November 20, 2025

Medline Industries, LP.
Payal Solanki
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K253070
Trade/Device Name: Namic Radial Arm Band, 23 cm (DYNJRADBAND); Namic Radial Arm Band, 26 cm (DYNJRADBANDL)
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 22, 2025
Received: September 23, 2025

Dear Payal Solanki:

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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2025.11.20 17:31:32 -07'00'

Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: 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.

510(k) Number *(if known)*
K253070

Device Name
Namic Radial Arm Band

Indications for Use *(Describe)*
The Namic Radial Arm Band is indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 08
510(k) SUMMARY
[According to 21 CFR 807.92]

510(k) Summary Preparation Date
September 22, 2025

Submitter/Applicant
Medline Industries, LP.
Three Lakes Drive
Northfield, IL 60093

Contact Person
Name: Payal Solanki, Regulatory Affairs Specialist
Email: psolanki@medline.com
Phone: 847-404-5474

Type of 510(k) Submission
Traditional

Subject Device
Trade Name: Namic Radial Arm Band
Common Name: Radial compression device
Classification Name: Clamp, Vascular
Product Code: DXC
Review Panel: Cardiovascular
Regulatory Class: Class II
Regulation Number: 21 CFR 870.4450

Predicate Device
K213531 - TR BAND Radial Compression Device

Device Description
The Namic Radial Arm Band is a tourniquet-style device consisting of a soft wristband with a secure hook and loop adjustable fastener on each end, two compression balloons, a support plate, flexible tubing with the input valve, and an inflation device. The device is offered in two lengths, 23 cm and 26 cm.

The use of the Namic Radial Arm Band begins after the transradial catheterization procedure is concluded and as the introducer sheath is gradually withdrawn from the patient. The wristband is placed around the patient's wrist with the adjustable hook and loop fastener. Once the Radial Arm Band is secured in place,

the inflation device is connected via the input valve and tubing. The inflation device is used to apply pressure to the patient's access site. Both radial compression balloons (RCB) are filled with air at the same time to allow for efficient compression for hemostasis. The volume of air can be increased or decreased using the inflation device, thus allowing the physician to adjust the pressure in the Radial Arm Band. The Namic Radial Arm Band is a disposable, single use only device. The Namic Radial Arm Band is for use with the adult population.

Intended Use / Indications for Use

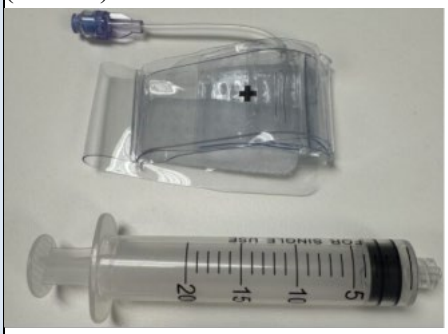
The Namic Radial Arm Band is indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).

Comparison of Technological Characteristics

The subject device, Namic Radial Arm Band is substantially equivalent in function and intended use to the legally marketed device, TR BAND Radial Compression Device cleared in K213531. The comparative table below (**Table 1**) offers details pointing to similarities and differences.

Table 1: *Subject and Predicate Device Comparison Table*

Feature	***Subject Device***	***Predicate Device***	***Comparison Analysis***
Product Name	Namic Radial Arm Band	TR BAND Radial Compression Device	N/A
510(k) Number	TBD	K213531	N/A
510(k) Owner	Medline Industries, LP.	Terumo Medical Corporation	N/A
Product Code	DXC	DXC	Identical
Regulation No.	21 CFR 870.4450	21 CFR 870.4450	Identical
Regulation Description	Clamp, Vascular	Clamp, Vascular	Identical
Review Panel	Cardiovascular	Cardiovascular	Identical
Intended Use / Indications for Use	The Namic Radial Arm Band is indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).	The TR Band® is a compression device indicated to apply compression in order to achieve hemostasis while allowing the user to maintain patency of the radial artery after a transradial procedure (patent hemostasis).	Identical
Principle of Operation	Operated manually. Pneumatic compression balloons are filled to apply pressure to the access site.	Operated manually. Pneumatic compression balloons are filled to apply pressure to the access site.	Identical
Design Features	A tourniquet style device consisting of a wristband with a secure hook and	A tourniquet style device consisting	Identical

