August 30, 2023

Shenzhen SINO-K Medical Technology Co.,Ltd
% Yang Jie
Consultant
Shenzhen Choncorut Medical Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K231961
Trade/Device Name: Reusable NIBP Cuff, Disposable NIBP Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: June 30, 2023
Received: July 3, 2023

Dear Yang Jie:

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
Asistant Director
Division of Cardiac Electrophysiology
Diagnostic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231961

Device Name
Reusable NIBP Cuff, Disposable NIBP 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, 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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/06/30

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 NIBP Cuff: SC1311, SC1511, SC1611, SC1711, SC1811. Disposable NIBP Cuff: SC0101, SC0102, SC0103, SC0104, SC0105, SC0106, SC0107, SC0108, SC0109, SC0110, SC0111, SC0112.
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

Shenzhen Caremed Medical Technology Co., Ltd. Caremed Reusable Blood Pressure Cuff, Caremed Disposable Blood Pressure Cuff under K182433.

5. Device Description

The proposed device is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is available in neonatal, infant, child and adult sizes.

The proposed device includes disposable blood pressure cuff and reusable blood pressure cuff. Both disposable and reusable blood pressure cuff have the same structure, which contains Cuff with bladder and single-tube Air Hose.

The subject device is categorized into two types of models according to its reusability. Refer to the master list of models below.

Reusable NIBP Cuff: SC1311, SC1511, SC1611, SC1711, SC1811.

Disposable NIBP Cuff: SC0101, SC0102, SC0103, SC0104, SC0105, SC0106, SC0107, SC0108, SC0109, SC0110, SC0111, SC0112.

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, infant, child and adult sizes. 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 devices.

Comparison to Predicate Device Caremed Reusable Blood Pressure Cuff:

Features	**Predicate Device** **Caremed Reusable Blood Pressure Cuff** **K182433**	**Subject Device** **Reusable NIBP Cuff** **K231961**	**Remark**
Applicant	Shenzhen Caremed Medical Technology Co., Ltd.	Shenzhen SINO-K Medical Technology Co., Ltd	/
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
Intended use	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile	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	Same

Features	Predicate Device Caremed Reusable Blood Pressure Cuff K182433	Subject Device Reusable NIBP Cuff K231961	Remark
	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.	available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One	Different
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	Same
Limb Circumference (Range in cm)	Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm) Adult Thigh (44-66cm)	Neonatal (6-11cm) Infant (10-19cm) Pediatric (18-26cm) Adult (25-35cm) Large Adult (33-47cm)	Different
Pressure Range	0-300 mmHg	Cuff for neonate and infant: 180mmHg(24kPa) Cuff for small child, child, small adult, adult, large adult: 360mmHg(48kPa)	Different
Sterility	Non-sterile	Non-sterile	Same
Max. Leakage	< 4mm Hg/ min.	< 4mm Hg/ min.	Same
Material	Cuff (Patient contacted): PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Cuff (Patient contacted): PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Same
Biocompatibility	Comply with ISO 10993-5;	Comply with ISO 10993-5;	Same

Features	Predicate Device Caremed Reusable Blood Pressure Cuff K182433	Subject Device Reusable NIBP Cuff K231961	Remark
	Comply with ISO 10993-10	Comply with ISO 10993-10	

Comparison to Predicate Device **Caremed Disposable Blood Pressure Cuff**:

Features	Predicate Device Caremed Disposable Blood Pressure Cuff	Subject Device Disposable NIBP Cuff	Remark
Applicant	Shenzhen Caremed Medical Technology Co., Ltd.	Shenzhen SINO-K Medical Technology Co., Ltd	/
Intended 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 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
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One	Different
Limb Circumference (Range in cm)	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)	Neonatal (3-6 cm) Neonatal (4-8 cm) Neonatal (6-11 cm) Neonatal (7-13 cm) Neonatal (8-15 cm) Neonatal (7.7-10.5 cm) Infant (9.8-13.3 cm) Small Child (12.4-16.8 cm) Child (15.8-21.3 cm) Small Adult (20-27 cm) Adult (25.3-34.3 cm) Large Adult (32.1-43.4 cm)	Different
Pressure Range	0-300mmHg	Cuff for neonate and infant: 180mmHg(24kPa) Cuff for small child, child, small	Different

Features	Predicate Device Caremed Disposable Blood Pressure Cuff	Subject Device Disposable NIBP Cuff	Remark
		adult, adult, large adult: 360mmHg(48kPa)	
Sterility	Non-sterile	Non-sterile	Same
Material	Non-woven (Patient contacted); nylon; PVC	Cuff (Patient contacted): Non-woven clad PVC Bladder: PVC Tubing: PVC Hook: PVC Loop: PVC	Different
Biocompatibility	Comply with ISO 10993-5; Comply with ISO 10993-10	Comply with ISO 10993-5; Comply with ISO 10993-10	Same

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the proposed devices 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

The NIBP Cuffs are considered surface contacting for a duration of exceed 24 hours but not 30 days.

Non-clinical data

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.
- 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

9. Conclusion

It has been shown in the 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.