April 1, 2024

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

Re: K240397
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
Dated: February 8, 2024
Received: February 9, 2024

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.

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.04.01 09:38:02 -04'00'

For

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.

Submission Number *(if known)*

K240397

Device Name

AlphaVac Multipurpose Mechanical Aspiration System (MMA) F1885 System

Indications for Use *(Describe)*

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

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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510(K) SUMMARY FOR THE ALPHAVAC MULTIPURPOSE MECHANICAL ASPIRATION (MMA) F18^{85} SYSTEM

A. SPONSOR

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B. CONTACT

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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)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K180466
Trade Name:	FlowTriever Retrieval/Aspiration System
Common/Usual Name:	Embolectomy catheter
Classification Name:	Embolectomy catheter (21 CFR § 878.5150, Class II, Pro-Code QEW)
Classification Panel:	Cardiovascular

E. REFERENCE DEVICE

510(k):	K213388
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 AlphaVac Multipurpose Mechanical Aspiration (MMA) F18^{85} 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 F18^{85} System is comprised of six main components packaged together:

- a flexible AlphaVac Cannula with self-expandable, nitinol reinforced, angled funnel shaped distal tip (18F)
- AlphaVac Sheath (22F)
- AlphaVac Obturator (17F)
- AlphaVac Handle
- Waste Bag and 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 is 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° (AlphaVac F18^{85}) angled configuration.

G. INDICATION FOR USE

The Cannula is indicated for:

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

H. STERILIZATION/SHELF LIFE

The AlphaVac MMA F18^{85} System 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 AlphaVac MMA F18^{85} System 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 the most extreme environmental conditions while maintaining packaging integrity and sterility.

I. BIOCOMPATIBILITY

The AlphaVac MMA F18^{85} System is a sterile single-use disposable instrument. The AlphaVac MMA F18^{85} System 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.

J. TECHNOLOGY CHARACTERISTICS

Predicate device, the FlowTriever Retrieval/Aspiration System, cleared via K180466, was used to support substantial equivalence of the subject device. Both the subject device and specified predicate 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.
- Both devices are intended to be used with commonly available vascular access tools
- (e.g., guidewire, vascular introducer, etc.) to facilitate the removal of thrombus,
- embolus, and clot during minimally invasive percutaneous procedures.
- Both devices are large bore catheters with a syringe-like aspiration source.
- Both devices have similar operating principles by being advanced through a sheath over a guidewire to target location with a mechanical aspiration source that is used to aspirate thrombus/emboli from vasculature.

The technological characteristics of the proposed AlphaVac MMA F18^{85} System are substantially equivalent with respect to the basic system design and function to that of the specified predicate device.

Additionally, a reference predicate (K213388 – AlphaVac F18^{85}) has been identified to provide additional support as it is identical in materials, dimensions, manufacture, as the proposed device.

K. PERFORMANCE DATA

Comprehensive bench testing (integrity and functional performance) was performed to support substantial equivalence of the specified predicate device. The AlphaVac MMA F18^{85} System met all specified design and performance requirements below:

- 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
- Product Interface (Compatibility) Testing
- Push/Pull/Retraction Force
- Leak Testing
- Siphoning Testing
- Fluid Volume Removal
- Handle Lock Testing
- Pressure Testing
- Handle Pull Force
- Human Factors Evaluation/Usability Evaluation
- Simulated Use
- Torque

L. CLINICAL TESTING

AngioDynamics conducted the APEX-AV trial, a multicenter pivotal study to assess the use of the AlphaVac Multipurpose Mechanical Aspiration (MMA) F1885 System in subjects with acute intermediate-risk pulmonary embolism (PE). The trial enrolled 122 subjects at 25 clinical sites in the US with confirmed PE symptoms for ≤ 14 days and a right ventricle to left ventricle ratio (RV/LV ratio) of ≥ 0.9 on Computed Tomography Angiography (CTA). The primary safety endpoint was the rate of major adverse events (MAEs) within 48 hours after the index procedure. MAEs were defined to include device-related death, major bleeding, and device-related serious adverse events (SAEs) of clinical deterioration, pulmonary vascular injury, and cardiac injury. The primary effectiveness endpoint was the reduction in RV/LV ratio from baseline to 48 hours. Both the primary safety and effectiveness endpoints were met. Refer to the Instructions for Use for detailed clinical study information.

M. 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.