March 25, 2019

Shenzhen Changke Connect Electronics Co., Ltd.
% Kevin Wang, Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, NanShan Medical devices Industrial Park
Nanshan District, Shenzhen, 518067
CHINA

Re: K193629
Trade/Device Name: Disposable NIBP Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: December 24, 2019
Received: December 26, 2019

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/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,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193629

Device Name
Disposable NIBP 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.

***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:** 2019/12/24

## 1. Submission sponsor

Name: Shenzhen Changke Connect Electronics Co., Ltd.
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## 2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
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Contact person: Kevin Wang
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Tel: +86-755 33941160

## 3. Subject Device Information

| | |
|---|---|
| Trade/Device Name | Disposable NIBP Cuff |
| Model | CK-XT-88062-001, CK-XT-88062-003, CK-XT-88062-005, CK-XT-88062-007, CK-XT-88062-008, CK-XT-88062-010 |
| 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

Manufacturer: Shenzhen Caremed Medical Technology Co., Ltd.
Device: Caremed Disposable Blood Pressure Cuff
510(k) No.: K182433.

## 5. 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 includes disposable blood pressure cuff. All the disposable blood pressure cuff has same structure, which contains Cuff and single tube.

The disposable blood pressure cuff is single use device, and which is made of non-woven fabrics (Cuff) and PVC (Air tube), thereinto, the non-woven fabrics (Cuff) is the material used to contacting with the patient. The disposable blood pressure cuff has 6 models with different size for different population with different circumference size.

## 6. 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.

## 7. Comparison to the Predicate Device

| **Features** | **Subject Device**<br>**Disposable NIBP Cuff** | **Predicate Device K182433**<br>**Disposable Blood Pressure Cuff** | **Remark** |
|---|---|---|---|
| Applicant | Shenzhen Changke Connect Electronics Co., Ltd. | Shenzhen Caremed Medical Technology Co., Ltd. | / |
| Classification Regulation | 21CRF 870.1120 | 21CRF 870.1120 | Same |
| Classification and Code | Class II,<br>DXQ | Class II,<br>DXQ | Same |
| Common name | Non-invasive Blood Pressure Cuff | Non-invasive Blood Pressure Cuff | Same |
| 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 | One | 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 | Conform to AHA bladder sizes | Conform to AHA bladder sizes | Different |

| | | | |
|---|---|---|---|
| Circumference (Range in cm) | recommendations<br>Neonatal (7-13 cm)<br>Infant (9-14.8 cm)<br>Child (13.8-21.5 cm)<br>Adult (27.5-36.5 cm)<br>Large Adult (35.5-46 cm)<br>Adult Thigh (45-56.5 cm) | recommendations<br>Neonatal 1 (3-6 cm)<br>Neonatal 2 (4-8 cm)<br>Neonatal 3 (6-11 cm)<br>Neonatal 4 (7-13 cm)<br>Neonatal 5 (8-15 cm)<br>Infant (9-14.8 cm)<br>Child (13.8-21.5 cm)<br>Small Adult (20.5-28.5 cm)<br>Adult (27.5-36.5 cm)<br>Adult Long (27.5-36.5/46.5 cm)<br>Large Adult (35.5-46 cm)<br>Large Adult Long (35.5-46 cm) | (1) |
| 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 | Non-woven (Patient contacted);<br>PVC;<br>ABS. | Non-woven (Patient contacted);<br>nylon;<br>PVC. | Different (2) |
| Biocompatibility | No potential cytotoxicity;<br>No sensitization observed;<br>Negligible (no observed primary irritation) | No potential cytotoxicity;<br>No sensitization observed;<br>Negligible (no observed primary irritation) | Same |

**Justification of differences:**

Justifications for differences between subject device and the predicate device are shown as below:

Different (1): The difference in the limb circumference. Performance testing accordance with ISO 81060-1 has been conducted and provided with this submission. Therefore, this difference does not raise any safety or effectiveness issue.
Different (2): The difference in the material. Biocompatibility testing accordance with ISO 10993-1 has been conducted and provided with this submission. Therefore, this difference does not raise any safety or effectiveness issue.

## 8. Performance Data

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

**Biocompatibility testing**

The biocompatibility evaluation for the subject device 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 subject devices 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 subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject 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.

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

## 9. Conclusion

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject Disposable NIBP Cuff has been shown to be substantially equivalent to legally marketed predicate device.