April 13, 2026

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

Re: K260091
Trade/Device Name: Aventus Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 12, 2026
Received: January 12, 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

MISTI L. MALONE -S

Misti Malone, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260091

Device Name

Aventus Introducer Sheath

Indications for Use *(Describe)*

The Aventus Introducer Sheath is indicated to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

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."

510(k) Summary

I. SUBMITTER

Inquis Medical
1530 O'Brien Drive, Ste. A
Menlo Park, CA 94025
Tel: 888-526-7738
E-mail: info@inquismedical.com

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

Date Prepared: 13 March 2026

II. DEVICE

Name of Device:	Aventus Introducer Sheath
Common or Usual Name:	Introducer Sheath
Classification Name:	Catheter Introducer
Regulatory Class:	Class II
Product Code:	DYB
Regulation Number:	21 CFR 870.1340

III. PREDICATE DEVICES

Predicate Device:	Gore DrySeal Flex Introducer Sheath (K160254)

IV. DEVICE DESCRIPTION

The Aventus Introducer Sheath is a catheter-based device designed for minimally invasive catheter access and hemostasis management. The Aventus Introducer Sheath is comprised of the sheath and the dilator, is single use only, and is provided sterile to the end user.

The Aventus Introducer Sheath is compatible with standard with 0.035" guidewires and includes an atraumatic radiopaque Distal Soft Tip. The Introducer Sheath assists the clinician in insertion of catheters as it includes a User-Actuatable Valve that operates with the push of a single button. The Introducer Sheath shaft incorporates a metallic reinforcement layer made of stainless steel, an inner liner and polymeric outer jacket, and includes a hydrophilic coating applied to the outside of the catheter shaft.

The Aventus Introducer Sheath is provided with a Dilator containing a flexible tapered tip to allow for a smooth transition of the Introducer Sheath into the vasculature of the patient over a standard .035" guidewire. The Dilator extrusion is radiopaque for ease of visibility under fluoroscopic imaging.

V. INDICATIONS FOR USE

The Aventus Introducer Sheath is indicated to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device, Aventus Introducer Sheath, is substantially equivalent to the predicate device: Gore DrySeal Flex Introducer Sheath cleared under K160254. The intended use of the subject device is the same as the predicate, namely providing a conduit for the insertion of endovascular devices while minimizing blood loss associated through way of a user-actuatable hemostasis valve.

The subject and predicate devices share the same technological characteristics in that both devices are single patient use, large bore Introducer Sheath shafts which have a hemostasis valve which can be opened and closed by the user. From a manufacturing standpoint, both devices utilize shafts made with metallic (stainless steel) reinforced polymeric jackets and lubricious liners, radiopaque features at the distal tip for fluoroscopic visualization, the use of stopcocks to direct the flow of fluids from side ports, flexible dilators with a tapered distal tip for ease of insertion into patient vasculature, and hydrophilic coating on the outside of the introducer sheath 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) This testing demonstrated the materials of the Aventus Introducer Sheath do not pose a risk of negative interaction with patients.
Sterilization	Sterilization testing 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} and per AAMI TIR28:2016(R)2020. 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 has demonstrated preservation of the System's properties for the labeled shelf-life.
Software Testing	N/A – No software present in this device.
Electrical Safety / EMC Testing	N/A – No electronics present in this device.
Performance Testing – Bench	Design verification testing confirmed physical and functional requirements were met. Specifically, the following was tested:

Performance Testing	Data provided
	• Critical Dimensions – IDs, ODs, and Lengths • Functional Testing - Compatibility with Devices and Guidewires • Radiodetectability • Simulated Use • Kink Radius / Tortuosity Testing • Torque Testing • Peak Tensile Force – Critical Junctions • Dilator Hub to Valve Housing Tensile Strength • Dilator Removal Force • Catheter Advancement Force and Retraction Force • System Freedom from Leakage • Lubricity and Particulate Testing • Usability
Performance Testing – Non-Clinical	N/A – No Animal Testing conducted in support of this submission in equivalence with the predicate device.

VIII. CONCLUSIONS

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