March 28, 2024

Argon Medical Devices, Inc.
Ana Jimenez-Hughes
Sr. Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K233909
Trade/Device Name: Cleaner™ Plus 18F Thrombectomy System - Cleaner™ Plus 18F Aspiration Catheter, Cleaner™ Plus 18F Handpiece with Maceration Wire, Cleaner™ Plus 18F Aspiration Canister
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: February 13, 2024
Received: February 13, 2024

Dear Ana Jimenez-Hughes:

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.03.28 09:16:25 -04'00'

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)*
K233909

Device Name
Cleaner™ Plus 18F Thrombectomy System - Cleaner™ Plus 18F Aspiration Catheter, Cleaner™ Plus 18F Handpiece with Maceration Wire, Cleaner™ Plus 18F Aspiration Canister

Indications for Use *(Describe)*
The Cleaner™ Plus 18F Thrombectomy System is indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature.

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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Date Prepared:	March 26, 2024
Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
Contact:	Ana Jimenez-Hughes Sr. Regulatory Affairs Specialist Phone: 903-676-4276 Fax: 903-677-9396 Email: ana.hughes@argonmedical.com
Device Trade Name:	Cleaner™ Plus 18F Thrombectomy System - Cleaner™ Plus 18F Aspiration Catheter, Cleaner™ Plus 18F Handpiece with Maceration Wire, Cleaner™ Plus 18F Aspiration Canister
Device Common Name:	Mechanical Thrombectomy Device
Device Classification Name:	Embolectomy Catheter Catheter, Continuous Flush Class II Product code QEW/KRA 21 CFR 870.5150 Review Panel: Cardiovascular Devices
Predicate Device(s):	*Primary*: K211798 Cleaner Plus™ Thrombectomy System
Description of the Device:	The Cleaner Plus™ 18F Thrombectomy System is a single use device used to provide thrombectomy in the peripheral venous vasculature. The device provides additional features, such as aspiration and over-the-wire device placement. The disposable system consists of: (1) the Aspiration Catheter & Dilator, (2) the Handpiece that includes an aspiration control and an integrated Maceration Wire, and a Peel-Away Introducer and (3) the external vacuum reservoir with pump known as the Aspiration Canister. The system is inserted percutaneously into the vessel using an introduction catheter, the system Aspiration Catheter and Dilator may be placed over-the-wire to the site of thrombus. The device macerates intra-lumen and wall adherent thrombus with a maceration wire. The macerated thrombus is removed from the vessel using an aspiration system. The aspiration of the clot can be performed simultaneous or independently. Additionally, the device may be used for infusion of thrombolytics and/or contrast media. Once thrombus resolution is achieved, the device is removed from the patient and discarded.
Technological Characteristics:	A comparison of the technological characteristics of the subject device and the predicate devices shows the Cleaner Plus 18F Thrombectomy System to be substantially equivalent to the current marketed predicate device.

Equivalence is established on in vitro performance testing, and similarities in indications for use, materials, technological characteristics, principle of operation, design features and sterilization process.

	Subject Device	Predicate Device
	Cleaner™ Plus 18F Thrombectomy System	**Cleaner Plus™ Thrombectomy System**
Manufacturer	Argon Medical Devices, Inc.	Argon Medical Devices, Inc
FDA Clearance	TBD	K211798
Class	II	II
Device Classification Name	Peripheral Mechanical Thrombectomy with Aspiration; Catheter, Continuous Flush	Peripheral Mechanical Thrombectomy with Aspiration; Catheter, Continuous Flush
Regulation Description	Embolectomy Catheter; Catheter, Continuous Flush	Embolectomy Catheter; Catheter, Continuous Flush
Regulation	21 CFR 870.5150	21 CFR 870.5150
Product Code	QEW/KRA	QEW/KRA
Intended Use	Thrombus removal	Thrombus removal
Principle of Operation	Inserted percutaneously into the vessel using an introduction catheter, the system Aspiration Catheter and Dilator may be placed over-the-wire to the site of thrombus. The device macerates intra-lumen and wall adherent thrombus with a maceration wire. The macerated thrombus is removed from the vessel using an aspiration system. The aspiration of the clot can be performed simultaneous or independently. The device allows for infusion of physician-specified fluids, including thrombolytics, during the procedure. The infused solution penetrates the clot increasing the effectiveness of the treatment	SAME
Mechanism of Action	Mechanical maceration and aspiration of thrombus	SAME
Indication for Use	Indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature	SAME
Contraindication	The Cleaner Plus 18F Thrombectomy System is contraindicated in the following: • For infusion of blood or blood products. • In native vessels smaller than 6mm in diameter	The Cleaner Plus™ Thrombectomy System is contraindicated in the following: • When, in the medical judgment of the physician, such a procedure may compromise the patient's condition. • For infusion of blood or blood products. • In native vessels smaller than 6mm in diameter.
Single Use	Yes	SAME
Supplied Sterile	Yes	SAME

