October 24, 2025

AngioDynamics, Inc.
Sameer Mansour
Sr. Regulatory Affairs Specialist
603 Queensbury Avenue
Queensbury, New York 12804

Re: K253106
Trade/Device Name: AngioVac Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 22, 2025
Received: September 24, 2025

Dear Sameer Mansour:

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,

Meaghan Erlewein -S

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.

510(k) Number *(if known)*
K253106

Device Name
AngioVac Cannula

Indications for Use *(Describe)*
The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

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:

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"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 FOR THE ANGIOVAC CANNULA

A. SPONSOR

AngioDynamics, Inc.
603 Queensbury Ave
Queensbury, NY 12804
USA

B. CONTACT

Sameer Mansour
Sr. Specialist, Regulatory Affairs
Tel: 901.268.2878
Email: sameer.mansour@angiodynamics.com

C. DEVICE NAME

Trade Name:	AngioVac Cannula
Common/Usual Name:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass (21 CFR § 878.4210, Class II, Pro-Code DWF)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K190594
Trade Name:	AngioVac Cannula
Common/Usual Name:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass (21 CFR § 878.4210, Class II, Pro-Code DWF)
Classification Panel:	Cardiovascular

E. REFERENCE DEVICE

510(k):	K211081
Trade Name:	AlphaVac Multipurpose Mechanical Aspiration (MMA) $F22^{20}$ System AlphaVac Multipurpose Mechanical Aspiration (MMA) $F22^{180}$ System
Common/Usual Name:	Aspiration Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR § 878.5150, Class II, Pro-Code QEZ)
Classification Panel:	Cardiovascular

F. DEVICE DESCRIPTION

The AngioVac Cannula is a venovenous cannula with a nitinol basket reinforced, self-expandable funnel shaped distal tip collapsed using an over-sheath that can be advanced through a 26 Fr sheath and over a guidewire into the venous system percutaneously or via a surgical cut-down. During use, the cannula is connected to an extracorporeal circuit, an AngioVac Circuit, a commercially available centrifugal pump and bubble trap. A commercially available reinfusion cannula is placed for venous return (typically within internal jugular or one of the common femoral veins) and connected to the extracorporeal circuit. The funnel tip is actuated by advancing the AngioVac Cannula out of the sheath deploying the self-expanding nitinol reinforced funnel shaped tip at the desired tip angle. Once optimal flow rate is achieved, the AngioVac Cannula is advanced under image guidance towards the undesirable intravascular (i.e. thrombus or emboli) until it is engaged, suctioned into the cannula and removed from the vasculature. The blood is then circulated though the filter and returned to the patient via the venous return cannula. A benefit of the AngioVac Cannula is that it allows for removal of thrombus and embolic material, while minimizing blood loss via recirculation of blood through a standard extracorporeal (venovenous) bypass circuit. Target vessels for the thrombus/embolus extraction include but are not limited to, the iliofemoral vein, Inferior Vena Cava (IVC), Superior Vena Cava (SVC) and Right Atrium (RA). The device is provided in ~20° (AngioVac C20) and ~180° (AngioVac C180) angled configurations.

G. INDICATION FOR USE

The AngioVac Cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for up to 6 hours.

H. STERILIZATION/SHELF LIFE

The predicate AngioVac Cannula is sterilized via ethylene oxide (EtO). A series of tests, performed by AngioDynamics and independent test houses, had been conducted to assess the suitability of the sterile packaging to protect the proposed AngioVac Cannula and ensure its sterility within its stated shelf life at point of use. These tests confirm the packaging integrity, sterility and distribution cycle. Testing demonstrated that the packaging is robust enough to withstand extreme distribution scenario at the most extreme environmental conditions while maintaining packaging integrity and sterility.

I. BIOCOMPATIBILITY

The AngioVac Cannula is a sterile single-use disposable instrument. AngioVac Cannula has fulfilled the biocompatibility testing requirements identified in ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing in the risk management process for an externally communicating device with circulation blood of a limited duration. Specifically, the following test were performed with acceptable results; cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity, and hemocompatibility.

J. TECHNOLOGY CHARACTERISTICS

Predicate device, AnigoVac Cannula, cleared via K190594, was used to support safety and effectiveness of the subject device. Both the subject device and specified reference device include the following technological characteristics:

- Both the proposed and predicate devices are designed for the non-surgical removal of thrombi or emboli from vasculature.
- Designed for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass for 6 hours.
- Wire reinforced to enhance trackability and vessel navigation and are designed with atraumatic tips to prevent vessel damage.

- Funnel shaped distal tip that allows for engagement and entrapment of undesirable intravesical material such as soft emboli and thrombi.
- Radiopaque markers on distal tip to assist tip visualization.
- Used in connection with the AngioVac Circuit (an extracorporeal bypass circuit) with centrifugal pump, bubble trap and reinfusion cannula.

Technological characteristics that are different between the subject and specified reference device are as follows:

- The obturator has been changed to be identical to the current F22 AlphaVac obturator, cleared under K211081.

The technological characteristics of the proposed AngioVac Cannula are substantially equivalent with respect to the basic system design and function to that of the specified predicate device.

K. PERFORMANCE DATA

Comprehensive bench testing (integrity and functional performance) was performed to support substantial equivalence of the specified predicate device. The AngioVac Cannula met all specified design and performance requirements below:

- Tensile Testing
- Stiffness Testing
- Aspiration Strength
- Cannula Actuation
- Distal Cannula Shape Manipulation
- Bend Angle
- Hub Rotation
- Distal Tip Functionality
- Kink Resistance
- Radiopacity
- Sheath Flushability
- Flow Rate
- Product Interface (Compatibility) Testing
- Dimensional Testing
- Visual Inspection

L. CONCLUSIONS

The results of the non-clinical testing and a comparison of similarities and differences demonstrates that the proposed and predicate devices are substantially equivalent.