October 30, 2026

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

Re: K263076
Trade/Device Name: AngioVac F1885
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 1, 2026
Received: September 1, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

NICOLE M. GILLETTE -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

AngioVac F1885 (H965252000)

Please provide your Indications for Use below.

The AngioVac F1885 is indicated as a venous drainage cannula for the non-surgical removal of thrombi or emboli during extracorporeal bypass for up to 6 hours.

The Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of the AngioVac Cannula/Obturator and other endovascular devices while minimizing blood loss associated with such insertions.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Number:_____

510(K) SUMMARY FOR THE ANGIOVAC F18[85] SYSTEM

A. SPONSOR

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

B. CONTACT

Sameer Mansour
Sr. Regulatory Affairs Specialist

C. DEVICE NAME

Trade Name:	AngioVac F18[85]
Common/Usual Name:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (21 CFR § 870.4210, Class II, Pro-Code DWF)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K212386
Trade Name:	AngioVac F18[85]
Common/Usual Name:	Cardiopulmonary Bypass Venous Cannula Extraction Catheter
Classification Name:	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (21 CFR § 870.4210, Class II, Pro-Code DWF)
Classification Panel:	Cardiovascular

E. REFERENCE DEVICES

510(k):	K252509
Trade Name:	AlphaVac Multipurpose Mechanical Aspiration (MMA) F18[85] 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 F18[85] 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 22 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 F18[85] 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 F18[85] 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 circuit and returned to the patient via the venous return cannula. A benefit of the AngioVac F18[85] 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 Heart. The device is provided in an ~85° (AngioVac F18[85]) angled configuration.

G. INDICATION FOR USE

The AngioVac F18[85] is indicated as a venous drainage cannula for the non-surgical removal of thrombi or emboli during extracorporeal bypass for up to 6 hours.

The sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of the AngioVac Cannula/Obturator and other endovascular devices while minimizing blood loss associated with such insertions.

H. DEVICE MODIFICATIONS

The proposed modification to the AngioVac F18[85] includes:

1. modified proximal cannula end/handle to allow for aspiration and injection of contrast media and other fluids from and into the vasculature.
2. sheath indicated to act as conduit for the insertion of endovascular devices into the vasculature while minimizing blood loss associated with such insertions

I. STERILIZATION/SHELF LIFE

The AngioVac F18[85] is sterilized via ethylene oxide (EO). A series of tests, performed by AngioDynamics and independent test houses, have been conducted to assess the suitability of the sterile packaging to protect the proposed AngioVac F18[85] and ensure 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 conditions at extreme environmental conditions while maintaining packaging integrity and sterility.

J. BIOCOMPATIBILITY

The AngioVac F18[85] is a sterile single-use disposable instrument. The AngioVac F18[85] has met the biocompatibility testing requirements identified in ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process. Specifically, the following tests were performed with acceptable results; cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, and hemocompatibility.

K. TECHNOLOGY CHARACTERISTICS

The indication for use and principles of operation for the AngioVac F18[85] and the predicate(s) are substantially the same. Both the subject devices and specified predicate devices include the following technological characteristics:

- Designed for the non-surgical removal of thrombi or emboli from vasculature
- Injection and aspiration of contrast media and other fluids from vasculature
- intended to be used with commonly available vascular access tools (e.g.: guidewire, vascular introducer, etc.) to facilitate removal of thromboemboli during minimally invasive percutaneous procedures.
- Large bore catheters with an aspiration source.
- Sheaths that act as conduit for the insertion and removal of endovascular devices
- 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 thromboemoli.
- 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.

The technological characteristics of the proposed AngioVac F18[85] is substantially equivalent with respect to the basic system design and function to that of the predicate devices.

L. PERFORMANCE DATA

Comprehensive bench testing (integrity and functional performance) was performed to support substantial equivalence of the specified predicate device. The AngioVac F18[85] met all specified design and performance requirements:

- Dimensional Testing
- Visual Inspection
- Tensile Testing
- Column Strength
- Cannula and Funnel Actuation
- Distal Cannula Shape Manipulation
- Hub Rotation
- Distal Tip Functionality
- Kink Resistance
- Radiopacity
- Flushability
- Bend Angle
- Product Interface (Compatibility) Testing
- Push/Pull/Retraction Force
- Leak Testing
- Siphoning Testing
- Fluid Volume Removal
- Pressure Testing
- Simulated Use
- Torque
- Flow Rate
- Contrast Injection

M. CONCLUSIONS

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