January 15, 2026

Inquis Medical
Zachary Woodson
VP of Regulatory Affairs & Quality Assurance
1530 O'Brien Dr.
Suite A
Menlo Park, California 94025

Re: K253925
Trade/Device Name: Aventus Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ, KRA, CAC
Dated: December 8, 2025
Received: December 8, 2025

Dear Zachary Woodson:

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: 2026.01.15 12:57:06 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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)*
K253925

Device Name
Aventus Thrombectomy System

Indications for Use *(Describe)*
The Aventus Thrombectomy System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Aventus Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

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.

510(k) Summary

I. SUBMITTER

Inquis Medical
1530 O'Brien Drive, Ste. A
Menlo Park, CA 94025

Contact Person: Zachary Woodson, VP of Regulatory Affairs & Quality Assurance

Date Prepared: 15 January 2026

II. DEVICE

Name of Device:	Aventus Thrombectomy System
Common or Usual Name:	Aspiration Thrombectomy Catheter
Classification Name:	Embolectomy Catheter
Regulatory Class:	Class II
Product Code:	QEZ, KRA, CAC
Regulation Number:	21 CFR 870.5150

III. PREDICATE DEVICES

Predicate Device:	Aventus Thrombectomy System (K251189)
Predicate Device:	Aventus Clot Management System (K240426)
Reference Device:	Flowtriever – Triever 24 (K213402)

IV. DEVICE DESCRIPTION

The Aventus Thrombectomy System is a catheter-based manual aspiration system designed for minimally invasive removal of emboli and thrombi from pulmonary arteries, the peripheral vasculature and/or infusing fluids. The System is comprised of the following major components:

- Aventus Thrombectomy Catheter
- Clot Management System consisting of:
    - Aspiration Syringe
    - Clot Canister

The System is compatible with a standard 24-French (24F) introducer sheath, Navigation Catheters and is to be used with 0.035" guidewires. The System is provided sterile and is intended for single use only.

The Aventus Thrombectomy Catheter includes an atraumatic radiopaque Distal Tip with embedded sensors, and an angled aspiration orifice for directional aspiration and navigation without a dilator. The Catheter Handle assists the clinician in navigating within the vasculature and includes a Sensing Indicator and houses the Sensing electronics.

The Aspiration Catheter shaft incorporates a metallic reinforcement layer made of stainless steel, an inner liner and polymeric outer jacket having variable stiffness, and includes a hydrophilic coating applied to the outside of the catheter shaft.

The System is provided with a 60-cc dual action manual syringe which allows for directional flow control and directs aspirated blood and clot into the Clot Canister.

V. INDICATIONS FOR USE

The Aventus Thrombectomy System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Aventus Thrombectomy System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, Aventus Thrombectomy System, is substantially equivalent to the predicate device: Aventus Thrombectomy System cleared under K251189. The intended use of the subject device is the same as the predicate, namely removal of thrombi or emboli from the pulmonary arteries, the peripheral vasculature system and infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The subject and predicate devices share the same technological characteristics in that both devices are single patient use, large bore aspiration catheters which utilize a 60-cc manual syringe as the aspiration source. Both the subject and predicate device incorporate disposable powered electronics and embedded software. From a manufacturing standpoint, both devices utilize shafts made with metallic (stainless steel) reinforced polymeric jackets with variable stiffness, radiopaque markings at the distal tip for fluoroscopic visualization, and use of stopcocks to direct the flow of fluids.

The subject device has been modified from the predicate device by the addition of a hydrophilic coating to the outer catheter shaft.

