January 19, 2024

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

Re: K232679
Trade/Device Name: Cleaner™ Pro Thrombectomy System; Cleaner™ Pro Aspiration Catheter with Handpiece; Cleaner™ Pro Aspiration Canister
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: August 30, 2023
Received: September 1, 2023

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: 2024.01.19 13:52:30 -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)*
K232679

Device Name
Cleaner™ Pro Thrombectomy System
Cleaner™ Pro Aspiration Catheter with Handpiece
Cleaner™ Pro Aspiration Canister

Indications for Use *(Describe)*
The Cleaner™ Pro Thrombectomy System is indicated for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature, and for the infusion of physician-specified fluids, including thrombolytics.
The Cleaner™ Pro Thrombectomy System is not intended for use in the pulmonary vasculature for treating of pulmonary embolism.

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.

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510(k) Summary - K232679

Date Prepared:	January 19, 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™ Pro Thrombectomy System Cleaner™ Pro Aspiration Catheter with Handpiece Cleaner™ Pro Aspiration Canister
Device Common Name:	Mechanical Thrombectomy Device
Device Classification:	Embolectomy Catheter Continuous Flush Catheter Product code, QEW/KRA 21 CFR 870.5150 Class II Review Panel: Cardiovascular Devices
Predicate Device:	*Predicate Device*: K222358 Indigo® Aspiration System – Lighting® Flash *Reference Device*: K223176 Cleaner Plus™ Thrombectomy System
Description of the Device:	The Cleaner Pro Thrombectomy System is a single use device in the removal of fresh, soft emboli and thrombi and for the infusion of physician-selected fluids through the side-port of the aspiration catheter. The disposable system consists of: (1) the Aspiration Catheter with Dilator, (2) the Handpiece with Flushing Adapter, and (3) the external vacuum reservoir with pump known as the Aspiration Canister. The Aspiration Catheter with Dilator may be placed over-the-wire to navigate the device to the target site. Once in the target site, to complete the system, the Aspiration Canister is connected to the handpiece. The dilator is removed, and the device is activated by the user to aspirate soft emboli and thrombi. The clot is aspirated from the distal portion of the device through the handpiece and then collected in the aspiration canister reservoir. 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.
Indication for Use:	The Cleaner™ Pro Thrombectomy System is indicated for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature, and for the infusion of physician-specified fluids, including thrombolytics. The Cleaner™ Pro Thrombectomy System is not intended for use in the pulmonary vasculature for treating of pulmonary embolism.

Technological Characteristics:

A comparison of the technological characteristics of the subject device and the predicate devices shows the Cleaner Pro Thrombectomy System to be substantially equivalent to the current marketed predicate devices.

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

	Subject Device	**Predicate Device**	**Reference Device**
	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister	**Indigo® Aspiration System – Lighting® Flash**	**Cleaner Plus™ Thrombectomy System**
Manufacturer	Argon Medical Devices, Inc	Penumbra, Inc.	Argon Medical Devices
FDA Clearance	K232679	K222358	K223176
Class	II	SAME	SAME
Device Classification Name	Embolectomy Catheter Continuous Flush Catheter	Embolectomy Catheter	Embolectomy Catheter Continuous Flush Catheter
Regulation	21 §CFR 870.5150	21 §CFR 870.5150	21 §CFR 870.5150
Product Code	QEW KRA	QEW	QEW KRA
Clinical Comparison			
Indication for Use	Indicated for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature, and for the infusion of physician-specified fluids, including thrombolytics. The Cleaner Pro Thrombectomy System is not intended for use in the pulmonary vasculature for treating of pulmonary embolism.	INDIGO Aspiration Catheters and Separators: As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism. INDIGO Aspiration Tubing: As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump: The Penumbra Aspiration Pump is indicated as a vacuum source for the Penumbra Aspiration Systems.	Indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral venous vasculature.
Principle of Operation	The device is advanced over a guidewire to the target site. The access point may be the common femoral vein, internal jugular vein, or popliteal vein in select patients. The target site may be the peripheral venous vasculature. Once in the target site, the device is activated by the user, to remove fresh, soft thrombi and emboli. The user may maintain guidewire access throughout the procedure. Additionally, the device may be used for infusion of physician-	The INDIGO Aspiration Catheter targets aspiration from the pump directly to the thrombus. The INDIGO Aspiration Catheter is introduced through a guide catheter or vascular sheath into the peripheral vasculature and guided over a guidewire to the site of the primary occlusion. The INDIGO Aspiration Catheter is used with the Penumbra Aspiration Pump to aspirate thrombus from an occluded vessel. As needed, an INDIGO Separator may be deployed from the INDIGO Aspiration Catheter to	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

