May 14, 2024

Inquis Medical
Mojgan Sadaat
Official Correspondent
127 Independence Drive
Menlo Park, California 94025

Re: K240426
Trade/Device Name: Aventus Clot Management System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: February 13, 2024
Received: April 22, 2024

Dear Mojgan Sadaat:

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.

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,

Eric E. Richardson -S 2024.05.14 11:31:38 -04'00'

for Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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.

Submission Number *(if known)*

K240426

Device Name

Aventus Clot Management System

Indications for Use *(Describe)*

The Aventus Clot Management System is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion.

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
127 Independence Drive
Menlo Park, CA 94025
408-209-8326

Contact Person: Mojgan Saadat, President Inquis Medical

Date Prepared: April 22, 2024

II. DEVICE

Name of Device:	Aventus Clot Management System
Common or Usual Name:	Autotransfusion Apparatus
Classification Name:	Autotransfusion Apparatus
Regulatory Class:	Class II
Product Code:	CAC
Regulation Number:	21 CFR 868.5830

III. PREDICATE DEVICES

Predicate Device:	FlowSaver Blood Return System (K210176)

IV. DEVICE DESCRIPTION

The Aventus Clot Management System accessory allows for autologous injection of aspirated blood from the Aventus Thrombectomy System embolectomy procedure. The sterile, single-use Aventus Clot Management System is comprised of the following two components:

- Aspiration Syringe
- Clot Canister

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.

The Clot Canister connects to the Aspiration Syringe via quick disconnect connector at the inlet port on the side of the Canister. The aspirant from the Aventus Thrombectomy System procedure is injected into the Clot Canister. The blood passes through the Clot Canister dual layer nominal 40µ/200µ polyester screen filter, filling a syringe pre-connected to the female luer lock that is positioned below the filter assembly. The clinician can then return the filtered blood back to the patient via a standard sterile syringe with a required suitable blood transfusion filter (not provided).

The Clot Canister also has a flush port with a standard 3-way stopcock positioned above the filter assembly where an additional syringe can be attached to inject saline or air to assist in clot visualization without removing the lid.

V. INDICATIONS FOR USE

The Aventus Clot Management System is indicated for use with the Aventus Thrombectomy System for autologous blood transfusion.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, Aventus Clot Management System, is substantially equivalent to the predicate device: FlowSaver Blood Return System cleared under K210176. The intended use of the subject device is the same as the predicate in that both devices are intended to be used to return blood to a patient after filtration. The collection method for both the subject device and predicate device is through vacuum aspiration.

The subject device and predicate device share the same technological characteristics in that both devices include an aspiration syringe that connects to the aspiration catheter and injects the blood/clot into the blood return device using positive pressure and a second syringe for removing the filtered blood via negative pressure. Both devices have a dual layer filtration for separating clot from aspirated blood. Both devices use a suitable blood transfusion filter (not provided). Both devices can be opened to remove clot and flushed between filtrations. Both devices utilize a dedicated “inlet” for aspirated blood and “outlet” to remove filtered blood.

The subject device includes a third port for flushing the filter assembly which improves the convenience of use but does not change the principle of operation or blood filtration.

VII. PERFORMANCE DATA

Inquis Medical performed comprehensive testing on the Clot Management System, including non-clinical bench testing to demonstrate that the device met all required specifications and performs as intended. The following performance data were provided in support of the substantial equivalence determination.

Performance Testing	Data provided
Biocompatibility Testing	Biocompatibility testing was conducted in accordance FDA Guidance Document for the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 2023). Testing included: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material Mediated Pyrogenicity • Hemocompatibility (Hemolysis, Complement Activation, Thrombogenicity) This testing demonstrated the materials of the Aventus Clot Management System do not pose a risk of negative interaction with patients.
Sterilization	Sterilization testing 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 subject 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 testing and accelerated aging were successfully completed on the subject device; final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of the subject device's properties through the labeled shelf-life.
Performance Testing – Bench	Design verification testing was performed demonstrated that the physical and functional requirements were met. Specifically, the following was tested: • Visual and Dimensional Inspection • Tensile Strength • Pressure/ Leak Integrity • Clot Burden Removal Validation • Vacuum Test • Leak Test • Compatibility Testing • Simulated-Use • Particulate Testing • Hematocrit Testing • Mechanical Hemolysis Testing • Filtration Efficiency

Performance Testing	Data provided
Performance Testing – Non-Clinical	The GLP animal study 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)* for the subject device and demonstrated that the device was able to be used safely to return aspirated blood in a chronic large animal GLP study and met all pre-defined study endpoints.

VIII. CONCLUSIONS

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