July 29, 2026

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

Re: K253526
Trade/Device Name: NAMIC Dilator and Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 15, 2026
Received: June 16, 2026

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 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,

MISTI L. MALONE -S

for
Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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)*
K253526

Device Name
NAMIC Dilator and Sheath

Indications for Use *(Describe)*
The NAMIC Dilator and Sheath are intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

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

510(k) Summary Preparation Date
June 15th, 2026

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

Contact Person
Name: Payal Solanki, Senior Regulatory Affairs Specialist
Email: psolanki@medline.com

Subject Device
Type of 510(k) Submission: Traditional
Trade Name: NAMIC Dilator and Sheath
Device Classification Name: Catheter Introducer
Product Code: DYB
Classification Panel: Cardiovascular
Regulatory Class: Class II
Regulation Number: 21 CFR 870.1340

Predicate Device
K171275 – Cook Micropuncture Introducer Set

Device Description
The NAMIC Dilator and Sheath are used to gain access to the body for safe and accurate placement of guidewires. The design consists of a dilator tube (Polypropylene-'regular'; or Stainless Steel-'stiff') and a sheath tube (Polypropylene on both regular and stiff versions). There will be four variations offered – stiff and regular, in 4FRx10cm and 5FRx10cm sizes. The subject device will be provided sterile to users either (1) packaged independently ("Single-sterile" configuration) or (2) co-packaged in a tray configuration with two additional components (entry needle and guidewire, that are outside the scope of this 510(k)). Both sterile packaging configurations have the same intended use.

Prior to utilization of the NAMIC Dilator and Sheath, the procedure (Seldinger technique) involves other devices (not in scope of this submission) to gain access to the vein or artery i.e. the entry needle and mini guide wire. Firstly, an entry needle (cannula) is used to gain access to the vein or artery for placement of the mini guide wire. Then, the mini guide wire is inserted through the cannula into the patient's blood vessel and is used for placement of the dilator and sheath into the vein or artery. Following guide wire insertion, the cannula is removed, and the dilator and sheath are advanced over the mini guide wire and into the blood vessel. The dilator maintains the integrity of the sheath and

dilates the blood vessel during insertion. Once the sheath is situated in the vessel, the dilator is removed along with the mini guidewire as a single unit. Afterwards, an appropriate guidewire (up to 0.038") can then be inserted through the sheath. Once the Dilator and Sheath are removed, they are disposed as they are intended for single use only.

The NAMIC Dilator and Sheath is to be used in a clinical setting by trained medical professionals such as physicians, technologists and registered nurses during percutaneous vascular and cardiovascular procedures. The patient population extends to adults and pediatrics.

Intended Use / Indications for Use

The NAMIC Dilator and Sheath are intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.

Comparison of Technological Characteristics

The subject device, NAMIC Dilator and Sheath is substantially equivalent in function and intended use to the legally marketed device, Cook Micropuncture Introducer Set cleared in K171275. The comparative table below (**Table 1**) offers details pointing to similarities and differences.

Table 1: *Predicate Device Comparison Table*

Feature	***Subject Device***	***Predicate Device***	***Comparison Analysis***
Product Name	NAMIC Dilator and Sheath	Micropuncture Introducer Set	N/A
Product Code	DYB	DYB	Identical
Regulation No.	870.1340	870.1340	Identical
Intended Use	The NAMIC Dilator and Sheath are intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.	The Micropuncture Introducer Set is intended for the placement of wire guides up to .038 inch diameter into the peripheral vascular system when a small 21 gage needle stick is desired.	Identical
French Size	4 Fr, 5 Fr	4 Fr, 5 Fr	Identical
Sheath Length	10 cm	10 cm	Identical
Medical procedure (Principle of Operation)	Seldinger technique	Seldinger technique	Identical
Guidewire compatibility	Up to 0.038 inch	Up to 0.038 inch	Identical
Materials of construction	Dilator Hub – Polypropylene Copolymer Dilator (Regular) – Polypropylene Dilator (Stiff) - 304V Stainless steel Dilator Luer Lock – Methyl Metha Acryla ABS Sheath Hub - Polypropylene Copolymer Sheath – Polypropylene	Not specified in 510(k) summary	Differences may exist - Supported by biocompatibility testing.

Feature	*Subject Device*	*Predicate Device*	*Comparison Analysis*
	X-ray contrasting (mixed in both the Dilat and Sheath Polypropylene) - Barium Sulfa		
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
Rx vs OTC	Rx	Rx	Identical

Both the subject and predicate device have identical intended use, principle of operation, method of sterilization, and design features. Both devices are prescription use, sterile, disposable and single use. The predicate introducer sets are comprised of the same components as the subject device co-packaged tray configuration: either 4.0 French or 5.0 French outer introducer and inner dilator (regular or stiff) coaxial pair, an entry needle, and a guidewire.

The material composition of the predicate device is not specified in its publicly available 510(k) summary. Although a direct material-to-material comparison cannot be made, the subject device has undergone a full biocompatibility evaluation in accordance with ISO 10993-1:2018 based on the nature and duration of contact.

Summary of Non-Clinical Testing

Performance Testing (Bench)

The following non-clinical testing was conducted on the NAMIC Dilator and Sheath to demonstrate substantial equivalence to the predicate.

- Visual Inspection - ISO 11070:2014+A1:2018
- Peak Tensile Force - ISO 11070:2014+A1:2018
- Freedom from Leakage - ISO 11070:2014+A1:2018
- Luer Connector Tests - ISO 80369-7:2021
- Insertion and Drag Force – Internal Test Method
- Dimensional verification of Sheath and Dilator – 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 Dilator and Sheath was conducted in accordance with FDA guidance document, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*" 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 10993-1:2018, the materials of the NAMIC Dilator and Sheath are categorized as Externally Communicating Device with Circulating Blood for Limited Exposure (< 24h). As such, the following biological endpoints were evaluated:

- Physical and Chemical Information
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
  - Hemolysis
  - Partial Thromboplastin Time
  - Platelet and Leukocyte Count
  - Complement Activation
  - Comparative surface assessment (40X SEM)

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. In accordance with 21 CFR Part 807.92 (b) (3), the NAMIC Dilator and Sheath is substantially equivalent to the predicate device.