



February 6, 2026

VascuTech Medical, LLC  
Katy Feeny  
Regulatory Affairs  
98 Highland Ave.  
Oaks, Pennsylvania 19456

Re: K254236

Trade/Device Name: Peel-Away Introducer Sheath  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: December 22, 2025  
Received: December 29, 2025

Dear Katy Feeny:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely, FINN E. DONALDSON - S

Digitally signed by FINN E. DONALDSON -S  
Date: 2026.02.09 14:50:49 -05'00'

For  
Misti Malone  
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

## Indications for Use

510(k) Number (if known)  
K254236

Device Name  
Peel-Away Introducer Sheath

Indications for Use (Describe)

The Peel-Away Introducer Sheath is intended for the percutaneous introduction of catheters and other intravascular devices into the vasculature.

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

### Submitter Information

Sponsor and Application Correspondent: Vascutech Medical, Llc  
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Email: [kjclinconsulting@gmail.com](mailto:kjclinconsulting@gmail.com)  
Date Prepared: December 22, 2025

**Device Identification:** Peel-Away Introducer Sheath  
Common Name: Catheter Introducer  
Device Class: Class II  
Review Panel: Cardiovascular  
Product Code: DYB  
Regulation Number: 870.1340

Predicate Device: Tear Away Introducer Sheath (K153533)

### Device Description

#### Indication for Use

The Peel-Away Introducer Sheath is used for the percutaneous introduction of catheters and other intravascular devices into the vasculature.

#### Substantial Equivalence

The subject device Peel-Away Introducer Sheath is substantially equivalent to the predicate device Tear Away Introducer Sheath cleared under K153533. Both the subject device and the predicate device introduce catheters and other intravascular devices into the vasculature percutaneously. Evaluation of the technology characteristics demonstrates that the subject device is substantially equivalent to the predicate device. The subject device does not give rise to any new safety or performance questions.

<b>Specification</b>	<b>Subject Device</b>	<b>Predicate Device</b>
Device Name	Peel Away Introducer Sheath	Tearaway Introducer Sheath
Manufacturer	VascuTech Medical LLC	Galt Medical Corp.

<b>Specification</b>	<b>Subject Device</b>	<b>Predicate Device</b>
510k Number	TBD	K153533
Product Code	DYB	DYB
Classification	II	II
Intended Use	The Peel-Away Introducer Sheath is intended for the percutaneous introduction of catheters and other intravascular devices into the vasculature.	The Tear-Away Introducer Sheath is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.
Patient Population	Adults	Adults
Placement	Percutaneous	Percutaneous
Design	Outer peelable sheath and a dilator. Peelable sheath has a winged hub to facilitate the tear in the sheath	Outer peelable sheath and a dilator. Peelable sheath has a winged hub to facilitate the tear in the sheath
Shape	Introducer Sheath: Winged hub, cylindrical cannula. Dilator: Round hub, cylindrical cannula.	Introducer Sheath: Winged hub, cylindrical cannula. Dilator: Round hub, cylindrical cannula.
Introducer Sheath and Dilator Diameter	3.5-16F	3-16 F
Sheath Length	5, 7, 10, 13 cm	5 to 30 cm

Dilator Materials	HDPE with 20% BaSO4	Unknown
Sheath Materials	HDPE with 20% BaSO4 MDPE	Polytetrafluoroethylene (PTFE)

Specification	Subject Device	Predicate Device
Duration of Use	Single Use Limited Duration	Single Use Limited Duration
Sterilization	Ethylene Oxide	Ethylene Oxide

### Non-Clinical Testing

The subject device has been evaluated through a series of nonclinical studies to demonstrate that the device meets the acceptance criteria for its intended use.

#### 1. Biocompatibility Testing

Biocompatibility testing has been performed per the requirements of ISO 10993-1:2025 as a medical device in contact with circulating blood for a limited duration. The Peel-Away Introducer Sheath complies with all biocompatibility tests:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- SC5B-9 Compliment Activation

## 2. Performance Bench Testing

The following tests were performed:

- Compatibility
- Sheath Leak
- Dimensional Verification (Sheath and Dilator)
- Rigidity
- Integrity
- Visual inspection
- Break Force Test (Sheath and Dilator)
- Peel Away

As part of design verification testing, representative samples of the device underwent dimensional, tensile, and performance testing. The results demonstrate that all device performance specifications are met.

## 3. Sterilization

The Peel-Away Introducer Sheath is terminally sterilized using ethylene oxide to a sterility assurance level of  $10^{-6}$ .

## Conclusion

The indications for use, sterilization, dimensions, and duration of use are the same as the predicate. Testing demonstrates that the different materials have substantially equivalent biocompatibility. It was concluded that the subject device is substantially equivalent to the predicate device.