November 24, 2025

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

Re: K253407
Trade/Device Name: NeVa PV Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEX, QEW, KRA
Dated: September 30, 2025
Received: September 30, 2025

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 and the limitations described below. 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.

The OHT2: Office of Cardiovascular Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling:

1. The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Brian D. Pullin -S

for Bram Zuckerman, M.D.
Director
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)*
K253407

Device Name
NeVa PV Thrombectomy Device

Indications for Use *(Describe)*
The NeVa PV Thrombectomy Device is indicated for:
• The non-surgical removal of thrombus burden from coronary blood vessels,
• Use with adjunctive aspiration and with the injection or infusion of contrast media and other fluids.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K253407

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: September 30, 2025

Name Of Medical Device:

Proprietary Name:	NeVa PV Thrombectomy Device
Common/Usual Name:	Embolectomy catheter
Classification Name:	Coronary Mechanical Thrombectomy With Aspiration

Device Classification:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	QEX
Regulation Number:	21 CFR 870.5150

Primary Predicate:

Proprietary Name:	MegaVac Mechanical Thrombectomy System
Product Code:	QEX
510(k) Number:	K171493

Secondary Predicate

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

Device Description:

The NeVa PV Thrombectomy Device ("NeVa") is a mechanical thrombectomy device that is temporarily inserted into the coronary vasculature under angiographic visualization in order to remove emboli and thrombus to restore blood flow to occluded vessels. The overall design of NeVa is similar to other commercially mechanical thrombectomy devices that use a self-expanding nitinol basket attached to a core pusher wire. To optimize emboli and thrombus removal, NeVa employs a capture cell design within the nitinol basket structure that incorporates a proprietary drop zone pattern. This proprietary drop zone design maximizes clot retrieval efficiency without changing the mechanism of action used by mechanical thrombectomy devices. As with other mechanical thrombectomy devices, NeVa is intended to be delivered through a compatible commercially available microcatheter to the target vessel. NeVa is intended to be retrieved into a guiding catheter with adjunctive aspiration to reduce potential emboli. NeVa is provided sterile and intended for single-use only. To accommodate different vessel diameters and clot sizes, NeVa is provided in multiple expandable tip sizes and configurations.

Intended Use/Indication For Use:

The NeVa PV Thrombectomy Device is indicated for:

- The non-surgical removal of thrombus burden from coronary blood vessels,
- Use with adjunctive aspiration and with the injection or infusion of contrast media and other fluids.

Indications for Use Comparison:

The NeVa PV Thrombectomy Device (subject device) has the same intended use and similar Indications for Use as primary predicate, MegaVac Mechanical Thrombectomy System ("MegaVac") (K171493). Both devices are mechanical thrombectomy devices that are temporarily inserted into the coronary vasculature under angiographic visualization to remove emboli and thrombus to restore blood flow to occluded vessels. Both devices are indicated for prescription use only.

Any differences between the subject device and primary predicate (K171493) regarding the Indications for Use, do not raise different questions of safety and effectiveness as confirmed through the performance testing, including simulated use and human factors testing.

Similarly, the NeVa subject device and the secondary predicate, NeVa PV Thrombectomy Device (K201085) are identical with respect to materials, components, design, manufacturing, and sterilization processes. The secondary predicate is indicated to remove emboli and thrombus to restore blood flow to occluded vessels in the peripheral vasculature. Performance testing was conducted to demonstrate the subject device performs as intended in the coronary vasculature, and the proposed indication for use is narrower than the predicate, therefore the differences in Indications for Use between the two devices do not raise different questions of safety and effectiveness.

Technological Comparison:

The subject device, NeVa PV Thrombectomy Device, and the primary predicate, MegaVac Mechanical Thrombectomy System ("MegaVac") (K171493) and the secondary predicate, the NeVa PV Thrombectomy Device (K201085), share many technological similarities and principles of operation. All devices are mechanical thrombectomy devices that are temporarily inserted into the vasculature under angiographic visualization to remove emboli and thrombus to restore blood flow to occluded vessels.

The overall design of the subject device is similar to MegaVac and uses an expandable nitinol basket that deploys distal to the clot to retrieve it. Both devices retrieve the expanded basket towards an aspiration catheter to remove the clot from the vasculature. Therefore, both devices utilize similar components to retrieve emboli and thrombus.

Vesalio has performed simulated use testing and Human Factors Usability testing to demonstrate that the subject device meets all required specifications for clot removal in the coronary vasculature. This test demonstrated that any technological differences between NeVa PV Thrombectomy Device and MegaVac Mechanical Thrombectomy System (K171493) do not raise different questions of safety or effectiveness, specifically when viewed in relation to retrieval components, accessories and workflow. A comparison of the subject device with the primary device is summarized in Table 1.

