January 6, 2026

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

Re: K251097
Trade/Device Name: V-DAC Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 3, 2025
Received: December 3, 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. 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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
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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)*
K251097

Device Name
V-DAC Catheter

Indications for Use *(Describe)*
The V-DAC Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral and neurovascular systems.

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

K251097

As required by 21 CFR 807.92

Submitter:
Vesalio, Inc.
2305 Historic Decatur Road
Suite 100
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United States

Contact Person:
Sharon Shachar
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Email: sshachar@vesalio.com

Date Prepared: January 2, 2026

Device:

Proprietary Name:	V-DAC Catheter
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Regulatory Class:	Class II
Product Codes:	QJP, DQY
Regulation Number:	21 CFR 870.1250

Predicate:

Proprietary Name:	AXS Catalyst Distal Access Catheter (AXS Catalyst 7)
Product Code:	DQY
510(k) Number:	K183463

Device Description:

The V-DAC Catheter consists of 1) Distal Access Catheter and 2) Peel-Away Introducer Sheath.

The V-DAC Catheter is a single lumen, coil-reinforced, flexible, variable stiffness composite catheter. The catheter distal shaft has an external hydrophilic coating aimed at reducing friction during use. The distal end of the catheter shaft is radiopaque for fluoroscopic visualization, and the proximal end contains a luer hub that allows the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular system. Complete dimensions of the catheter are included on the device label.

The Peel-Away Introducer is an accessory provided with the catheter to aid in the delivery of the catheter.

The V-DAC Catheter and a Peel-Away Introducer are packaged together, they are provided sterile, non-pyrogenic, and are intended for single use only.

Intended Use/Indications For Use:

The V-DAC Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral and neurovascular systems.

Indications for Use Comparison:

While the predicate has a broader indication for insertion and guidance of interventional devices and as conduit for retrieval devices, the subject device indication is limited to the insertion and guidance of microcatheters only.

Technological Comparison:

The V-DAC Catheter has the same fundamental technological characteristics as the predicate device, AXS Catalyst Distal Access Catheter (AXS Catalyst 7) (K183463) and has a similar design, composition and materials as the predicate device and the reference device, Penumbra System with Reperfusion Catheter RED 72 (K211654). The technological differences do not raise new or different questions of safety or effectiveness. A comparison of the subject device with the predicate and reference devices is summarized in Table 1.

Table 1: Comparison of Subject Device and the Predicate and Reference Devices

Device Name	V-DAC Catheter (Subject Device)	AXS Catalyst Distal Access Catheter (AXS Catalyst 7) (Predicate Device)	Penumbra System (Reperfusion Catheter RED 72) (Reference Device)
510(k) Number	K251097	K183463	K211654
Company	Vesalio, Inc.	Stryker Neurovascular	Penumbra, Inc.
Classification	21 CFR 870.1250: Percutaneous Catheter	21 CFR 870.1250: Percutaneous Catheter	21 CFR 870.1250: Percutaneous Catheter
Product Code	QJP: Catheter, Percutaneous, Neurovasculature DQY: Percutaneous Catheter	DQY: Percutaneous Catheter	NRY: Catheter, Thrombus Retriever
Intended Use	A percutaneous catheter is a device that is introduced into a blood vessel through the skin using a sheath (introducer) or guide wire.	A percutaneous catheter is a device that is introduced into a blood vessel through the skin using a sheath (introducer) or guide wire.	Restore blood flow by removing thrombus/clots in patients experiencing ischemic stroke.

Indications for Use	The V-DAC Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral and neurovascular systems.	The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	**Penumbra Reperfusion Catheters and Separators**: As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment. **Penumbra 3D Revascularization Device:** As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment. **Penumbra Aspiration Tubing**: As part of the Penumbra System, the
			Penumbra Sterile Aspiration Tubing is intended to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. **Penumbra Aspiration Pump**: The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration System.
Product Feature Comparison of Subject Device to Predicate and Reference Devices			
Materials	Stainless Steel, PTFE, Polyurethane, Pebax, Nylon 12, Tungsten, Platinum/Iridium	Nitinol, Polyolefin, PTFE, Pebax, Nylon, Tecoflex, Platinum/iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium
Length	115cm, 125cm, 132cm, 140cm	115cm, 125cm, 132cm	115cm, 120cm, 125cm, 127cm, 132 cm
Tip configuration	Straight	Straight	Straight
Min ID	0.070” (1.78mm)	0.068’’	0.072” (1.83mm)
Max OD	0.0865” (2.16mm)	0.0825’’	0.085” (2.16mm)
Coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating
Coating length	50cm		30cm

Accessories	Peel Away Introducer Sheath	Peel-Away Introducer Sheaths, RHV, Tuohy Borst Valve with Sideport	Peelable Sheath, Shaping Mandrel, RHV
Packaging Materials	Polyethylene, Tyvek, Paperboard.	Polyethylene Tube and HDPE Packaging Card	Polyester/Polyethylene/Tyvek, Polystyrene, SRS Paperboard
Sterilization	Yes (Ethylene Oxide)	Yes (Ethylene Oxide)	Yes (Ethylene Oxide)

Performance Data:

Bench Testing:

Bench testing was conducted after subjecting the test articles to simulated use conditions, environmental conditioning, and simulated distribution, in order to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate device. Performance specifications and test methods were based primarily on ISO 10555-1 standard and included the following:

