August 5, 2026

Vesalio, Inc.
Sharon Shachar
Director of Regulatory & Clinical
2305 Historic Decatur Rd.
Suite 100
San Diego, California 92106

Re: K254211
Trade/Device Name: pVasc Net Mechanical Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: July 10, 2026
Received: July 10, 2026

Dear Sharon Shachar:

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,

KRINA M. PATEL -S

Digitally signed by KRINA M. PATEL -S
Date: 2026.08.05 13:38:17 -04'00'

For,

Gregory O'Connell
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254211

Please provide the device trade name(s).

pVasc Net Mechanical Thrombectomy Device

Please provide your Indications for Use below.

The pVasc Net Mechanical Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels.
- Temporary use in peripheral vessel occlusion.
- Use with aspiration and with the injection or infusion of contrast media and other fluids.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(K) SUMMARY

K254211

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:
Vesalio Inc.
2305 Historic Decatur Rd Suite 100
San Diego CA 92106 United States

Contact Person:
Sharon Shachar
Director of Regulatory & Clinical
Phone: (248) 697-6616
Email: sshachar@vesalio.com

Date Prepared: August 4, 2026

NAME OF MEDICAL DEVICE:

Proprietary Name:	pVasc Net Mechanical Thrombectomy Device
Common/Usual Name:	Embolectomy catheter
Classification Name:	Peripheral Mechanical Thrombectomy With Aspiration

1. DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	QEW, KRA
Regulation Number:	21 CFR 870.5150

2. PRIMARY PREDICATE:

Proprietary Name:	NeVa PV Thrombectomy System
Product Code:	QEW, KRA
510(k) Number:	K201085

Device Description:

The pVasc Net Mechanical Thrombectomy Device is a mechanical thrombectomy device with an expandable distal tip which is temporarily inserted into the peripheral vasculature to restore blood flow in vessels blocked by emboli and thrombus. The expandable tip is a tubular mesh structure laser cut from Nitinol. It contains radiopaque markers to enable visualization under fluoroscopy. In its expanded shape, the device creates a highly flexible, hybrid closed cell structure.

The pVasc Net Mechanical Thrombectomy Devices include a NET filter component which is a small-mesh nitinol component that is integrated at the distal portion of the basket.
The pusher assembly is composed of an introducer sheath and delivery pusher-wire that are used to deliver the device to the treatment site.
The introducer sheath is a polymer tube, which protects the device and distal segment of the delivery pusher-wire from damage and creates an uninterrupted passage for the device to be transferred into a delivery catheter. The pusher controls the deployment of the pVasc Net Device and facilitates advancement through a delivery catheter and retrieval of the device. It is used to track the device to the intended delivery site.

The pVasc Net Mechanical Thrombectomy Devices are intended to be delivered through a compatible commercially available delivery catheters to the target vessels. The pVasc Net Mechanical Thrombectomy Device is provided sterile and intended for single-use only.

Intended Use/Indication For Use:

The pVasc Net Mechanical Thrombectomy Device is indicated for:

- The non-surgical removal of emboli and thrombi from peripheral blood vessels.
- Temporary use in peripheral vessel occlusion
- Use with aspiration and with the injection or infusion of contrast media and other fluids.

Indications for Use Comparison:

The subject device and predicate device have identical Intended Use and Indications for Use. A detailed comparison of regulatory information in a tabular format is presented within Table 1 which compares the predicate to the pVasc Net Mechanical Thrombectomy Device.

Table 1: Regulatory Substantial Equivalence Table (Subject Device and Predicate Device)

Device Name	pVasc Net Mechanical Thrombectomy Device Subject Device)	NeVa PV Thrombectomy Device (Primary predicate)
510(k) Number	K254211	K201085
Company	Vesalio Inc.	Vesalio Inc.
Classification	21 CFR §870.5150: Embolectomy Catheter	21 CFR §870.5150: Embolectomy Catheter
Product Code	QEW: peripheral mechanical thrombectomy with aspiration	QEW: peripheral mechanical thrombectomy with aspiration
Indications for Use	The pVasc Net Mechanical Thrombectomy Device is indicated for: •The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Temporary use in peripheral vessel occlusion. • Use with aspiration and with the injection or infusion of contrast media and other fluids.	The NeVA PV Thrombectomy Device is indicated for: •The non-surgical removal of emboli and thrombi from peripheral blood vessels. • Temporary use in peripheral vessel occlusion. • Use with aspiration and with the injection or infusion of contrast media and other fluids.
Principal of operation	The basket is deployed distal to the occluded vessels, captures the embolic material and retracts back to the guide catheter in order to restore blood flow	The basket is deployed distal to the occluded vessels, captures the embolic material and remaining embolic debris and retracts back to the guide catheter in order to restore blood flow.