The NeVa PV subject device and the secondary predicate, NeVa PV Thrombectomy Device (K201085) are identical with respect to materials, components, design and manufacturing and sterilization processes and are equivalent from a technological standpoint.

Table 1: Comparison of Subject Device and the Primary Predicate Device

Device Name	NeVa PV (Subject Device)	MegaVac Mechanical Thrombectomy System (Primary Predicate)
510(k) Number	K253407	K171493
Company	Vesalio	Capture Vascular, Inc.
Classification	870.5150: Embolectomy catheter.	870.5150: Embolectomy catheter.
Product Code	QEX: Coronary Mechanical Thrombectomy With Aspiration	QEX: Coronary Mechanical Thrombectomy With Aspiration QEW: Peripheral Mechanical Thrombectomy With Aspiration
Intended Use	Removal of emboli and thrombus to restore blood flow to occluded vessels	Removal of removing emboli and thrombus to restore blood flow to occluded vessels
Indications for Use	The NeVa PV Thrombectomy Device is indicated for: • The non-surgical removal of thrombus burden from coronary blood vessels, • Use with adjunctive aspiration and with the injection or infusion of contrast media and other fluids.	The MegaVac Mechanical Thrombectomy System is indicated for: • The non-surgical removal of emboli and thrombi from blood vessels. • The non-surgical removal of thrombi from synthetic grafts. • Use in temporary blood vessel/graft occlusion. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft Catheter placement over a guidewire
Components	• Expandable Tip • Pusher Assembly	• MegaVac Catheter with SafeSeal Technology • ThromboWire Clot Retractor
Use of basket to capture clot?	Yes	Yes
Basket Type	Self-Expanding Closed Cell Basket	Woven nitinol thrombectomy element
Material	Nitinol	MegaVac Catheter: Silicone coated nitinol braided funnel ThromboWire (Clot Retractor): Nitinol
Basket – Maximum Available Diameters	4.0, 4.5, and 6.0 mm	Deployed Diameters: • MegaVac Catheter: 2 – 12 mm • ThromboWire (Clot Retractor): 2 – 9 mm
Compatibility	Compatible Microcatheter Sizes: 0.021”, 0.027”	Guidewire compatibility: • MegaVac Catheter: Up to 0.044” • ThromboWire (Clot Retractor): N/A
Deployment Mechanism	Operator controlled – linear actuation	Operator controlled – linear actuation
Provided Sterile?	Yes	Yes
Single Use?	Yes	Yes

Non-Clinical And/Or Clinical Tests Summary

To demonstrate that the subject NeVa PV device performs as intended in the coronary vasculature, Vesalio has conducted a Simulated Use study and Human Factors Usability study using NeVa PV introduced into a coronary model.

Simulated use and Fatigue test results was performed on a coronary model to demonstrate that the NeVa devices met all its acceptance criteria and performed as intended for Device Transfer and Deployment (Device Preparation, Device Introduction, Device Marker Band, Device Trackability/Compatibility, Device Flexibility, Device Navigation and Accessibility, Device Characteristics, Device-Microcatheter Compatibility), Device Torque (Torqueability) and Device Removal, in the coronary vasculature.

Vesalio also performed a Human Factors Usability study to confirm that the subject device's characteristics performs as intended using the worst case conditions during testing. All acceptance criteria were met. Results demonstrated that NeVa PV met all acceptance criteria and performed as intended in the coronary vasculature model.

Since the subject device is identical to the secondary predicate device, verification testing that were previously conducted as part of K201085 and are applicable to the design of the subject device, were leverage to demonstrate substantial equivalence. Testing included the following:

- Physical and Dimensional Inspection
- Tensile Strength Testing
- Af Temperature Verification
- Radial Forces Evaluation
- Torque Strength Testing
- Navigation/Steerability
- Delivery / Retrieval Testing
- Multiple Re-Sheathing Durability
- Flexibility/Kink Resistance
- Tip Deflection Testing
- Corrosion Resistance
- Radiopacity Verification
- Physician Usability Testing.
- Biocompatibility
- Sterilization Validation
- Shelf-life Validation

No clinical data are required to support this 510(k) submission, as substantial equivalence is demonstrated by bench, simulated use, animal, and usability testing.

Conclusion:

The collective results of non-clinical performance testing demonstrate that the subject device meets all design specifications and performs as intended for its intended use. Therefore, the results of these tests confirm that any technological differences between the subject device and the selected predicate devices do not raise different questions of safety or effectiveness and support that the subject device is substantially equivalent to as the predicate device for the intended use.