November 24, 2025

AngioDynamics, Inc
Kasey Newcomb
Sr. Manager Regulatory Affairs
603 Queensbury Ave
Queensbury, New York 12804

Re: K252509
Trade/Device Name: AlphaVac Multipurpose Mechanical Aspiration (MMA) F18^{85} System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA
Dated: October 28, 2025
Received: October 29, 2025

Dear Kasey Newcomb:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.11.24 13:43:03 -05'00'

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

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)*
K252509

Device Name
AlphaVac Multipurpose Mechanical Aspiration (MMA) F1885 System

Indications for Use *(Describe)*

The Cannula is indicated for:
• the non-surgical removal of thrombi or emboli from the vasculature
• aspiration and injection of contrast media and other fluids from and into the vasculature

The Cannula is intended for use in the venous system and for the treatment of pulmonary embolism.

The Handle is indicated as a vacuum source for the AlphaVac Multipurpose Mechanical Aspiration System.

The Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of the AlphaVac Cannula/Obturator and other 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.

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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 ALPHAVAC MMA F18^{85} SYSTEM

A. SPONSOR

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

B. CONTACT

Kasey E Newcomb
Sr. Manager, Regulatory Affairs

C. DEVICE NAME

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) Catheter, Continuous Flush (21 CFR § 878.1210, Class II, Pro-Code KRA)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K213402
Trade Name:	Triever24, Triever20
Common/Usual Name:	Aspiration Thrombectomy Catheter
Classification Name:	Embolectomy Catheter (21 CFR § 878.5150, Class II, Pro-Code QEW, KRA)
Classification Panel:	Cardiovascular

E. REFERENCE DEVICES

510(k):	K240397
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

510(k):	K212392
Trade Name:	Intri24 Sheath
Common/Usual Name:	Catheter Introducer
Classification Name:	Embolectomy Catheter (21 CFR § 878.1340, Class II, Pro-Code DYB)
Classification Panel:	Cardiovascular

F. DEVICE DESCRIPTION

The AlphaVac Multipurpose Mechanical Aspiration (MMA) System is a single use-over-wire catheter-based system that facilitates the removal of thrombus, embolus, or clot during minimally invasive percutaneous procedures. The AlphaVac MMA Systems are comprised of six main components packaged together:

- a flexible AlphaVac Cannula with self-expandable, nitinol reinforced, angled funnel shaped distal tip
- AlphaVac Sheath
- AlphaVac Obturator
- AlphaVac Handle
- Collection Bags
- AlphaVac Tubing

The AlphaVac Cannula is placed within target vasculature using standard percutaneous vascular access techniques (i.e., Seldinger) and commonly available vascular access tools (e.g., guidewire, vascular introducers, etc.). Once the cannula is in place, the AlphaVac Handle and waste bag are connected and primed. The AlphaVac Cannula is advanced out of the sheath and the nitinol basket automatically expands into a funnel, aiding in the removal of thrombus, emboli, and clot. The aspiration handle is pulled back creating suction and pulling the material into the catheter, removing it from the vasculature. The aspirated material is captured and contained within the waste bag for disposal. Target vessels include, but are not limited to, the iliofemoral vein, Inferior Vena Cava (IVC), Superior Vena Cava (SVC), Right Heart (Atrium (RA)), and Pulmonary Artery Vasculature. The device is provided in ~85° angled configuration.

G. INDICATION FOR USE

The Cannula is indicated for:

- the non-surgical removal of thrombi or emboli from the vasculature
- aspiration and injection of contrast media and other fluids from and into the vasculature

The Cannula is intended for use in the venous system and for the treatment of pulmonary embolism.

The Handle is indicated as a vacuum source for the AlphaVac Multipurpose Mechanical Aspiration System.

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

H. DEVICE MODIFICATIONS

The proposed modification to the AlphaVac MMA F18^{85} System 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
3. shorter tubing that connects handle to collection bag

I. STERILIZATION/SHELF LIFE

The AlphaVac MMA Systems are 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 AlphaVac MMA Systems 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 AlphaVac MMA Systems is a sterile single-use disposable instrument. The AlphaVac MMA Systems have 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 AlphaVac MMA Systems 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 a syringe-like aspiration source
- sheaths that act as a conduit for the insertion and removal of endovascular devices

The technological characteristics of the proposed AlphaVac MMA Systems are 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 to the specified predicate device. The AlphaVac MMA F18[85] System met all specified design and performance requirements:

- Contrast Injection
- Tensile Testing
- Dimensional Testing
- Visual Inspection
- Product Interface (Compatibility) Testing
- Leak Testing
- Pressure Testing
- Push/Pull/Retraction Force
- Torque
- Leveraged from K420397, K213388, K212386, and K211081:
  - Column Strength
  - Cannula and Funnel Actuation
  - Distal Cannula Shape Manipulation
  - Hub Rotation
  - Distal Tip Functionality
  - Kink Resistance
  - Radiopacity
  - Flushability
  - Siphoning Testing
  - Fluid Volume Removal
  - Handle Lock Testing
  - Handle Pull Force
  - Simulated Use

M. CONCLUSIONS

The results of the non-clinical testing and a comparison of similarities and differences demonstrates that the subject device is substantially equivalent the predicate device.