September 30, 2021

AngioDynamics, Inc.
Kasey Newcomb
Specialist II, Global Regulatory Affairs
603 Queensbury Ave
Queensbury, New York 12804

Re: K212386
Trade/Device Name: AngioVac F18 85
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: July 30, 2021
Received: August 2, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Nicole Gillette
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212386

Device Name
AngioVac F18 85

Indications for Use *(Describe)*

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.

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 ANGIOVAC F18^{85}

A. SPONSOR

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

B. CONTACT

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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 § 878.4210, Class II, Pro-Code DWF)
Classification Panel:	Cardiovascular

D. PREDICATE DEVICE

510(k):	K190594
Trade Name:	AngioVac Canula C20 and C180
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. DEVICE DESCRIPTION

The AngioVacF18^{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 filter 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.

F. 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.

G. STERILIZATION/SHELF LIFE

The AngioVac F18[85] is sterilized via ethylene oxide (EtO). 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 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.

H. BIOCOMPATIBILITY

The AngioVac F18[85] is a sterile single-use disposable instrument. AngioVac F18[85] 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.

G. TECHNOLOGY CHARACTERISTICS

Predicate device, AnigoVac Cannula C20 and C180, 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:

- Designed for use as a venous drainage cannula and for removal of 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:

- Addition of 18F Cannula and 22F Sheath
- Addition of 85° angled configuration.
- Addition of hemostatic valve on the proximal end of sheath

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

H. 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 below:

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

Additionally, the AngioVac F18[85] 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.

I. 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.