October 24, 2025

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

Re: K251312
Trade/Device Name: Vesalio Peripheral System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ, KRA
Dated: September 24, 2025
Received: September 24, 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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.10.24 11:13:23 -04'00'

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

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)*
K251312

Device Name
Vesalio Peripheral System

Indications for Use *(Describe)*

The Vesalio Peripheral Catheter is intended for use in the peripheral arterial vasculature for:
• the removal of fresh, soft emboli and thrombi
• infusion of diagnostic agents, such as contrast media

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

Complying with 21 CFR 807.92 I.

I. SUBMITTER:

Vesalio Inc.
2305 Historic Decatur Rd, Suite 100
San Diego, CA 92106

Phone: 248-697-6616

Contact Person: Sharon Shachar
Date Prepared: May 9, 2025

II. DEVICE

Name of Device: Vesalio Peripheral System
Common Name: Aspiration thrombectomy catheter
Regulatory Classification: Embolectomy Catheter (21 CFR 870.5150)
Regulatory Class: II
Product Code: QEZ, KRA

III. PREDICATE DEVICE

Primary Predicate: QuickClear Mechanical Thrombectomy System, K193197
Reference Device: JETi AIO Peripheral Thrombectomy System, K213565
The predicate and reference devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Vesalio Peripheral System consists of 1) Peripheral Catheter, 2) Peel away Introducer Sheath and 3) an Aspiration Tubing Set.
The Peripheral Catheter is a single-lumen, coil-reinforced, flexible, variable stiffness composite catheter that facilitates the removal of thrombus from the peripheral arterial vasculature when connected to a compatible aspiration pump and the Aspiration Tubing Set.
The catheter is a hollow cylindrical tube constructed using a combination of medical-grade polymers with metal reinforcement, a lubricous inner liner made from PTFE and the outer jacket consisting of thermoplastics made of polyurethane, polyether block amide, and nylon 12.

The distal end of the catheter has a hydrophilic coating aimed to reduce friction and aid

tracking through the vasculature. The catheter employs radiopaque characteristics for angiographic visualization.

On the proximal end, the catheter incorporates a flexible strain relief, which provides kink resistance, and a translucent, polycarbonate female luer hub to allow attachment of ancillary devices for navigation, infusion of fluids, and aspiration through the catheter.
A peel-away introducer sheath is provided in the package to facilitate the insertion of the Peripheral Catheter's distal tip into an appropriate vascular sheath.

The Aspiration Tubing Set is provided in a separate package and is made of common medical grade polymers. It comprises of a hollow cylindrical tube that is bonded to a standard male rotator fitting on one end. The male rotator allows the tubing to connect to an RHV or the female luer hub of the catheter. The other end of the tubing consists of a hose fitting to enable connection with a vacuum pump. A flow switch is connected in line to provide vacuum control.
The Peripheral System is provided sterile, non-pyrogenic, and is intended for single use only.

V. INDICATIONS FOR USE

The Vesalio Peripheral Catheter is intended for use in the peripheral arterial vasculature for:

- the removal of fresh, soft emboli and thrombi
- infusion of diagnostic agents, such as contrast media

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device, Vesalio Peripheral System, the primary predicate device Volcano, QuickClear Mechanical Thrombectomy System, the reference device, Walk Vascular, JETi AIO Peripheral Thrombectomy System share the same fundamental technological characteristics.
The overall design of the system is similar to the primary predicate device as they consist of a single-lumen, reinforced, catheter and an aspiration tube.
The subject device characteristics, including composition, dimensions and materials are similar as those of the predicate device.

The subject device and the predicate and reference devices are provided sterile and are intended for single use only.

Table 1 below demonstrates the comparison of the device characteristics between the Vesalio Peripheral System, the predicate device and reference device.

Table 1: Regulatory Substantial Equivalence Table (Subject Device, Primary and Reference Devices)

Device Name	Vesalio Peripheral Catheter (Subject Device)	QuickClear Mechanical Thrombectomy System (Primary predicate)	JETi AIO Peripheral Thrombectomy System (Reference Device)
510(k) #	K251312	K193197	K213565
Company	Vesalio Inc.	Volcano AtheroMed Inc.	Walk Vascular, LLC
Classification	21 CFR 870.5150 Embolectomy catheter 21 CFR 870.1250 Percutaneous Catheter	21 CFR 870.5150 Embolectomy catheter	21 CFR 870.5150 Embolectomy Catheter
Product Code	QEZ: aspiration thrombectomy catheter KRA: catheter, continuous flush	QEZ: aspiration thrombectomy catheter	QEZ: aspiration thrombectomy catheter
Intended use and Indications for Use	The Vesalio Peripheral Catheter is intended for use in the peripheral arterial vasculature for: • the removal of fresh, soft emboli and thrombi • infusion of diagnostic agents, such as contrast media	The QuickClear Mechanical Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.	The JETi AIO Peripheral Thrombectomy System is intended to: - remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and - subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.
Principal of operation	Temporarily inserted into the peripheral arteries, using a compatible sheath and guidewire and under angiographic guidance, to the target occlusion site to perform aspiration thrombectomy.	The catheter is introduced over a guidewire to the site of the target occlusion to perform aspiration when connected to the aspiration pump that serves as a vacuum source.	The Catheter is connected to the Pump Set and Suction Tubing, the thrombus enters the distal catheter tip via the suction force provided by the vacuum pump.

