September 23, 2021

Shenzhen Coreray Technology Co., Ltd.
Simon Fan
General Manager
Floor 5, Building 10, Huangbeiling Jingxuan Industrial Park
Yousong Community, Longhua District
Shenzhen, Guangdong 518109
China

Re: K211747
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: August 17, 2021
Received: August 23, 2021

Dear Simon Fan:

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,

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211747

Device Name
Reusable NIBP Cuff

Indications for Use *(Describe)*
The Reusable NIBP 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 adult size.

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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Section 5 - 510(k) Summary

Prepared Date: May 26, 2021

This is a traditional 510k submission, and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: Shenzhen Coreray Technology Co., Ltd.

Address: Floor 5, Building 10, Huangbeiling Jingxuan Industrial Park, Yousong Community, Longhua District, Shenzhen, Guangdong, China

Contact Person: Simon Fan

Title: General Manager

Phone: +86-755-21010817

E-mail: manager@core-ray.com

2. Subject Device Information

Type of 510(k) submission: Traditional

Trade/Device Name: Reusable NIBP Cuff

Model: CR009-R-PU-005

Classification Name: Blood pressure cuff

Review Panel: Cardiovascular

Classification Product Code: DXQ, 21 CFR 870.1120

Regulation Class: 2

3. Predicate Device Information

Sponsor: Orantech Inc.

Device Name: Reusable NIBP Cuff

Classification Name: Blood pressure cuff

510(k) number: K173197

Review Panel: Cardiovascular

Classification Product Code: DXQ, 21 CFR 870.1120

Regulation Class: 2

4. Device Description

Reusable NIBP Cuff is a reusable accessory used in conjunction with a non-invasive blood pressure measurement system. It 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.

Reusable NIBP Cuff is made of PU synthetic leather (Cuff), TPU film (bladder) and TPU (Air Hose), and the PU synthetic leather is the material used to contacting with the patient's intact skin.

5. Intended Use

Reusable NIBP 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 adult size.

6. Test Summary

Reusable NIBP Cuff has been evaluated the safety and performance by lab bench testing according to 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, Biological evaluation of medical devices -- Part 5: Tests for In

Vitro cytotoxicity, 2009

☒ ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, 2010

7. Biocompatibility

During noninvasive blood pressure measuring process, the patient-directly contacting component information according to ISO 10993-1 in the subject device is in the following list.

Component of Device	Material	Body Contact Category	Contact Duration
Cuff	PU synthetic leather	Surface-contacting device: Patient Skin	< 24 hours
Air hose	TPU	Surface-contacting device: Patient Skin	< 24 hours

So, we conduct biocompatibility test on Reusable NIBP Cuff including the following as ISO 10993-1 required.

- Cytotoxicity
- Sensitization
- Irritation

8. Comparison to Predicate Device

Compare with predicate device, the subject device is quite similar in design principle, intended use, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Shenzhen Coreray Technology Co.,	Orantech Inc.	--

Elements of comparison	Subject Device	Predicate Device	Verdict
	Ltd.		
510K number	TBD	K173197	--
Product Name	Reusable NIBP Cuff	Reusable NIBP Cuff	--
Classification Name	Blood pressure cuff	Blood pressure cuff	SE
Regulation Class	2	2	SE
Regulation Number	21 CFR 870.1120	21 CFR 870.1120	SE
Product Code	DXQ	DXQ	SE
OTC & Rx	Rx	Rx	SE
Indications for Use	Reusable NIBP 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 adult size.	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.	SE Note 1
Patient Populations	Adults/Pediatrics/Infants/Neonates	Adults/Pediatrics/Infants/Neonates	SE
Material	Cuff: PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: TPU Hook: Molded Nylon Loop: Nylon	Cuff: PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	SE Note 2
Tube Number	One	One	SE
Limb Circumference (Range in cm)	Conform to AHA bladder sizes recommendations Adult (25-35cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (8-13cm) Child (12-19cm) Small Adult (17-25cm) Adult (23-33cm)	SE Note 1

Elements of comparison	Subject Device	Predicate Device	Verdict
		Adult Extra Long (23-33cm) Large Adult (31-40cm) Large Adult Long (31-40cm) Adult Thigh (38-50cm)	
Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures	SE
Pressure limits	0-300mmHg	0-300mmHg	SE
Sterility	Non-sterile	Non-sterile	SE
Biocompatibility	Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation	SE

Note 1

Although the subject device is only intended for adults and has one size, which is covered by the predicate device, and performance testing accordance with ISO 81060-1 has been conducted and provided with this submission. Therefore, these differences do not affect the safety and effectiveness.

Note 2

Although the tubing material of subject device is different to predicate device, the subject device is complied with ISO 10993 standards, the difference does not affect the safety and effectiveness.

9. Summary for clinical test

Clinical performance is not deemed necessary.

10. Conclusion

The subject device Reusable NIBP Cuff has all features of the predicate device for intended use. Thus, the subject device is substantially equivalent to the predicate device.