Test	Test Method	Conclusions
Visual Inspection	The device and packaging were visually inspected.	The device met the acceptance criteria.
Dimensional Verification	Catheter dimensions were measured.	All dimensions met specified tolerances.
Simulated Use	The catheter was delivered, deployed, and retracted per the instructions for use within a simulated neurovasculature model.	The device performs as intended under simulated use conditions.
Dynamic Burst Pressure	The catheter was tested in clinically relevant conditions for resistance to dynamic burst pressure.	The device met the acceptance criteria.
Air and Liquid Leakage	The catheter was evaluated for liquid and air leakage.	The device met the acceptance criteria.
Static Burst Pressure	The catheter was tested in clinically relevant conditions for resistance to static pressure.	The device met acceptance criterion.
Tensile Force	The catheter shaft was tested for peak tensile strength.	The device met the acceptance criteria.
Kink Resistance	The catheter shaft was tested around clinically relevant bend radii.	The device met the acceptance criteria.
Torque Strength	The proximal end of the catheter was rotated with the catheter tip constrained from movement.	The device met the acceptance criteria.
Corrosion Resistance	The catheter tested for signs of corrosion.	The device met the acceptance criteria.
Tip Buckle	The distal tip of the catheter was tested for buckling force.	The subject device tip buckling force is comparable to the predicate device.
Particulate Evaluation and Coating Integrity	Particulates generated during simulated use and coating integrity before/after simulated use were tested.	The device is comparable to the predicate device.
Lumen Collapse	Resistance of the catheter to lumen collapse was tested.	The device met the acceptance criteria.

Additionally, packaging testing and sterile barrier integrity validation were performed

per ISO 11607-1 and ISO 11607-2.

All results met their predefined acceptance criteria.

Shelf Life Testing:

Shelf life testing of samples aged and subjected to transportation simulation were performed and the results met predefined acceptance criteria.

Sterilization:

The V-DAC Catheter is Ethylene Oxide (EO) sterilized. The device is provided sterile for single use while demonstrating a sterility assurance level (SAL) of 10^{-6}.

The V-DAC Catheter meets the requirements for EO residuals per EN ISO 10993-7 for a limited contact delivery system - externally communicating.

Biocompatibility:

The V-DAC Catheter was assessed for biocompatibility in accordance with ISO 10993-1 and FDA guidance document entitled, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process","* issued September 8, 2023. The V-DAC Catheter is considered an external communicating device with direct contact with circulating blood for a limited (≤24 hours) duration of exposure. The Peel Away Introducer Sheath is considered an external communicating device with indirect blood contact (via the fluid path) for a limited (≤24 hours) duration of exposure.

Based on this classification, tests relevant to the device components were selected and conducted in accordance with ISO 10993-1 and its applicable sub-parts. The V-DAC Catheter passed all biocompatibility testing. The results of the biocompatibility testing are summarized in the table below.

Test and Standard	Results	Conclusion
Cytotoxicity (MEM Elution)	Non-cytotoxic	Pass
Irritation (Intracutaneous Reactivity)	Non-irritant	Pass
Sensitization (Guinea Pig Maximization)	Non-sensitizer	Pass
Acute Systemic Toxicity (Injection study)	Non-toxic	Pass
Systemic Toxicity (Material-Mediated Pyrogenicity)	Non-pyrogenic	Pass
Direct and Indirect Hemolysis (ASTM F756)	Non-hemolytic	Pass
SC5b-9 Complement Activation	Comparable results to historical negative controls and <5% of the Cobra Venom Factor positive control.	Pass
Partial Thromboplastin Time Assay with Comparison Article	Materials do not significantly affect the coagulation system.	Pass
Heparinized Blood Platelet and Leukocyte Count Assay	Materials do not significantly affect platelets.	Pass
In Vitro Blood Loop Assay with Comparison Article	Non-thrombogenic	Pass

Animal Study:

Non-clinical animal testing comparing the safety, usability, and performance of the V-DAC Catheter (as part of the NeVasc Aspiration System, K251006) to the reference device was conducted in a swine model. Testing was performed in accordance to Good Laboratory Practice (GLP) regulations (21 CFR Part 58). Sub-acute (4-day) and chronic (28-day) timepoints were assessed. Device usability, radiopacity, and compatibility with ancillary devices were evaluated and found to be comparable between the test and control devices. Angiographic and histological evaluations demonstrated that the V-DAC Catheter was comparable to the control device at both timepoints. No vessel dissection, perforation, or device related thrombosis were observed. The results of the animal studies support the safety and performance of the V-DAC Catheter.

Clinical:

No clinical studies were conducted as bench testing and the animal study were determined sufficient for verification and validation purposes and to support substantial equivalence.

Conclusion:

The V-DAC Catheter is substantially equivalent to the predicate device, AXS Catalyst Distal Access Catheter (AXS Catalyst 7) (K183463) based on the same intended use and similar indications for use, similar materials and design, and the same operating principles.

The collective results of non-clinical performance testing demonstrated that the subject device meets all design specifications and performs as intended. The technological differences between the subject device and the predicate device do not raise new or different questions of safety or effectiveness. Therefore, it is concluded that the subject device is substantially equivalent to the predicate device.