October 31, 2024

Shenzhen Medke Technology Co., Ltd.
℅ Jie Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue
Nanshan District
Shenzhen, Guangdong 518067
China

Re: K242623
Trade/Device Name: Disposable Blood Pressure cuff; Reusable Blood Pressure cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: August 30, 2024
Received: September 3, 2024

Dear Jie Yang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) 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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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242623

Device Name

Disposable Blood Pressure cuff;
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 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 size. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2024/10/29

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Reusable NIBP Cuff, Disposable NIBP Cuff
Model	Reusable blood pressure cuff: C6711, C6721, C6911, C6921, C6811, C6821, C6611, C6621, C6511, C6521, C6311, C6321 Disposable blood pressure cuff: C0101, C0102, C0103, C0104, C0105
Common Name	Non-invasive Blood Pressure Cuff
Regulatory Class	Class II
Classification	21CFR 870.1120 / Blood pressure cuff / DXQ
Submission type	Traditional 510(K)

4. Predicate Device

Predicate device	Blood Pressure Cuff	K232772	Shenzhen Plinma Technology Co. Ltd.
Reference device	Unimed Blood Pressure Cuff	K112544	UNIMED MEDICAL SUPPLIES INC.

5. Device Description

The device comprises tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped 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. It is available in neonatal, infant, child and adult sizes. The subject device includes disposable blood pressure cuff and reusable blood pressure cuff and contains Cuff with/without bladder and single/dual tubes Air Hose.

The subject device is categorized into two types of models according to its usage.

Reusable blood pressure cuff: C6711, C6721, C6911, C6921, C6811, C6821, C6611, C6621, C6511, C6521, C6311, C6321

Disposable blood pressure cuff: C0101, C0102, C0103, C0104, C0105

6. Intended use & Indication for use

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 size. The cuff is not designed, sold, or intended for use except as indicated.

7. Comparison to the Predicate Device

The following tabulation indicates the detailed differences between the subject devices and the predicate device.

Features	**Predicate Device** **Blood Pressure Cuff**	**Subject Device** **NIBP CUFFs**	**Remark**
K#	K232772	K242623	/
Classification Regulation	21CRF 870.1120	21CRF 870.1120	Same
Classification and Code	Class II, DXQ	Class II, DXQ	Same
Common name	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	Same
Reusable blood pressure cuff Comparison			
Intended Use& Indications for use	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	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood	Same

Features	Predicate Device Blood Pressure Cuff	Subject Device NIBP CUFFs	Remark
	available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	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.	
Prescription/over-the counter-use	Prescription	Prescription	Same
Target population	Adults/Pediatrics/neonatal	Adults/Pediatrics/neonatal	Same
Application site	Arm or leg	Arm or leg	Same
Limb Circumference (Range in cm)	For Bladder Neonate 5 (6-11) Infant (10-19) Child (15.8-21.3) Small Adult (20-28) Adult (25-35) Adult Long (25-35) Large Adult (33-47) Large Adult Long (33-47) Thigh (44-56)	For Bladder Neonate 5 (6-11) Infant (10-19) Pediatric (18-26) Adult (25-35) Large Adult (33-47) Adult Thigh(46-66)	Similar
Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures	Same
Tube Configuration	One	One or two tube	Similar, note 2. Same as K112544 reference device.
Pressure Range	0-300 mmHg	0-300 mmHg	Same
Sterility	Non-sterile	Non-sterile	Same
Material	Sleeve of reusable cuff : PU, Synthetic Leather	Sleeve of reusable cuff : PU	Similar,

Features	Predicate Device Blood Pressure Cuff	Subject Device NIBP CUFFs	Remark
	Bladder: Transparent Polyurethane(TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Bladder: TPU Tubing: PVC Hook: Nylon Loop: Nylon	
Disposable blood pressure cuff Comparison			
Intended Use& Indications 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 neonatal, pediatric 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 size. The cuff is not designed, sold, or intended for use except as indicated.	Same. The neonate use of the subject device is covered by the predicate device.
Prescription/over-the counter-use	Prescription	Prescription	Same
Target population	Adults/Pediatrics/neonatal	neonatal	Same. The neonate use of the subject device is covered by the predicate device.
Application site	Arm or leg	Arm or leg	Same
Limb Circumference (Range in cm)	Neonate 1 (3-6) Neonate 2 (4-8) Neonate 3 (6-11) Neonate 4 (7-13) Neonate 5 (8-15) Infant (12.3-16.8) Child (15.8-21.3) Small Adult (20.5-28.5)	Neonate 1 (3-6) Neonate 2 (4-8) Neonate 3 (6-11) Neonate 4 (7-13) Neonate 5 (8-15)	Same. The neonate use of the subject device is covered by the predicate device.

Features	Predicate Device Blood Pressure Cuff	Subject Device NIBP CUFFs	Remark
	Adult (27.5-36.5) Adult Long (27.5-36.5) Large Adult (35.5-46) Large Adult Long (35.5-46) Thigh (44-56)		
Tube Configuration	One	One	Same
Pressure Range	0-300 mmHg	0-300 mmHg	Same
Sterility	Non-sterile	Non-sterile	Same
Material	Sleeve of disposable cuff: PVC, composite nonwoven Tubing: PVC Hook: Molded Nylon Loop: Nylon	Sleeve of disposable cuff: Nylon Tubing: PVC Hook: Nylon Loop: Nylon	Similar

8. Non-clinical data

The following non-clinical data were provided in support of the substantial equivalence determination.

Biocompatibility

The subject device is in contact with intact skin only AND all the component materials are included in Attachment G, Section B of the FDA Biocompatibility Guidance, 2023 (Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process").

Performance testing

Non-clinical tests were conducted to verify that the proposed devices 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.

9. Clinical study

No clinical study is included in this submission

10. Conclusion

Substantial equivalence comparisons, performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate device.