Table 2: Technological Substantial Equivalence Table (Subject Device, Primary and Reference Devices)

Device Name	Vesalio Peripheral Catheter (Subject Device)	QuickClear Mechanical Thrombectomy System (Primary predicate)	JETi AIO Peripheral Thrombectomy System (Reference Device)
Catheter	Peripheral Catheter	QuickClear Catheter	JETi AIO Catheter
Materials	Stainless steel, Polymeric blends commonly utilized for interventional devices	Polymeric blends commonly utilized for interventional devices	Biocompatible Materials
Length	115cm, 125cm, 132cm, 140cm	6F= 130 cm 8F= 85 cm 10F=85 cm	100 cm
Max OD	0.085”	6F=0.081" 8F= 0.107" 10F=0.130"	8 Fr
Tip Configuration	Straight	Straight	Flared
Coating length	50cm	30cm	Unknown
Accessories	Peel Away Introducer Sheath	Hemostatis Valve Y Connector	Unknown
	Aspiration tubing set	Aspiration Tubing	Aspiration Tubing
Packaging Materials	Polyethylene, Tyvek, paperboard.	Tyvek Pouch and chipboard boxes	Unknown
Provided Sterile?	Yes	Yes	Yes
Single Use?	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing: The biocompatibility evaluation for the Vesalio Peripheral System was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" September 2023, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The Vesalio Peripheral System is classified as an external communicating device with direct and indirect blood contact intended for a limited duration of exposure (≤24 hrs.) and therefore, the following biocompatibility tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Partial Thromboplastin Time
- Blood Loop Assay

Bench testing were conducted after subjecting the test articles to simulated use conditions, in order to evaluate device characteristics. Performance specifications and test methods were based primarily on ISO 10555-1 standard and included:

- Visual Inspection
- Physical Attribute
- Compatibility with ancillary devices
- Dynamic Burst Pressure
- Air and liquid Leakage
- Static Burst Pressure
- Tensile Force
- Reperefusion Testing
- Kink Resistance
- Torque Strength
- Corrosion Resistance
- Pump Flow Rate (FIPO)
- Tip Buckle
- Coating Integrity

- Particulate Evaluation

Additionally, Packaging qualification and sterile barrier integrity was validated as per ISO 11607-1 and ISO 11607-2.
All results met their predefined acceptance criteria.

Pre-Clinical Data: An animal study was conducted in compliance with applicable requirements of the GLP regulation (21 CFR Part 58) to evaluate the usability and to support a determination of substantial equivaent safety and effectiveness profile of the Vesalio Peripheral System during deployment and clot retrieval in worst case vessels, to the identified predicate device.

A usability study was conducted to evaluate the maneuverability, flexibility and trackability of the Catheter in a porcine model simulating clinical use compared to predicate device.

The animal study evaluated hemorrhagic potential and thrombogenic potential. The effectiveness of thrombi capture was assessed via angiographic, mTICI score, and histopathology.

Study results demonstrated that the Vesalio Peripheral System was able to aspirate clots without loss of device integrity. The Vesalio Peripheral Catheter demonstrated reperfusion of occluded arteries in the animals.

Clinical Studies: No clinical data were generated to establish substantial equivalence. Bench and pre-clinical data are considered adequate to support a determination of substantial equivalence.

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

VIII. CONCLUSIONS

The Vesalio Peripheral System has the same Intended Use, similar Indication for Use statement and Principal of Operation as both, the primary predicate and reference devices. It is intended to remove emboli and thrombi (as the primary predicate and reference device) and for and for infusion of diagnostic agents, such as contrast media (as the reference device). The subject device, and both predicate and reference devices, QuickClear and the Jeti AIO System, are indicated for use in the peripheral arterial vasculature.

The subject device and the predicate and reference devices (K193197 and K213565) are indicated to be used with an aspiration pump while utilizing aspiration tubing,
Overall, the minor differences in the indication for use do not raise any different questions of safety and effectiveness as confirmed through the performance testing utilizing compatible pump.

The Vesalio Peripheral System has the same fundamental technological characteristics as the predicate and reference devices, QuickClear and the Jeti AIO System of using aspiration to remove the clot. The Vesalio Peripheral System has met its design specification and performs as intended through the peripheral vasculature as demonstrated through bench testing and pre-clinical studies. Any materials, dimensions or other technological differences, do not raise different questions of safety or effectiveness per the device Intended Use.