasive blood pressure cuff
Classification name: Blood Pressure Cuff
Classification Product Code: DXQ
Regulation number: 870.1120
Classification: Class II
Panel: Cardiovascular

3.0 Predicate Device Information

Predicate Device:
Manufacturer: Shenzhen Caremed Medical Technology Co., Ltd.
Trade/Device Name: Caremed Reusable Blood Pressure Cuff, Caremed Disposable Blood Pressure Cuff

510(k) number: K182433

4.0 Device Description

The subject device is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is available in neonatal, infant, child and adult sizes.
The subject device contains Cuff with bladder and Air Hose. Air hose has single tube and double tube. Wrapped the cuff around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive blood pressure measurement system.
The device is single use device, and which is made of non-woven fabrics & PVC (Cuff) and PVC (Air Hose), thereinto, the non-woven fabrics & PVC (Cuff) is the material used to contacting with the patient.
The disposable blood pressure cuff has 22 models with different size for different population with different arm size, and the 11 models of 22 are use single tube of air hose and other 11 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

5.0 Indication for Use Statement

The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

6.0 Technological Characteristic Comparison Table

Item	Subject Device	Predicate Device	Comparison Analysis
Product Name	**Disposable Blood Pressure Cuff**	**Caremed Disposable Blood Pressure Cuff**	**----**
510(k) No.	Pending	K182433	----
Product Code	DXQ	DXQ	Same
Regulation No.	21 CFR 870.1120	21 CFR 870.1120	Same
Class	II	II	Same
Intended Use/Indication for Use	The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	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 neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated. The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Same with the Indication for Use of the Disposable Blood Pressure Cuff
Material Composition	Cuff (Patient contacted): PVC film stick non-woven fabric; Bladder:PVC Air Hose:PVC Hook tape: Nylon Loop: Nylon	Non-woven (Patient contacted); nylon; PVC	Same
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One or two	Same

Limb Circumference (Range in cm)	Conform to AHA bladder sizes recommendations Neonatal 1 (3-6 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm) Neonatal 5 (8-15 cm) Infant (9-15 cm) Child (13-20 cm) Small Adult (18-26 cm) Adult (25-35 cm) Large Adult (32-42 cm) Thigh (42-50 cm)	Conform to AHA bladder sizes recommendations Neonatal 1 (3-6 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm) Neonatal 5 (8-15 cm) Infant (9-14.8 cm) Child (13.8-21.5 cm) Small Adult (20.5-28.5 cm) Adult (27.5-36.5 cm) Adult Long (27.5-36.5/46.5 cm) Large Adult (35.5-46 cm) Large Adult Long (35.5-46 cm)	Different
Pressure Range	0-300mmHg	0-300mmHg	Same
Max. Pressure	400mmHg	400mmHg	Same
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	Conform with ISO10993-1 (ISO10993-5, ISO10993-10)	No potential cytotoxicity; No sensitization observed (test sample score 0); Negligible (no observed primary irritation, test sample score 0)	Same

The Subject Device has the same Intended Use/Indication for Use, basic construction, and technology specification as the predicated device. Both devices are wrapped the patient's arm or leg and secured by a hook and loop fastener commonly called Velcro. The materials of both devices are all conformed to ISO 10993. Both devices are available in the similar size and range and are intended for the same patient populations, and the size for Infant, Child, Small Adult, Adult and Large Adult are little different. Based on the performance testing in this submission, the slight difference on the range of these blood pressure cuffs does not raise any safety or effectiveness issue.

7.0 Summary of Non-clinical Testing

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, Non-Invasive Sphygmomanometers - Part 1: Requirements and Test Methods for Non-Automated Measurement Type, First Edition 2007.

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.

Biocompatibility testing

The biocompatibility evaluation for the Disposable Blood Pressure Cuffs was conducted in accordance with the FDA Biocompatibility guidance, 2016 (Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process") 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 battery of testing included the following tests:

Cytotoxicity
Sensitization
Irritation

8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K182433 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.