November 29, 2023

Shenzhen Plinma Technology Co. Ltd.
Zhang Mongdi
QA Manager
401, Xinheng Building No.22, Row 3, Shiling Road
Jinsha Community, Kengzi Street, Pingshan District
Shenzhen, Guangdong 518122
China

Re: K232772
Trade/Device Name: Blood Pressure Cuff (1201D1, 12L2D1, 1202D1, 12L3D1, 1203D1, 1204D1, 1205D1, 1206D1, 1207D1-1#, 1207D1-2#, 1207D1-3#, 1207D1-4#, 1207D1-5#, 1201B1, 12L2B1, 1202B1, 12L3B1, 1203B1, 1204B1, 1205B1, 1206B1, 1207B1-1#, 1207B1-2#, 1207B1-3#, 1207B1-4#, 1207B1-5#, 1201W2, 12L2W2, 1202W2, 12L3W2, 1203W2, 1204W2, 1205W2, 1206W2 and 1207W2)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: September 9, 2023
Received: September 11, 2023

Dear Zhang Mongdi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232772

Device Name

Blood Pressure Cuff
(1201D1,12L2D1,1202D1,12L3D1,1203D1,1204D1,1205D1,1206D1,1207D1-1#,1207D1-2#,1207D1-3#,1207D1-4#,1207D1-5#,1201B1,12L2B1,1202B1,12L3B1,1203B1,1204B1,1205B1,1206B1,1207B1-1#,1207B1-2#,,1207B1-3#,1207B1-4#,1207B1-5#,1201W2,12L2W2,1202W2,12L3W2,1203W2,1204W2,1205W2,1206W2 and 1207W2)

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 neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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 neonatal, pediatric 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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"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	November 1, 2023
Sponsor	Name: Shenzhen Plinma Technology Co.,Ltd Address: 401, Xinheng Building, No.22, Row 3, Shiling Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen, Guangdong,China
Contact person	Sandra Zhai E-mail: Master@plinma.com Tel: +86-755- 28097345
Device Trade Name	Blood pressure cuff
Device Common Name	Blood pressure cuff
Classification Names	Blood pressure cuff
Regulation Number	21 CFR 870.1120
Product Code	DXQ
Regulatory Class	Class II
Predicate Device 1	UNIMED MEDICAL SUPPLIES INC. Unimed Blood Pressure Cuff under K112544
Predicate Device 2	UNIMED MEDICAL SUPPLIES INC. Unimed Disposable Blood Pressure Cuff under K120364

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 subject device is categorized into two types of models according to its usage.

Reusable Blood Pressure Cuff models:

1201B1,12L2B1,1202B1,12L3B1,1203B1,1204B1,1205B1,1206B1,1207B1-1#,1207B1-2#,1207B1-3#,1207B1-4#,1207B1 5#,1201W2,12L2W2,1202W2,12L3W2,1203W2,
1204W2,1205W2,1206W2 and 1207W2

Disposable Blood Pressure Cuff models:

1201D1,12L2D1,1202D1,12L3D1,1203D1,1204D1,1205D1,1206D1,1207D1-1#,1207D1-2#,1207D1-3#,1207D1-4#,1207D1-5#

Connector models: PLINMA-03-127-003, PLINMA-03-T, PLINMA-03-Z3

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 neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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 neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

