



July 15, 2025

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory Affairs Specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan,
Baoan District
Shenzhen,
China

Re: K251045

Trade/Device Name: Disposable Neonatal NIBP Cuff (U1682S-C51N); Disposable Neonatal NIBP Cuff (U1683S-C51N); Disposable Neonatal NIBP Cuff (U1684S-C51N); Disposable Neonatal NIBP Cuff (U1685S-C51N)

Regulation Number: 21 CFR 870.1120

Regulation Name: Blood Pressure Cuff

Regulatory Class: Class II

Product Code: DXQ

Dated: April 3, 2025

Received: June 10, 2025

Dear Huanyu Zeng:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251045

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Please provide the device trade name(s).

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Disposable Neonatal NIBP Cuff (U1682S-C51N);
Disposable Neonatal NIBP Cuff (U1683S-C51N);
Disposable Neonatal NIBP Cuff (U1684S-C51N);
Disposable Neonatal NIBP Cuff (U1685S-C51N)

Please provide your Indications for Use below.

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The Unimed disposable blood pressure cuff (Models U1682S-C51N to U1685S-C51N) is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is non-sterile and for single-patient use. The cuff is available in neonatal sizes (4–15 cm limb circumference). The cuff is not designed, sold, or intended for use except as indicated.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510K Summary

1. Submitter

Date Prepared: Apr. 3, 2025
Submitter/Manufacturer: Unimed Medical Supplies Inc.
 Bld#8, Nangang 3rd Industrial Park, Tangtou,
 Shiyang, Baoan District, Shenzhen, China 518108
 FDA Establishment Number: 3007307487
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 RA Specialist
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510(k) Submission Type This is a Traditional 510(k).

2. Proposed Device

Trade Name: Disposable Neonatal NIBP Cuff
Common Name: Blood Pressure Cuff
Model Numbers U1682S-C51N, U1683S-C51N, U1684S-C51N,
 U1685S-C51N
Classification: Medical Specialty: Cardiovascular
 Regulation: 21 CFR 870.1120 –Blood Pressure Cuff
 Product Code: DXQ
 Class: II

3. Predicate Device

Predicate Device	
510(K) No.	Trade Name
K120364	Unimed Disposable Blood Pressure Cuff

4. Device description

The Unimed Disposable Neonatal NIBP Cuffs (Models U1682S-C51N, U1683S-C51N, U1684S-C51N, U1685S-C51N) are single-patient-use accessories for non-invasive blood pressure (NIBP) measurement. Each cuff is designed for neonatal limb circumferences ranging from 4 cm to 15 cm (Neonate 2 through Neonate 5) as follows.

U1682S-C51N: 4 cm - 8 cm.

U1683S-C51N: 6 cm - 11 cm.

U1684S-C51N: 7 cm - 13 cm.

U1685S-C51N: 8 cm - 15 cm.

The cuffs are intended to be used with compatible blood pressure monitors employing oscillometry. They are non-sterile, and are disposed of after single-patient use to reduce cross-contamination risks.

5. Intended use/Indications for use

The Unimed disposable blood pressure cuff (Models U1682S-C51N to U1685S-C51N) is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is non-sterile and for single-patient use. The cuff is available in neonatal sizes (4–15 cm limb circumference). The cuff is not designed, sold, or intended for use except as indicated.

6. Comparison to predicate devices

Features	Subject Device (U1682S-C51N, U1683S-C51N, U1684S-C51N, U1685S-C51N)	Predicate Device (K120364)	Comment / Notes
Intended Use & Indications for Use	The Unimed disposable blood pressure cuff (Models U1682S-C51N to U1685S-C51N) 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 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 basic intended use; subject device is specifically neonatal only.
Prescription / Over-the-Counter Use	Prescription	Prescription	Same
Target Population	Neonatal	Neonatal, Pediatric, Adult	Difference #1: Subject device covers only Neonates 2–5. Predicate also includes pediatric/adult.
Application Site	Arm (for neonatal use)	Arm or leg	Same general application site.
Limb Circumference (cm)	- U1682S-C51N: Neonate 2 (4–8 cm) - U1683S-C51N: Neonate 3 (6–11 cm)	Includes Neonate 1–5 plus additional sizes (Infant, Child, Adult, etc.)	Difference #2: Subject device only has these 4 neonatal sizes. Predicate extends beyond neonates.

	cm)		
	- U1684S-C51N : Neonate 4 (7–13 cm)		
	- U1685S-C51N : Neonate 5 (8–15 cm)		
Material	- Cuff : TPU film	- Cuff : PVC composite nonwoven	Difference #3 : Subject device uses TPU as the material of construction for cuff.
	- Tubing : PVC	- Tubing : PVC	
	- Hook : Molded Nylon	- Hook : Molded Nylon	
	- Loop : Nylon	- Loop : Nylon	
Tube Configuration	One (single-tube)	One or two tubes	Difference #4 : Subject device only single-tube; predicate may have single or dual tubes.
Pressure Limits	0–300 mmHg	0–300 mmHg	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

Notes on Key Differences

- **Difference #1 (Target Population)**

The subject device (U1682S-C51N to U1685S-C51N) is intended for neonatal patients only, covering Neonate 2–5. The predicate device offers additional pediatric and adult sizes.

- **Difference #2 (Limb Circumference Range)**

The subject device specifically provides four neonatal circumference ranges. The predicate device includes more extensive sizing (infant, child, adult, large adult, etc.).

- **Difference #3 (Cuff Material)**

The subject device uses TPU as the material of construction, whereas the predicate device is based on PVC composite nonwoven. Both subject devices and predicate devices have passed biocompatibility testing and the differences are not expected to affect safety and effectiveness.

- **Difference #4 (Tube Configuration)**

The subject device is available only with a single-tube design, whereas the predicate device may have one or two tubes. Such differences are not expected to affect safety or effectiveness.

7. Verification and validation testing

Non-clinical test data

Non-clinical tests were conducted to verify that the proposed blood pressure cuffs meet all design specifications and are substantially equivalent (SE) to the predicate devices. The testing was performed in accordance with the following recognized consensus standards:

- ISO 81060-1:2007 – *Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type*
- ISO 80601-2-30:2018 – *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*
- ISO 10993-5 – *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10 – *Biological evaluation of medical devices – Part 10: Tests for skin sensitization*
- ISO 10993-23 – *Biological evaluation of medical devices – Part 23: Tests for irritation*

The subject device consists of patient-contacting materials, such as the cuff bladder and outer sleeve, which are in direct contact with intact skin. The contact duration is classified as short-term (i.e., less than 24 hours cumulative use) per ISO 10993-1:2018. Accordingly, the biocompatibility assessment was designed to address the relevant endpoints for short-term skin contact, and included the following tests:

- Cytotoxicity (ISO 10993-5)
- Skin Sensitization (ISO 10993-10)
- Skin Irritation (ISO 10993-23)

The results from these evaluations demonstrated that the materials used in the proposed cuffs are biocompatible and suitable for their intended use.

8. Substantial Equivalence Statement

Based on the comparison, analysis, and the submitted verification and validation data, Unimed believes that the Unimed Disposable Neonatal NIBP Cuff is as safe and effective and are substantially equivalent to the predicate device.