	Subject Device	Predicate Device
	Cleaner™ Plus 18F Thrombectomy System	**Cleaner Plus™ Thrombectomy System**
Device Description	The Cleaner Plus™ 18F Thrombectomy System consists of: • Cleaner Plus™ Aspiration Catheter with Dilator. • Cleaner Plus™ Handpiece that includes system controls, and an integrated Maceration Wire. • Cleaner Plus™ Aspiration Canister. The system also includes a peel-away introducer.	SAME
Technical and Biological Comparison		
Dispersion Wire (rpm)	4000rpm	4000rpm
Aspiration Catheter Diameter	18F	12F
Aspiration Catheter Length	115cm	65cm & 135cm
Maceration Wire (amplitude)	15mm (uncovered)	15mm (uncovered)
Maceration Wire Diameter	0.035”	0.035”
Maceration Wire Material	Stainless Steel, Pebax/BaSO4 and Virgin PTFE	Stainless Steel, Pebax/BaSO4 and Virgin PTFE
Reservoir size	400cc	400cc
Maximum vacuum	28 inHg	28 inHg
IEC 60601 Compliance	Yes	SAME

Performance Testing (In-Vitro)	• Cleaner Plus 18F Thrombectomy System Performance
	  ▪ Visual
	  ▪ Dimensional
	  ▪ Simulated Use
	  ▪ Leak Testing
	  ▪ Handpiece Performance
	  ▪ Aspiration and Maceration Performance
	  ▪ Tensile and Torque
	  ▪ Kink Testing
	  ▪ Catheter Torque
	  ▪ Canister Performance
	  ▪ Simulated Use Maceration and Aspiration Performance
	• Maceration Wire Performance
	  ▪ Bond Strength
	  ▪ Resistance to Corrosion
	  ▪ Shape Retention
	  ▪ Flexing and Fracture
	  ▪ Kink Radius
	  ▪ Fatigue
	  ▪ Endurance
	  ▪ Torque
	  ▪ Tensile
	  ▪ Dimensional
	  ▪ Visual
	• Handpiece and Catheter Performance
	  ▪ Peel-Away Introducer Removal Force
	  ▪ Maceration Wire RPM
	  ▪ Wire to Coupler Tensile
	  ▪ Peel-Away Introducer Functionality
	  ▪ Tip Collapse
	• Particulates
	• Canister Performance
	  ▪ Visual
	  ▪ Functional
	  ▪ Tensile (joint strength)
		• Wire – Atraumatic Tip Pull
		• Wire – Corrosion Resistance
		• Wire – Fatigue
		• Wire – Dynamic Retention
		• Wire – Flexing and Fracture
		• Wire – Kink
		• Wire – Tensile Break
		• Wire – Dimensional
		• Catheter – Dimensional
		• Catheter – Aspiration Tip Collapse
		• Catheter – Kink
		• Catheter – Hemostasis Valve Leak
		• Catheter – Torsional Break
		• Catheter – System Leak
		• Catheter – Tensile Break
		• Shipping Qualification
		• Luer Functional
		• Catheter – Coating Performance and Integrity
		• IEC 60601 Compliance
		• Canister & Dead Volume Study
		• Pump Functionality - Relief Valve
		• Pump Tubing – Pull
		• Pump Performance
		• Pump – Button Press Endurance
		• Simulated Use
		• Handpiece Dimensional
		• Handpiece Motor & Battery Performance
		• Pump Battery Performance
		• Handpiece – Functionality
		• Handpiece – Peel-away Introducer
		• Luer Dimensional
		• Radiopacity
		• Functional, Performance, and Software Testing
		• Float Valve Study
		• Wire – Torque Strength
		• Particulates

	Subject Device	Predicate Device
	Cleaner™ Plus 18F Thrombectomy System	**Cleaner Plus™ Thrombectomy System**
	• Luer Compliance • Pump Performance • IEC Compliance • Software Testing • Shipping Qualification	
Non-Clinical, Animal Study	Yes	Yes

