December 17, 2018

Shenzhen Caremed Medical Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, Nanshan Medical Devices Industrial Park
Nanshan District
Shenzhen, 518067 Cn

Re: K182433
Trade/Device Name: Caremed Reusable Blood Pressure Cuff, Caremed Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: November 26, 2018
Received: November 26, 2018

Dear Kevin 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Stephen C. Browning -S5

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182433

Device Name
Caremed Reusable Blood Pressure Cuff, Caremed Disposable 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, 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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2018/08/31

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Caremed Reusable Blood Pressure Cuff, Caremed Disposable Blood Pressure Cuff
Model	Caremed Reusable Blood Pressure Cuff: N1A-PS, N1N-PS, N1N-PD, N1I-PS, N1I-PD, N1C-PS, N1C-PD, N1S-PS, N1S-PD, N1A-PD, N1AL-PS, N1AL-PD, N1L-PS, N1L-PD, N1T-PS, N1T-PD. Caremed Disposable Blood Pressure Cuff: N1A-TS, N1LL-TS, N1LL-TD, N1L-TS, N1L-TD, N1AL-TS, N1AL-TD, N1A-TD, N1S-TS, N1S-TD, N1C-TS, N1C-TD, N1I-TS, N1I-TD, N1N1-TS, N1N1-TD, N1N2-TS, N1N2-TD, N1N3-TS, N1N3-TD, N1N4-TS, N1N4-TD, N1N5-TS, N1N5-TD
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

By submission of the Traditional 510(k), Shenzhen Caremed Medical Technology Co., Ltd. is requesting clearance for Reusable Blood Pressure Cuff and Disposable Blood Pressure Cuff. It is comparable to the following legally marketed system:

1. Unimed Medical Supplies Inc. Reusable Blood Pressure Cuff under K112544.
2. Unimed Medical Supplies Inc. Disposable Blood Pressure Cuff under K120364.

The subject device has same intended use, same target patient population, same performance effectiveness, performance safety as the predicate devices and no question is raised regarding to effectiveness and safety. So, the conclusion is that the subject device is substantial equivalent to the predicate.

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 has same structure, which contains Cuff with bladder and Air Hose. Air hose has single tube and double tube.

The disposable blood pressure cuff 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 24 models with different size for different population with different arm size, and the 12 models of 24 are use single tube of air hose and other 12 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

The reusable blood pressure cuff is reusable device, and which is made of PU & PVC (Cuff) and PVC (Air Hose), thereinto, the PU & PVC (Cuff) is the material used to contacting with the patient.

The reusable blood pressure cuff has 16 models with different size for different population with different arm size, and the 8 models of 16 are use single tube of air hose and other 8 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

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 Primary Predicate Device Unimed Reusable Blood Pressure Cuff:

Features	**Subject Device Caremed Reusable Blood Pressure Cuff**	**Predicate Device K112544 Unimed Reusable Blood Pressure Cuff**	**Remark**
Applicant	Shenzhen Caremed Medical Technology Co., Ltd.	Unimed Medical supplies Inc.	/
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 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 Unimed Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Different (1)
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One or two	Same
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)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm) Pediatric (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm)	Different (2)

Features	**Subject Device** **Caremed Reusable Blood Pressure Cuff**	**Predicate Device K112544** **Unimed Reusable Blood Pressure Cuff**	**Remark**
	Adult Thigh (44-66cm)	Large Adult Long (33-47cm) Adult Thigh (44-66cm)	
Pressure Range	0-300 mmHg	0-300 mmHg	Same
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	No potential cytotoxicity; No sensitization observed (test sample score 0); Negligible (no observed primary irritation, test sample score 0)	Comply with ISO 10993-5; Comply with ISO 10993-10	Same

Comparison to Reference Device Unimed Disposable Blood Pressure Cuff:

Features	**Subject Device** **Caremed Disposable Blood Pressure Cuff**	**Predicate Device K120364** **Unimed Disposable Blood Pressure Cuff**	**Remark**
Applicant	Shenzhen Caremed Medical Technology Co., Ltd.	Unimed Medical supplies Inc.	/
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 neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Different (3)
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One or two	Same

Features	Subject Device Caremed Disposable Blood Pressure Cuff	Predicate Device K120364 Unimed Disposable Blood Pressure Cuff	Remark
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 (9-14.8 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)	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 cm) Large Adult (35.5-46 cm) Large Adult Long (35.5-46 cm) Thigh (45-56 cm)	Different (4)
Pressure Range	0-300mmHg	0-300mmHg	Same
Max. Pressure	400mmHg	400mmHg	Same
Sterility	Non-sterile	Non-sterile	Same
Material	Non-woven (Patient contacted); nylon; PVC	Non-woven (Patient contacted); nylon; PVC	Same
Biocompatibility	No potential cytotoxicity; No sensitization observed (test sample score 0); Negligible (no observed primary irritation, test sample score 0)	Comply with ISO 10993-5; Comply with ISO 10993-10	Same

Justification of differences:

Justifications for differences between Caremed Blood Pressure Cuff and the predicate device are shown as below:

Different (1): We claim the applicable population in more detail. Neonatal, infant and child are subsets of the pediatric patient population. Thus, this descriptive difference does not raise any safety or effectiveness issue.

Different (2): The limb circumference of subject device and predicate device is same. The subject device is less than predicate device with Large Adult Long. This difference limits use within the subject device and does not raise any safety or effectiveness issue.

Different (3): We claim the applicable population in more detail. Neonatal, infant and child are subsets of the pediatric patient population. Thus, this descriptive difference does not raise any safety or effectiveness

issue.

Different (4): The limb circumference of subject device and predicate device is same. The subject device is less than predicate device with Thigh. This difference limits use within the subject device and does not raise any safety or effectiveness issue.

Conclusion:

The proposed devices share the same indications for use, device operation, overall technical and functional capabilities, meet the same standards and requirements and therefore, are substantially equivalent to the predicate device(s).

8. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for the Caremed 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

The Caremed Blood Pressure 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 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

The test was selected to show substantial equivalence between the subject device and the predicate.

9. Conclusion

It has been shown in this 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.