January 9, 2026

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory Affairs Specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou
Shiyan, Baoan District
Shenzhen, 518108
China

Re: K253964
Trade/Device Name: Disposable Neonatal NIBP Cuff (U1681S-C51N)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: December 7, 2025
Received: December 11, 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,

Jackson Hair -S 2026.01.09 14:57:12 -05'00'

for

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.	K253964

Please provide the device trade name(s).

Disposable Neonatal NIBP Cuff (U1681S-C51N)

Please provide your Indications for Use below.

The Unimed disposable blood pressure cuff (Models U1681S-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 (3–15 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 (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

A brand of Xinwell
unimed
medical supplies

510K Summary

1. Submitter

Date Prepared:	Dec. 11, 2025
Submitter/Manufacturer:	Unimed Medical Supplies Inc. Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, Baoan District, Shenzhen, China 518108 FDA Establishment Number: 3007307487
Contact:	Zeng Huanyu RA Specialist Tel: +86-755 26695165 E-mail: zenghy@unimed.cn
510(k) Submission Type	This is a Special 510(k).

2. Proposed Device

Trade Name:	Disposable Neonatal NIBP Cuff
Common Name:	Blood Pressure Cuff
Model Numbers	U1681S-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
K251045	Disposable Neonatal NIBP Cuff (U1682S-C51N); Disposable Neonatal NIBP Cuff (U1683S-C51N); Disposable Neonatal NIBP Cuff (U1684S-C51N); Disposable Neonatal NIBP Cuff (U1685S-C51N)

4. Device description

The Unimed Disposable Neonatal NIBP Cuff (Model U1681S-C51N) is a single-patient-use accessory for non-invasive blood pressure (NIBP) measurement. The cuff is designed for neonatal limb circumferences ranging from 3 cm to 6 cm.

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

5. Intended use/Indications for use

The Unimed disposable blood pressure cuff (Models U1681S-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 (3–15 cm limb circumference). The cuff is not designed, sold, or intended for use except as indicated.

A brand of Xinwell unimed medical supplies

6. Comparison to predicate devices

Features	Subject Device (U1681S-C51N)	Predicate Device (K251045)	Comment / Notes
Intended Use & Indications for Use	The Unimed disposable blood pressure cuff (Models U1681S-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 (3–15 cm limb circumference). The cuff is not designed, sold, or intended for use except as indicated.	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.	Same basic intended use; add U1681S-C51N to the product family
Prescription / Over-the-Counter Use	Prescription	Prescription	Same
Target Population	Neonatal	Neonatal	Same
Application Site	Arm (for neonatal use)	Arm (for neonatal use)	Same general application site.

Add: Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108 Shenzhen, People's Republic of China
http: //www.unimed.cn E-mail: sales@unimed.cn

Limb Circumference (cm)	- **U1681S-C51N**: Neonate 1 (3–6 cm)	- **U1682S-C51N**: Neonate 2 (4–8 cm) - **U1683S-C51N**: Neonate 3 (6–11 cm) - **U1684S-C51N**: Neonate 4 (7–13 cm) - **U1685S-C51N**: Neonate 5 (8–15 cm)	**Difference #1**: Different circumference due to difference cuff size
Material	- **Cuff**: TPU film	- **Cuff**: TPU film	Same
	- **Tubing**: PVC	- **Tubing**: PVC	
	- **Hook**: Molded Nylon	- **Hook**: Molded Nylon	
	- **Loop**: Nylon	- **Loop**: Nylon	
Tube Configuration	One (single-tube)	One (single-tube)	Same
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 10993-23	ISO 81060-1, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23	Same

Notes on Key Differences

- Difference #1 (Limb Circumference Range)

The subject device specifically adds U1681S-C51N to provide 3-6 cm circumference range. The safety and effectiveness of the product is not affected.

Add: Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108 Shenzhen, People's Republic of China
http: //www.unimed.cn E-mail: sales@unimed.cn

A brand of Xinwell
unimed
medical supplies

7. Verification and validation testing

Non-clinical test data

The only potential risk-initiating difference between the subject device and the predicate device is the difference in cuff printing color. Non-clinical tests were conducted to verify that the proposed blood pressure cuff does not produce new risk in safety. The testing was performed in accordance with the following recognized consensus standards:

Performance testing 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*

Biocompatibility testing standards:

- 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*

Performance testing

The subject device is demonstrated to have the same performance as the predicate device through performance testing conducted in accordance with ISO 81060-1:2007 and ISO 80601-2-30:2018. The results demonstrated that the subject device meets the applicable requirements for its intended use and supports substantial equivalence to the predicate device.

Biocompatibility testing

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)

Add: Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108 Shenzhen, People's Republic of China
http: //www.unimed.cn E-mail: sales@unimed.cn

- Skin Irritation (ISO 10993-23)

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

8. Substantial Equivalence Statement

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

Add: Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108 Shenzhen, People's Republic of China
http: //www.unimed.cn E-mail: sales@unimed.cn