January 7, 2026

Avantec Vascular Corporation
Gene Reu
Vice President Commercialization
870 Hermosa Drive
Sunnyvale, California 94085

Re: K251207
Trade/Device Name: Sangria™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, BTA
Dated: April 17, 2025
Received: April 18, 2025

Dear Gene Reu:

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: 2026.01.07 14:09:24 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K251207

Device Name

Sangria™ Thrombectomy System

Indications for Use *(Describe)*

The Sangria™ Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral venous system ≥ 7mm in diameter.

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."

Sangria System 510(k) Summary

510(k) Summary

This 510(k) Summary was prepared in accordance with 21 CFR 807.92.

I. Submitter

Avantec Vascular Corporation
870 Hermosa Drive
Sunnyvale, CA 94085

Contact Person
Gene Reu
Vice President of Commercialization
Telephone: +1 (858) 945-0007
Email: GReu@avantecvascular.com

Date Prepared
December 5, 2025

II. Device

Trade Name:	Sangria™ Thrombectomy System
Common Name:	Rotational/Aspirational Thrombectomy
Classification Name:	Embolectomy catheter
Regulation Number:	21 CFR 870.5150
Product Code:	QEW, BTA
Device Class:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

Predicate Device: QuickClear Mechanical Thrombectomy System (K193197)

Reference Device: Cleaner 15/Cleaner XT Rotational Thrombectomy System (K141617)

IV. Device Description

The Sangria™ Thrombectomy System (Sangria™ System) is a sterile, single-use, percutaneous, 14 Fr catheter-based system (single-piece construction) designed for the removal of fresh, soft emboli and thrombi from vessels of the peripheral venous systems. The 14Fr, over-the-wire Catheter features a battery-operated handle with a slider

that deflects the Catheter to target thrombus. A power switch on the handle activates rotation of the tip. Once activated, the tip rotates to break down the thrombus, which is then cleared proximally through the Catheter lumen and aspiration port into an external canister via vacuum aspiration. The Catheter is offered in a Straight Sheath configuration.

V. Indications for Use

The Sangria™ Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral venous system ≥ 7mm in diameter.

VI. Comparison of Technological Characteristics with the Predicate Device

The Sangria™ Thrombectomy System has similar features as compared to the predicate device and reference device as shown in the following table:

	Subject Device	Predicate Device	Reference Device
Manufacturer	**Avantec Vascular**	**Philips**	**Argon Medical Devices**
Device Name	**Sangria Thrombectomy System**	**QuickClear Mechanical Thrombectomy System**	**Cleaner (Cleaner 15/Cleaner XT) Rotational Thrombectomy System**
510(k) Number	**K251207**	**K193197**	**K141617**
Indication for Use	The Sangria™ Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral venous system ≥ 7mm in diameter.	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 Cleaner Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts. The Cleaner Rotational Thrombectomy System is indicated for mechanical declotting and controlled and selective infusion of physician-specific fluids, including thrombolytics, in the peripheral vasculature.
Classification Name	Embolectomy Catheter	Embolectomy Catheter	Embolectomy Catheter
Regulation Description	Embolectomy Catheter	Embolectomy Catheter	Embolectomy Catheter/ Continuous Flush Catheter
Regulation Number	21 CFR 870.5150	21 CFR 870.5150	21 CFR 870.5150
Product Code	QEW/BTA	QEZ	QEW/KRA
Regulatory Class	Class II	Class II	Class II
Product Code Description	Peripheral Mechanical Thrombectomy With Aspiration	Aspiration Thrombectomy Catheter	Peripheral Mechanical Thrombectomy With

