



March 15, 2024

Inquis Medical
Mojgan Saadat
President
127 Independence Drive
Menlo Park, California 94025

Re: K240117

Trade/Device Name: Aventus Thrombectomy System (IM-2001/IM-0002)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 8, 2024
Received: January 16, 2024

Dear Mojgan Saadat:

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,

Gregory W.
O'Connell -S

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Gregory W. O'Connell -S
Date: 2024.03.15 14:45:43
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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

Indications for Use

Submission Number (if known)

K240117

Device Name

Aventus Thrombectomy System (IM-2001/IM-0002)

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.

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.

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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: January 5, 2024

II. DEVICE

Name of Device:	Aventus Thrombectomy System (IM-2001/IM-0002)
Common or Usual Name:	Aspiration Thrombectomy Catheter
Classification Name:	Embolectomy Catheter
Regulatory Class:	Class II
Product Code:	QEW, KRA
Regulation Number:	21 CFR 878.5150

III. PREDICATE DEVICE/REFERENCE DEVICE

Predicate Device: Aventus Thrombectomy System (K232730)

Reference Device: Indigo Aspiration System - Lightning Aspiration Tubing
(K193244)

IV. DEVICE DESCRIPTION

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

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

The System is compatible with a standard 24-French (24F) introducer sheath, 4-French (4F) Support Catheters and is to be used with 0.035" guidewires. The System is provided sterile and is intended for single use only.

The Aventus Aspiration Catheter II includes an atraumatic radiopaque Distal Tip with embedded sensors, and an angled aspiration orifice for directional aspiration and navigation without a dilator. A dedicated navigation catheter lumen for use with an off-the-shelf 4F Navigation

Catheter, and dedicated infusion lumen for injection of fluids is also included in the shaft. The Catheter Handle assists the clinician in navigating within the vasculature and also 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.

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.

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 K232730. The intended use of the subject device is the same as the predicate, namely removal of thrombi or emboli from the peripheral vasculature system. Additionally, the intended use of injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel is identical to the predicate.

The subject and predicate device share similar 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 devices utilize a dedicated infusion port/lumen for injection and infusion of contrast media and other fluids into or from the blood vessel. Both devices utilize the shaft made with metallic (stainless steel) reinforced polymeric jacketed shaft with variable stiffness, radiopaque markings at the distal tip for fluoroscopic visualization, and use of stopcocks to direct the flow of fluids. Neither the subject nor predicate device includes any coating or surface materials.

The subject device shares similar technological characteristics as the reference device in that it incorporates disposable powered electronics and embedded software.

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 leveraged from the predicate device which 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, Thrombogenicity) 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 - <i>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</i> 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: <i>USP <85> Bacterial Endotoxin Test</i> and <i>AAMI ST72 Bacterial endotoxins- test methodologies, routine monitoring and alternatives to batch testing</i> and confirmed that the System meets established pyrogen limit specifications.
Distribution, Packaging and Shelf-Life Testing	Distribution testing was successfully completed on the subject device; final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of the System's properties. Accelerated Aging simulating six-month shelf life was leveraged from the predicate and final packaging and device performance were successfully tested demonstrating integrity of the sterile barrier and preservation of the System's properties for the labeled six-month shelf-life.
Software Testing	Software documentation, including successful software verification and validation testing, was provided as recommended by <i>FDA Guidance: Content of Premarket Submissions for Device Software Functions</i>, issued June 14, 2023.
Electrical Safety / EMC Testing	Electrical Safety and EMC testing were conducted on the Aventus Thrombectomy System. 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 performed demonstrated that the physical and functional requirements were met. Specifically, the following was tested: • Visual and Dimensional Inspection

Performance Testing	Data provided
	• Tensile Strength • Pressure/ Leak Integrity • Clot Burden Removal Validation • Vacuum Test • Leak Test • Compatibility Testing • Torque Transmission Testing • Kink Testing • Simulated-Use • Verification and Validation of Sensing Kink and Torque to Failure testing was leveraged from the predicate based on no change in the shaft constructions or materials.
Performance Testing – Non-Clinical	The GLP animal study completed in compliance with GLP regulation (21 CFR Part 58) and in accordance with <i>FDA Guidance: General Considerations for Animal Studies for Cardiovascular Devices (July 2010)</i> and <i>FDA Guidance: General Considerations for Animal Studies Intended to Evaluate Medical devices (March 2023)</i> 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.

VIII. CONCLUSIONS

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