VII. PERFORMANCE DATA

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

Performance Testing	Data provided
Biocompatibility Testing	Biocompatibility testing was successfully completed in accordance with ISO 10993-1:2018 and the FDA Guidance re: Use of ISO-10993. Testing included: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material Mediated Pyrogenicity • Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time, Platelet Leukocyte Count, and Comparative Surface Assessment) This testing demonstrated the materials of the Aventus Thrombectomy System do not pose a risk of negative interaction with patients.
Sterilization	Sterilization testing was leveraged from the predicate device which was successfully completed in accordance with ISO 14937:2009 - *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices* and demonstrated an SAL of 10^{-6}. Bacterial endotoxins test (BET), a.k.a. Limulus amebocyte lysate (LAL) testing was conducted on the predicate device per current test guidelines: *USP <85> Bacterial Endotoxin Test* and *AAMI ST72 Bacterial endotoxins-test methodologies, routine monitoring and alternatives to batch testing* and confirmed that the System meets established pyrogen limit specifications.
Distribution, Packaging and Shelf-Life Testing	Distribution and packaging testing was leveraged from the predicate device which successfully demonstrated the integrity of the sterile barrier and preservation of the System's properties. Shelf-life testing was leveraged from the predicate device which has demonstrated preservation of the System's properties for the labeled six-month shelf-life.
Software Testing	Software documentation was leveraged from the predicate device as recommended by *FDA Guidance: Content of Premarket Submissions for Device Software Functions*, issued June 14, 2023.
Electrical Safety / EMC Testing	Electrical Safety and EMC testing were leveraged from the predicate device to ensure the subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6 and IEC 62366-1.
Performance Testing – Bench	Design verification testing was leveraged from the predicate device with limited additional performance testing to confirm physical and functional requirements were met. Specifically, the following was tested: • Visual Inspection • Simulated Use • Coating Integrity (particulate and durability)
Performance Testing – Non-Clinical	GLP animal testing completed in compliance with GLP regulation (21 CFR Part 58) and in accordance with *FDA Guidance: General Considerations for Animal Studies for Cardiovascular Devices (July 2010)* and *FDA Guidance: General Considerations for Animal Studies Intended to Evaluate Medical devices (March 2023)* provided for the predicate device, was leveraged for the subject device and demonstrated that the System was able to be used safely in a chronic large animal GLP study and met all pre-defined study endpoints.
Performance Testing – Clinical	New clinical data was not required to support this application, but the following information was leveraged from the predicate device. Inquis Medical completed the AVENTUS trial, a prospective, multicenter, single-arm, non-blinded clinical trial to evaluate the safety and effectiveness of the Aventus Thrombectomy System. A total of 130 subjects were enrolled (120 intent-to-treat and 10 roll-in) at 22 sites in the United States. Review of computed tomography angiography was conducted by a centralized core laboratory to determine change in RV/LV ratio from baseline to 48 hours. Major adverse events were adjudicated for clinical endpoint analysis by an independent clinical events committee (CEC). The primary safety endpoint was the composite of device related major adverse events (MAEs) within 48 hours of the index procedure. The primary effectiveness endpoint was the change in RV/LV ratio from baseline to 48 hours. Of the 120 subjects, the majority were men (58.8%), and the cohort had a mean BMI of 35.6. White non-Hispanic or Latino subjects were in the majority, with 17.2% of subjects being Black/African American. Key

Performance Testing | **Data provided**

medical history included hypertension (54.2%), concomitant deep vein thrombosis (84.3%), prior PE (8.3%) and history of cancer (9.2%).

The primary safety endpoint was met as there were no device-related MAEs in the study.

	ITT (N=120)		
48-Hr* Event Type	**# AEs**	**# (%) Subjects**	**p-value****
Death	0	0 (0.0%)	
Major Bleeding	0	0 (0.0%)	
Clinical Deterioration	0	0 (0.0%)	
Pulmonary Vascular Injury	0	0 (0.0%)	
Cardiac Injury	0	0 (0.0%)	
Total	0	0 (0.0%)	<0.0001

* Window for follow-up was 48 hours ± 8 hours. Data table includes device-related MAEs through 56 hours.
**p-value comparing the proportion of subjects with a MAE within 56 hours of the procedure to the performance goal of 25%

Information on non-device-related major adverse events at 48 hours is presented in the table below:

	ITT (N=120)	
48-Hr* Event Type	**# AEs**	**# (%) Subjects**
Death	0	0 (0.0%)
Major Bleeding	1	1 (0.8%)
Clinical Deterioration	2	2 (1.7%)
Pulmonary Vascular Injury	0	0 (0.0%)
Cardiac Injury	0	0 (0.0%)
Total	3	3 (2.5%)

* Window for follow-up was 48 hours ± 8 hours. Data table includes all MAEs through 56 hours.

The primary efficacy endpoint was met as the change in RV/LV from baseline to 48 hours was significantly better than the performance goal.

RV/LV Ratio	**Baseline**	**48 Hour/Discharge**	**Change from Baseline**	**Percent Change from Baseline**
N	119	116	116	116
Mean ± SD	1.57 ± 0.40	1.10 ± 0.20	0.47 ± 0.36	27.0% ± 17.1%
Median	1.50	1.08	0.40	27.5%
Min, Max	0.85, 3.01	0.70, 1.93	-0.45, 1.76	-52.9%, 58.5%
p-value			<0.0001	

The total number of days in the hospital following the index procedure was 2.6 ± 2.2 days and there were no thrombolytics used within 48 hours of the procedure, N=119.
As part of the AVENTUS trial, the cleared Blood Return Filter component of the Aventus Thrombectomy System was utilized to return blood to patients. Additional information may be found in the Instructions for Use.

VIII. CONCLUSIONS

In conclusion, the intended use, indications for use, and technological characteristics of the Aventus Thrombectomy System are the same or equivalent to the predicate devices. Performance testing has demonstrated that the Aventus Thrombectomy System is substantially equivalent to the predicate device.