July 27, 2026

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

Re: K261105
Trade/Device Name: Powered Aventus Thrombectomy System™
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA
Dated: June 25, 2026
Received: June 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.07.27 10:31:07 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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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)*
K261105

Device Name

Powered Aventus Thrombectomy System™

Indications for Use *(Describe)*

The Powered 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 Powered Aventus Thrombectomy System™ is intended for use in the peripheral vasculature.

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.

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510(k) Summary

I. SUBMITTER

Inquis Medical
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Tel: 888-526-7738
E-mail: info@inquismedical.com

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

Date Prepared: 25 July 2026

II. DEVICE

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

III. PREDICATE DEVICES

Predicate Device:	Aventus Thrombectomy System (K253925)
Reference Device:	Symphony Thrombectomy System (K252057)

IV. DEVICE DESCRIPTION

The Powered Aventus Thrombectomy System™ (ATS-P) is a catheter-based aspiration system designed for minimally invasive removal of emboli and thrombi from blood vessels. It is also indicated for injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The ATS-P is intended for use in the peripheral vasculature. The ATS-P is a single-use device that is provided sterile and resides within the sterile field.
The ATS-P is comprised of the following components:

- Thrombectomy Catheter
- Clot Management System

The Thrombectomy Catheter is a percutaneous device that is inserted into the patient anatomy via venous access to engage and remove thromboemboli via aspiration. The Thrombectomy Catheter is available in four (4) models differentiated by profile, tip shape (Max vs Sweep), and working length to enhance physician product selection based on patient anatomy within the vasculature. Each model is compatible with off-the-shelf 0.035" guidewires and includes a flexible hydrophilic coated catheter, atraumatic Distal Tip, a Catheter Body, and a Handle, designed to navigate within the vasculature without the need of a dilator. The 24F device is provided with an integrated Navigation Catheter.

- 24Fr x 92cm length – Max Tip
- 16Fr x 115cm length – Max Tip
- 16Fr x 85cm length – Sweep Tip
- 16Fr x 115cm length – Sweep Tip

The Thrombectomy Catheter includes embedded electronics and software which provide supplemental information about material sensed at the Thrombectomy Catheter tip via Sensing Indicators on the catheter handle and Clot Management System. The sensing functionality is meant for continuous operation throughout the procedure.

The Clot Management System is used in conjunction with the Thrombectomy Catheter to generate aspiration force at the catheter tip and power the Sensing Indicators and sensing functionality. The Clot Management System includes the Aspiration Syringe, Clot Canister, CO_2 Cartridge, De-Airing Chamber, and Blood Disposal Line. Upon actuation of the aspiration mechanism, the Syringe plunger retracts to a user determined aspiration volume (15 / 30 / 60-cc) then advances, pushing aspirated contents into the Clot Canister which separates clot and blood via a strainer and dual layered mesh filter (200 and 40 microns). The blood then passes through a De-Airing Chamber into the Blood Disposal Line for collection and disposal.

V. INDICATIONS FOR USE

The Powered 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 Powered Aventus Thrombectomy System is intended for use in the peripheral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, Powered Aventus Thrombectomy System™ , is substantially equivalent to the predicate, Aventus Thrombectomy System cleared under K253925. The intended use of the subject device is the same as the predicate, namely removal of thrombi or emboli and infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The devices are both used in the peripheral vasculature. However, the Powered Aventus Thrombectomy System is not indicated for use in the pulmonary artery or to treat pulmonary embolism.

The subject and predicate devices share the same technological characteristics in that both devices are single patient use, large bore catheters which utilize an aspiration syringe to remove thrombi and emboli. 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 removes thrombi and emboli by creating a negative pressure differential and pulling back a plunger on a large bore syringe using pneumatics versus the predicate device which is done manually.

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 • Irritation • Acute Systemic Toxicity • Material Mediated Pyrogenicity • Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time, and Platelet Leukocyte Count) This testing demonstrated the materials of the Powered Aventus Thrombectomy System do not pose a risk of negative interaction with patients.
Sterilization	Sterilization validation 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 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 successfully demonstrated the integrity of the sterile barrier and preservation of the System's properties. Shelf-life testing demonstrated preservation of the System's properties for the labeled six-month shelf-life.
Software Testing	Software documentation and testing was provided 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 conducted to ensure the subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-4-2, and IEC 62366-1.
Performance Testing – Bench	Design verification testing was performed and demonstrated that the physical and functional requirements were met. Specifically, the following was tested: • Visual & Dimensional Inspection • Tensile Strength • Pressure/Leak Integrity • Clot Burden Removal Validation • Vacuum • Leak • Compatibility (including visibility) • Torque Transmission • Kink / Bend • Simulated Use • Verification and Validation of Sensing • Particulate/Coating 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)* was provided 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.

VIII. CONCLUSIONS

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