Feature	*Subject Device*	*Predicate Device*	*Comparison Analysis*
	loop adjustable fastener on each end, two compression balloons, a support plate, inflation device input valve (injection port), and an inflation device (inflator). 	of a belt (wristband) with hook and loop adjustable fastener on each end, two compression balloons, a support plate and an injection port. The device also contains a TR Band Inflator. 	
Materials	Wristband – Polyvinyl chloride	Wristband (Belt) – Polyvinyl chloride	Identical
	Compression Balloons – Polyvinyl chloride	Compression Balloons – Polyvinyl chloride	Identical
	Flexible Tubing – Polyvinyl chloride	Flexible Tubing – Polyvinyl chloride	Identical
	Support Plate – Polycarbonate	Support Plate – Polycarbonate	Identical
	Hook and Loop Securement (Adjustable fastener) – Nylon	Hook and Loop Securement (Adjustable fastener) – Nylon	Identical
	Inflation Device Input Valve (Air Injection Port with Valve) – Polycarbonate; no colorant	Inflation Device Input Valve (Air Injection Port with Valve) – ABS Resin; colorant	Different
	Inflation Device (Inflator) – Polypropylene	Inflation Device (Inflator) – Polypropylene	Identical
Device Specifications (Length)	Regular band - 23 cm	Regular - 24 cm	Similar
	Large band - 26 cm	Large band - 29 cm	Similar
Sterile vs. Non-Sterile	Sterile	Sterile	Identical
Single Use vs. Reusable	Single Use	Single Use	Identical
Disposable vs. Non-Disposable	Disposable	Disposable	Identical
Sterilization	2X ETO	2X ETO	Identical

Feature	*Subject Device*	*Predicate Device*	*Comparison Analysis*
Prescription vs OTC	Prescription	Prescription	Identical

Both the subject and the predicate device have identical intended use, principle of operation, design features, and overall technological characteristics, and similar lengths. Both devices are prescription use, sterile, disposable and single use. The subject device is different from the predicate in one minor way: the material for the Inflation Device Input Valve (Air Injection Port with Valve) component.

Evidence of the safety and effectiveness of the subject device has been established via non-clinical and biocompatibility testing. Particularly, for minor material differences that exist as noted above, the biocompatibility testing demonstrates that such differences do not raise different questions of safety or effectiveness.

Therefore, it can be concluded that the subject device is substantially equivalent to the predicate device.

Summary of Non-Clinical Testing

Performance Testing (Bench)

The following non-clinical testing was conducted on the Namic Radial Arm Band to demonstrate substantial equivalence to the predicate.

- Visual Inspection - Internal test method
- Dimensional Analysis - Internal test method
- Sub-Atmospheric Air Leakage - ISO 80369-7:2021
- Resistance to Separation from Axial Load - ISO 80369-7:2021
- Resistance to Separation from Unscrewing - ISO 80369-7:2021
- Resistance to Overriding - ISO 80369-7:2021
- Shear Strength - ASTM D5169-98 (2021)
- Peel Strength - ASTM D5170-98 (2021)
- Air Leakage - Internal test method
- Tubing Disconnection Strength - Internal test method
- Packaging Visual Inspection - ASTM F1886/ASTM F1886M-16
- Dye Penetration - ASTM F1929-23
- Seal Strength - ASTM F88/F88M-23
- Bubble Leak Test - ASTM F2096-11 (2019)

Biocompatibility Testing

The biological evaluation for the Namic Radial Arm Band was conducted in accordance with FDA guidance document, "*Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* and ISO 10993-1:2018, *Biological Evaluation of the Medical*

Devices – Part 1: Evaluation of Testing within a Risk Management Process. In accordance with ISO 10993-1, the materials of the Namic Radial Arm Band are categorized as a surface contacting device with breached skin for limited (<24h) duration. As such, the following biological endpoints were evaluated:

- Physical and Chemical Information
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Summary of Clinical Testing

Not applicable.

Conclusion

Based on the above, the data supports that any differences in technological characteristics do not raise new questions of safety or effectiveness. The Namic Radial Arm Band is substantially equivalent to the predicate device.