Sangria System 510(k) Summary

			Aspiration / Catheter, Continuous Flush
Mechanism of Action	Mechanical maceration and removal of embolic and thrombus with tip rotation activated by ON/OFF switch, aided by aspiration pump	Continuous aspiration and removal of emboli and thrombus with aspiration pump	Mechanical maceration by a sinusoidal wire with rotation activated by ON/OFF switch and deployment of wire by slider lever
Rotational Speed	200-270 rpm	N/A	4000 rpm
Guidewire Exchange	Over-the-wire	Over-the-wire	Over-the-wire
Guidewire Compatibility	0.035”	0.035”	0.035”
Catheter Working Length	110cm	130 cm (6Fr) 85 cm (8Fr) 85 cm (10Fr)	65 cm (6Fr, 7Fr) 135 cm (6Fr, 7Fr)
Tip Diameter	.177”	0.084-0.088” (8Fr) 0.104-0.108” (10Fr)	Sinusoidal maceration wire diameter: 0.035” 0.044”
Catheter Outer Diameter	.185“ (14Fr)	0.079” (6Fr) 0.105” (8Fr)	6Fr 7Fr
Target Vessel Diameters	≥ 7.0mm (14Fr)	> 3.0mm (6Fr) > 4.0mm (8Fr) > 5.0mm (10Fr)	> 6mm (Cleaner 15)
Debris Collection & Removal	Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source	Continuous collection and removal of emboli and thrombus via a vacuum aspiration source with the catheter targeted at thrombus in the peripheral vasculature	N/A – no collection/removal through the Catheter
Tip Configuration	Deflectable, open spoon shape tip	Open catheter lumen, straight or shaped tip (deflected): 6Fr – Straight 8Fr – Shaped 10Fr – Shaped	Conical shape tip and sinusoidal shaped wire 6Fr: 9mm sinusoidal amplitude 7Fr: 15mm sinusoidal amplitude
Radiopacity	Radiopaque tip	Radiopaque marker band at tip	Radiopaque tip
Deflection Mechanism	Advancement and retraction of outer sheath	None	None
Recommended Vacuum Range	-100 mmHg to -250 mmHg	Capable of providing a vacuum source of ≥ 25inch Hg	N/A
Vacuum Source	Up to -22 inch Hg Vacuum	≥ 25 inch Hg Vacuum	N/A
Waste Collection Source	Collection Canister	Collection Bag	N/A
Catheter Coating	No	Yes	No

Aspiration Tubing Inner Diameter	.250”	0.100 – 0.125”	N/A
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1
Sterilization	Electron Beam Irradiation	Ethylene Oxide	Ethylene Oxide
Single Use Only	Yes	Yes	Yes

VII. Performance Data

To demonstrate the substantial equivalence of the subject Sangria Thrombectomy System to the selected predicate device, the performance and technological characteristics were evaluated by completion of the following bench tests:

Bench Testing

- Dimensional Inspection
- Visual Inspection
- Simulated Use
- Simulated Debulking/Declotting
- Catheter Kink Resistance
- Corrosion Resistance
- Catheter Joint/Tensile Strength
- Catheter Torque Strength
- Temperature Rise
- Run Time
- Aspiration Catheter Tests
- Guidewire Compatibility
- Device integrity and functionality as part of Shelf Life and Packaging Validation Testing

Biocompatibility

The following biocompatibility tests were conducted on the Sangria Thrombectomy System according to ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.

- Cytotoxicity: ISO Elution Method
- Sensitization: Magnusson-Kligman Method
- Irritation or Intracutaneous Toxicity (ISO)
- Acute Systemic Toxicity (ISO)
- Hemocompatibility:

- *in vivo* Thrombogenicity
- Complement Activation, SC5b-9
- Partial Thromboplastin Time (PTT)
- Hemolysis, Direct and Extract Methods (ISO)
- Material Mediated Pyrogenicity

Animal Testing

Two GLP animal studies were performed to evaluate the safety and performance of the Sangria™ Thrombectomy System as compared to the reference device, the Cleaner (Cleaner 15/Cleaner XT) Rotational Thrombectomy System (K141617) in a porcine model. Based on the results of the testing and histopathology findings, the safety and performance objectives for the studies were met.

Sterilization Validation

Sterilization validation was conducted on the Sangria™ Thrombectomy System and demonstrated a sterility assurance level of $10^{-6.}$

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and EMC testing was conducted on the Sangria™ Thrombectomy System and complies with IEC 60601-1 and IEC 60601-2.

VIII. Conclusions

The Sangria™ Thrombectomy System has been carefully compared to the legally marketed predicate device with respect to indications for use, technological characteristics, performance, and safety characteristics. Non-clinical testing was conducted to validate the performance of the devices and ensure the Sangria™ Thrombectomy System functions as intended and meet design specifications. The comparison and non-clinical results demonstrate that the Sangria™ Thrombectomy System is substantially equivalent to the predicate device for its intended use.