Comparison to the Predicate Device

Disposable

Features	Subject device-Disposable	Predicate device (K120364)	Comment
Intended Use& Indications 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 neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	The Unimed 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.	Same
Prescription/ over-the-counter- use	Prescription	Prescription	Same
Target population	Adults/Pediatrics/neonatal	Adults/Pediatrics/neonatal	Same
Application site	Arm or leg	Arm or leg	Same
Limb Circumference (cm)	Neonate 1 (3-6) Neonate 2 (4-8) Neonate 3 (6-11) Neonate 4 (7-13) Neonate 5 (8-15) Infant (12.3-16.8) Child (15.8-21.3) Small Adult (20.5-28.5) Adult (27.5-36.5) Adult Long (27.5-36.5) Large Adult (35.5-46) Large Adult Long (35.5-46)	Neonate 1 (3-6) Neonate 2 (4-8) Neonate 3 (6-11) Neonate 4 (7-13) Neonate 5 (8-15) Infant (9-14.8) Child (13.8-21.5) Small Adult (20.5-28.5) Adult (27.5-36.5) Adult Long(27.5-36.5) Large Adult (35.5-46) Large Adult Long (35.5-46)	Difference1

Features	Subject device-Disposable	Predicate device (K120364)	Comment
	Thigh (44-56)	Thigh (45-56)	
Material	Sleeve of disposable cuff: PVC composite nonwoven Tubing: PVC Hook: Molded Nylon Loop: Nylon	Sleeve of disposable cuff: PVC composite nonwoven Tubing: PVC Hook: Molded Nylon Loop: Nylon	Same
Tube Configuration	One	One or two tube	Difference 2
Pressure limits	0-300mmHg	0-300mmHg	Same
Sterile	Non-sterile	Non-sterile	Same
Standards met	ISO 81060-1 ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 81060-1 ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Reusable

Features	Subject device-Reusable	Predicate device (K112544)	Comment
Intended Use& Indications 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 neonatal, pediatric 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 noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Same
Prescription/ over-the-counter- use	Prescription	Prescription	Same
Target population	Adults/Pediatrics/neonatal	Adults/Pediatrics/neonatal	Same
Application site	Arm or leg	Arm or leg	Same
Limb Circumference (cm)	For Bladder Neonate 5 (6-11) Infant (10-19) Child (15.8-21.3)	Bladder Neonatal (6-11cm) Infant (10-19cm) Pediatric (18-26cm)	Difference 3

Features	Subject device-Reusable	Predicate device (K112544)	Comment
	Small Adult (20-28) Adult (25-35) Adult Long (25-35) Large Adult (33-47) Large Adult Long (33-47) Thigh (44-56) For bladderless Neonate 1 (3-6) Neonate 2 (4-8) Neonate 3 (6-11) Neonate 4 (7-13) Neonate 5 (8-15) Infant (12.3-16.8) Child (15.8-21.3) Small Adult (20.5-28.5) Adult (27.5-36.5) Adult Long (27.5-36.5) Large Adult (35.5-46) Large Adult Long (35.5-46) Thigh (44-56)	Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm) Large Adult Long (33-47cm) Adult Thigh (46-66cm)	
Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closure	Same
Material	Sleeve of reusable 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	Same
Tube Configuration	One	One or two tube	Difference 4
Pressure limits	0-300mmHg	0-300mmHg	Same
Sterile	Non-sterile	Non-sterile	Same
Standards met	ISO 81060-1 ISO 10993-1 ISO 10993-5	ISO 81060-1 ISO 10993-1 ISO 10993-5	Same

Features	Subject device-Reusable	Predicate device (K112544)	Comment
	ISO 10993-10	ISO 10993-10	

Different 1&3: Both devices have slightly different limb circumference range, the size of limb circumference of subject device met the requirements of ISO 81060-1, and the limb circumference was marked in the labeling. Thus, this difference does not raise any safety or effectiveness issue.

Different 2&4: The subject device with one tube differs from that of predicate device. The subject device met the requirements of ISO 81060-1. Thus, this difference does not raise any safety or effectiveness issue.

Performance Data

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

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993- "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The test results show that the proposed device has no issue of cytotoxicity, sensitization, or skin irritation.

The subject device has been tested according to ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

Clinical data

The subject and predicate devices are exactly the same. Since the blood pressure cuffs are identical, no further clinical testing is necessary.

Conclusion

The sponsor has demonstrated through performance testing and design and features comparison, that the subject device is substantially equivalent to the predicate device.