



June 22, 2026

Medline Industries, LP
Kelsey Closen
Regulatory Affairs Specialist
Three Lakes Dr.
Northfield, Illinois 60093

Re: K254287

Trade/Device Name: Medline Reusable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: May 29, 2026
Received: June 1, 2026

Dear Kelsey Closen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JENNIFER W. SHIH -S

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.

K254287

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Please provide the device trade name(s).

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Medline Reusable Blood Pressure Cuff

Please provide your Indications for Use below.

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The Medline Reusable Blood Pressure Cuffs are intended to be used by medical professionals in conjunction with non-invasive blood pressure measurement systems for the determination of a person's blood pressure. The cuffs are non-sterile, multi-patient use and are tested for up to 10,000 inflation cycles and 100 cleaning/Disinfection cycles.

Medline Blood Pressure cuff adapters and connectors are intended to be used by medical professionals in conjunction with non-invasive blood pressure systems and blood pressure cuffs for determination of a person's blood pressure. The Blood Pressure Cuff adapter is for single monitor use only. The Blood Pressure Cuff adapter has been validated for use for up to 10,000 cycles or up to 10,000 connections/disconnections.

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](#))

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Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

510(k) SUMMARY

[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person

Contact Person: Kelsey Closen, Regulatory Affairs Specialist
Phone: 847-949-2283
Fax: 847-643-4482
Email: KClosen@medline.com

Summary Preparation Date

December 30, 2025

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Reusable Blood Pressure Cuffs
Common Name: Medline Reusable Blood Pressure Cuffs
Product Code: DXQ
Classification Panel: Cardiovascular
Regulatory Class: II
Regulation Number: 21 CFR 870.1120

Predicate Device

Minhua Reusable Blood Pressure Cuffs cleared in K233276

Device Description

Medline Reusable Blood Pressure Cuff is an accessory of non-invasive sphygmomanometers for measurement of blood pressure. The device consists of an inflatable integral cuff bladder (the cuff, including the bladder, is one piece), air hose or tubing (single tube or double tube), hook & loop open-closure and standardized connectors that interface with various types of sphygmomanometers. One or two tubes extend from the bladder and connect to a non-invasive blood pressure measurement system via connectors and adapters. Medline Blood Pressure cuff connectors are attached to the blood pressure cuffs via the tubing. Medline adapters are attached to



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the monitors. Use Medline blood pressure cuffs only with Medline adapters or ISO 80369-5 adapters. Component materials are listed below in table 1.

Each cuff has rounded corners and finished edges for optimal comfort. The cuffs are color coded and come in a wide range of sizes from Infant, pediatric to adult sizes, but not neonatal. The cuffs are non-sterile, reusable, prescription only devices that are offered in a wide range of sizes.

Indications for Use

The Medline Reusable Blood Pressure Cuffs are intended to be used by medical professionals in conjunction with non-invasive blood pressure measurement systems for the determination of a person's blood pressure. The cuffs are non-sterile, multi-patient use and are tested for up to 10,000 inflation cycles and 100 cleaning/Disinfection cycles.

Medline Blood Pressure cuff adapters and connectors are intended to be used by medical professionals in conjunction with non-invasive blood pressure systems and blood pressure cuffs for determination of a person's blood pressure. The Blood Pressure Cuff adapter is for single monitor use only. The Blood Pressure Cuff adapter has been validated for use for up to 10,000 cycles or up to 10,000 connections/disconnections.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES



Medline Industries, LP
 Three Lakes Drive
 Northfield, IL 60093

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Reusable Blood Pressure Cuffs	Reusable Blood Pressure Cuff	N/A
510(k) Reference	TBD	K233276	N/A
Product Owner	Medline Industries, LP	Suzhou Minhua Medical Apparatus Supplies Co., LTD	N/A
Product Code	DXQ	DXQ	Same
Classification	II	II	Same
Regulation Number	870.1120	870.1120	Same
Intended Use	The Medline Reusable Blood Pressure Cuffs are intended to be used by medical professionals in conjunction with non-invasive blood pressure measurement systems for the determination of a person's blood pressure. The cuffs are non-sterile, multi-patient use and are tested for up to 10,000 inflation cycles and 100 cleaning/Disinfection cycles.	The Reusable Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in adult size	Similar <i>*The proposed device is also used on infants and pediatrics. The difference is support with the performance testing supporting these additional patient populations are not a safety concern.</i>
Patient Population	Infant, pediatric but not neonatal, and adult sizes.	Adult	Similar <i>*The proposed device is also used on infants and pediatrics. The difference is support with the performance testing supporting these additional patient populations are not a safety concern.</i>
Tube Configuration	One Tube	One Tube	Same
Bladder	Internal Bladder	Internal Bladder	Same
Principle of Operations	The cuffs are wrapped around a patient's limb and secured with a hook-and-loop closure. The hook-and-loop closure consists of a single layer of material. One tube extends from the bladder and is connected to a non-invasive blood pressure measurement system via connector(s). Reusable multi-patient blood pressure cuffs are intended to be used by medical professionals in conjunction with non-invasive blood pressure measurement systems for determination of a person's blood pressure. There is no defined shelf life.	Bladder is wrapped around the patient's limb and secured by hook and loop closure. Air hose is connected to the noninvasive blood pressure measurement systems	Similar <i>*The proposed device has more verbiage but the principles of operations are identical between the predicate and proposed device. The difference in verbiage does not pose any risk or concerns to the safety or effectiveness of the proposed device.</i>
Cuff Size	Infant: 9-14.8cm Infant Long: 9-14.8cm Child: 13.8-21.5cm Child Long: 13.8-21.8cm Small Adult: 20.5-28.5cm Small Adult Long: 20.5-28.5cm	Small adult: 17-22cm Small adult long / Adult: 22-30 cm	Difference <i>*The proposed device cuff sizes differ from the predicate device. Performance testing was conduct which illustrates that there are no safety or performance concerns with the difference in cuff sizes.</i>



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	Adult: 27.5-36.5cm Adult Long: 27.5-36.5cm Large Adult: 35.5-46cm Large Adult Long 35.5-46cm Thigh: 45-56.5cm	Large Adult: 30-42 cm Large Adult long: 42-48 cm Universal: 22-42 cm	
Sterile vs. Non-Sterile	Non Sterile	Non Sterile	Same
Single Use vs. Reusable	Reusable	Reusable	Same

Summary of Non-Clinical Testing

Biocompatibility Testing

The proposed device is categorized according to ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process* as an surface device with a limited (≤ 24 hours) contact duration with intact skin.

Performance Testing (Bench)

Performance testing was conducted per ISO 81060-1.

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Reusable Blood Pressure Cuffs are as safe and as effective for their intended use as the predicate device, Minhua Reusable Blood Pressure Cuffs cleared in K233276