August 21, 2018

Orantech Inc.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
22A, Haijing Square, No. 18, Taizi Road
Nanshan District, Shenzhen, P.R. China, 518067

Re: K173197
Trade/Device Name: Reusable NIBP Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: July 12, 2018
Received: July 18, 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

for 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)*
K173197

Device Name
Reusable 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.

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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"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: 2017/09/15

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Reusable NIBP Cuff
Model	BP-10BS, BP-20BS, BP-30BS, BP-40BS, BP-50BS, BP-60BS, BP-70BS, BP-80BS, BP-90BS
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), Orantech Inc. is requesting clearance for Reusable NIBP Cuff. It is comparable to the following legally marketed system:

1. Unimed Medical Supplies Inc. Blood Pressure Cuff under K112544.

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 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. The reusable NIBP cuff has 9 models with different size for different population with different arm size.

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.

7. Comparison to the Predicate Device

Features	**Subject Device** **Orantech Reusable NIBP Cuff**	**Predicate Device K112544** **Unimed Blood Pressure Cuff**
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 Unimed 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 pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.
Patient Populations	Adults/Pediatrics/Infants/Neonates	Adults/Pediatrics/Infants/Neonates
Material	Cuff: PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Cuff: PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon
Tube Number	One	One or two
Limb Circumference (Range in cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (8-13cm) Child (12-19cm) Small Adult (17-25cm) Adult (23-33cm) Adult Extra Long (23-33cm) Large Adult (31-40cm) Large Adult Long (31-40cm)	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) Large Adult Long (33-47cm)

	Adult Thigh (38-50cm)	Adult Thigh (46-66cm)
Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures
Pressure limits	0-300mmHg	0-300mmHg
Sterility	Non-sterile	Non-sterile
Biocompatibility	Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The Orantech Reusable NIBP Cuff has been tested according to the following standards:

(1) ISO 81060-1, Non-Invasive Sphygmomanometers - Part 1: Requirements and Test Methods for Non-Automated Measurement Type, First Edition 2007.
(2) ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, 2009
(3) ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, 2010

The tests were selected to show substantial equivalence between the subject device and the predicate.

9. Conclusion

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that subject device is substantially equivalent to the predicate device and don't raise any new safety and/or effectiveness issues.