Technological Comparison:

The pVasc Net Mechanical Thrombectomy Device maintains the same fundamental technological characteristics and core design as the predicate NeVa PV Thrombectomy Device (K201085). Both devices consist of a pusher wire with an expandable Nitinol basket designed to mechanically engage and retrieve emboli and thrombi from peripheral vessels. The only difference between the subject and predicate devices is the incorporation of a small-mesh Nitinol net integrated into the distal portion of the Nitinol basket in the pVasc Net Mechanical Thrombectomy Device.

A detailed comparison of technological information in a tabular format is presented within Table 2 which compares the predicate to the pVasc Net Mechanical Thrombectomy Device.

Table 2: Technological Substantial Equivalence Table (Subject Device and Predicate Device)

Device Name	pVasc Net Mechanical Thrombectomy Device (Subject Device)	NeVa PV Thrombectomy Device (predicate)
Design	1. Core pusher wire 2. Nitinol basket with drop and capture zones 3. A small-mesh net Component inside distal capture zone	1. Core pusher wire 2. Nitinol basket with drop and capture zones
Materials	Pusher wire: Nitinol Basket and Net: Nitinol	Pusher wire: Nitinol Basket: Nitinol
Vessel Diameter	2.0 – 6.0 mm	2.0 – 6.0 mm
Basket Length	22 – 46 mm	22 – 46 mm
Basket OD	4.0, 4.5, and 6.0 mm	4.0, 4.5, and 6.0 mm
Basket / Filter configuration	Closed Cell Basket with concentric net	Closed Cell Basket
Markers	Yes, Platinum	Yes, Platinum
Net Component	Integrated nitinol net	N/A
Working Length	180cm	200cm, 300cm
Soft Distal Tip	Yes	Yes
Tip Length	5 mm	5 mm
Accessories	Introducer sheath	Introducer sheath
Delivery catheter	.021”-.027”	.021” -.027”
Packaging Materials	Polyethylene, Tyvek, paperboard.	Polyethylene, Tyvek, paperboard.
Provided Sterile?	Yes	Yes
Single Use?	Yes	Yes

Summary of Non-Clinical Testing:

To demonstrate that the subject pVasc Net Mechanical Thrombectomy Device performs as described in the indications for use, Vesalio has performed the following bench and preclinical testing to demonstrate that the subject device meets all required specifications for clot removal in the peripheral vasculature including:

- Simulated use testing
    - Device Introduction
    - Trackability/Compatibility
    - Flexibility/Navigability
    - Device Deployment

  - Ancillary device Compatibility
  - Tip Expansion
  - Device Aspiration
  - Clot Retrieval
  - Torque
  - Kink Testing
  - Tensile Strength
  - Resheathing Force
- Radial force
- Biocompatibility
  - Cytotoxicity
  - Irritation
  - Sensitization
  - Acute Systemic Toxicity
  - Material Mediated Pyrogenicity
  - Hemolysis
  - Heparinized Platelet and Count Assay
  - Complement Activation
  - Thrombin-Antithrombin Complex
  - Thrombogenicity

Since the subject device shares much of the same design characteristics with the predicate device, a subgroup of testing on the predicate device was leveraged to demonstrate substantial equivalence. These tests included the following:

- Af Temperature
- Radiopacity
- Corrosion Resistance
- Usability Testing
- Sterilization Validation
- Shelf-life Validation

This testing demonstrates that the technological differences between the pVasc Net Mechanical Thrombectomy Device and the NeVa PV Thrombectomy Device do not raise new questions of safety and effectiveness.

Conclusion:

Based on the above information, it is concluded that the pVasc Net Mechanical Thrombectomy Device is substantially equivalent to the predicate the NeVa™ PV Thrombectomy Device.