Biological Comparison	Biocompatibility testing was leveraged from predicate device and a comparator device.	• Cytotoxicity (ISO 10993-5)
		• Sensitization (ISO 10993-10)
		• Irritation or Intracutaneous Reactivity (ISO 10993-10)
		• Material Mediated Pyrogen (ISO 10993-11)
		• Acute Systemic Toxicity (ISO 10993-11
		• Hemocompatibility (ISO10993-4)
		  ○ In-vitro Blood Assay
		  ○ Complement Activation, SC5b-9
		  ○ Heparinized Platelet and Leucocyte Counts
		  ○ Partial Thromboplastin Time (PTT)
		  ○ ASTM Hemolysis Assay, Direct and Extract Methods (ISO)

Packaging Configuration	1) Aspiration Catheter and Dilator are sealed in a Tyvek pouch. Pouch placed in a shelf carton. 2) Handpiece with Maceration Wire is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 3) Aspiration Canister is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 4) All the individual system components are placed in a single labeled shipper box. Packaging materials are commonly used for medical devices.	1) Aspiration Catheter and Dilator are sealed in a Tyvek pouch. Pouch placed in a shelf carton. 2) Handpiece with Maceration Wire is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 3) Aspiration Canister is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 4) All the individual system components are placed in a single labeled shipper box. Packaging materials are commonly used for medical devices.
Sterilization	Minimum SAL 10-6, EtO	SAME
Shelf-Life	6 months	SAME

Non-Clinical Data (Bench-top Testing):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices.

A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the Cleaner Plus 18F Thrombectomy System substantial equivalence:

- Cleaner Plus 18F Thrombectomy System Performance
  - Visual
  - Dimensional

  - Simulated Use
  - Leak Testing
  - Handpiece Performance
  - Aspiration and Maceration Performance
  - Tensile and Torque
  - Kink Testing
  - Catheter Torque
  - Canister Performance
  - Simulated Use Maceration and Aspiration Performance
- Maceration Wire Performance
  - Bond Strength
  - Resistance to Corrosion
  - Shape Retention
  - Flexing and Fracture
  - Kink Radius
  - Fatigue
  - Endurance
  - Torque
  - Tensile
  - Dimensional
  - Visual
- Handpiece and Catheter Performance
  - Peel-Away Introducer Removal Force
  - Maceration Wire RPM
  - Wire to Coupler Tensile
  - Peel-Away Introducer Functionality
  - Tip Collapse
- Particulates
- Canister Performance
  - Visual
  - Functional
  - Tensile (joint strength)
- Luer Compliance
- Pump Performance
- IEC Compliance
- Software Testing
- Shipping Qualification

Non-Clinical Data Biocompatibility

Biocompatibility is established for the Cleaner Plus 18F Thrombectomy System according to ISO 10993-1:2020 as an external communicating, circulating blood with limited duration <24hrs.

A Biological Risk Assessment was performed for the Cleaner Plus 18F Thrombectomy System, based on which biocompatibility testing was appropriately leveraged from the predicate device (K211798) and a comparator device, the Cleaner Pro Thrombectomy System (K232679).

Leveraged biocompatibility studies were performed following the approved protocol under Good Laboratory Practices (GLP) in compliance to FDA GLP, 21 CFR Part 58 were leveraged from the predicate device.

Non-Clinical - Animal Study

Two separate animal studies were performed to assess substantially equivalent safety and performance outcomes of the Cleaner™ Plus Thrombectomy System.

	First animal study was performed to assess substantially equivalent safety and performance outcomes of the Cleaner Thrombectomy System on vascular endothelium by evaluating for vessel patency, clot burden, and clinically significant pulmonary embolism after thrombectomy in the peripheral vasculature. There were no histological signs of thromboembolism noted in the treated vessels, there were no ruptures, hemorrhage, perforation, or dissection noted histologically in the treated veins. All the end points of this study were met and there are no new questions of safety or effectiveness. Second animal study was performed to assess substantially equivalent safety and performance of the aspiration aspect of the Cleaner Thrombectomy System by evaluating for vessel injury, patency and gross thrombogenicity. There were no histological signs of thromboembolism noted in the treated vessels, there were no ruptures, hemorrhage, perforation, or dissection noted histologically in the treated veins. All the end points of this study were met.
Substantial Equivalence:	Based on the Indication for Use, design, in vivo animal safety and in vitro performance testing, the Cleaner Plus 18F Thrombectomy System meets the requirements for its intended use and is substantially equivalent to the predicate device.
Conclusion:	The Cleaner Plus 18F Thrombectomy System introduces no additional clinical risk, based on its comparable indications for use and mechanism of action. Based on performance testing *in-vitro* and *in-vivo*, indications for use, materials, technological characteristics, principle of operation, design features and sterilization process; the Cleaner Plus 18F Thrombectomy System is substantially equivalent to the predicate device.