	Subject Device	Predicate Device	Reference Device
	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister	**Indigo® Aspiration System – Lighting® Flash**	**Cleaner Plus™ Thrombectomy System**
	specified fluids, including thrombolytics and/or contrast media. Once thrombus resolution is achieved, the device is removed from the patient and discarded.	assist with thrombus removal. The INDIGO Separator is advanced and retracted through the INDIGO Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the INDIGO Aspiration Catheter tip.	physician-specified fluids, including thrombolytics, during the procedure. The infused solution penetrates the clot increasing the effectiveness of the treatment
Contraindication	Not intended for use in the coronaries and neurovasculature	There are no known contraindications	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	SAME
Supplied Sterile	Yes	SAME	SAME
Device Description	The Cleaner Pro Thrombectomy System consists of: • An Aspiration Catheter/Dilator with Handpiece and Flushing Adapter • An external vacuum reservoir with pump known as the Aspiration Canister	The INDIGO® Aspiration System is comprised of the several devices: • INDIGO Aspiration Catheter • Penumbra Aspiration Pump • INDIGO Aspiration Pump Canister • INDIGO Aspiration Tubing • INDIGO Separator	The Cleaner Plus System consists of: • Cleaner Plus Aspiration Catheter with Dilator. • Cleaner Plus Handpiece with integrated Maceration Wire. • Cleaner Plus Aspiration Canister. • The system also includes a peel-away introducer.
Technical and Biological Comparison			
Aspiration Catheter Diameter	18F OD	16F sheath compatibility	12.7F
Aspiration Catheter Length	115cm	80cm, 100cm, & 115cm	65 & 135cm
Aspiration Catheter Materials	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices
Reservoir size	400cc	1000cc	SAME
Maximum vacuum	28 inHg	29 in Hg	SAME
IEC 60601-1-2 IEC 60601-1 Compliance	Yes	SAME	SAME

	Subject Device	Predicate Device	Reference Device
	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister	**Indigo® Aspiration System – Lighting® Flash**	**Cleaner Plus™ Thrombectomy System**
Performance Testing (In-Vitro)	• Catheter – Dimensional • Catheter – Visual • Catheter – Radiopacity • Catheter - Hemostasis Valve Leak • Catheter – System Leak Test • Catheter – Burst Test • Catheter – Kink Radius • Catheter – Tensile Break • Catheter – Torsional Break • Catheter – Aspiration Tip Collapse • Dilator – Dimensional • Dilator – Leak Test • Dilator Burst Test • Dilator – Functional • Dilator – Visual • Dilator – Tensile Break • Dilator – Radiopacity • Aspiration Canister – Visual • Aspiration Canister – Functional • Aspiration Canister Tubing – Tensile Break • Aspiration Canister – Weld Strength • Handpiece – Functional • Handpiece – Simulate Use • System – Functional • System Vacuum Decay • System – Noise Level • System Integrity • System – Visual • System – Simulated Use • Shipping Qualification • IEC-60601 Compliance • Software Validation	• <u>Lightning Flash Aspiration Tubing</u> • Dimensional/Visual Inspection • Performance/Simulated Use Testing • Tensile Testing • Indigo Aspiration System Compatibility • Valve Sense Testing • <u>Flash Aspiration Catheter and Select Catheter</u> • Dimensional/Visual Inspection • Friction Testing • Performance/Simulated Use and Torsion Testing • Vacuum Test • Coating Integrity Testing • Particulate Testing • Hub Air Aspiration • Catheter Pressure • Hub / Shaft Tensile Strength • Catheter Shaft Tensile o Elongation to Failure • Corrosion	• 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
Non-Clinical, Animal Study	Yes	Previously performed animal testing	Yes

	Subject Device	Predicate Device	Reference Device
	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister	**Indigo® Aspiration System – Lighting® Flash**	**Cleaner Plus™ Thrombectomy System**

Biological Comparison	• 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)
		• 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)
		  ○ C3a Complement Assay
		  ○ Complement Activation, SC5b-9
		  ○ ASTM Partial Thromboplastin Time (PTT)
		  ○ ASTM Hemolysis
		• Genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3).
			• 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/Dilator with Handpiece and Flushing Adapter on a backer card sealed in a Tyvek pouch. Pouch placed in a shelf carton. 2) Aspiration Canister is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 3) All the individual system components are placed in a single labeled shipper box. Packaging materials are commonly used for medical devices.	Individually packed components. Packaging materials are commonly used for interventional 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	SAL 10^{-6}, EtO	SAME	SAME
Shelf-Life	6 months Target 36 months	36 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 Pro Thrombectomy System substantial equivalence:

- Catheter – Dimensional
- Catheter – Visual
- Catheter – Radiopacity
- Catheter - Hemostasis Valve Leak
- Catheter – System Leak Test
- Catheter – Burst Test
- Catheter – Kink Radius
- Catheter – Tensile Break
- Catheter – Torsional Break
- Catheter – Aspiration Tip Collapse
- Dilator – Dimensional
- Dilator – Leak Test
- Dilator Burst Test
- Dilator – Functional
- Dilator – Visual
- Dilator – Tensile Break
- Dilator – Radiopacity
- Aspiration Canister – Visual
- Aspiration Canister – Functional
- Aspiration Canister Tubing – Tensile Break
- Aspiration Canister – Weld Strength
- Handpiece – Functional
- Handpiece – Simulate Use
- System – Functional
- System Vacuum Decay
- System – Noise Level
- System Integrity
- System – Visual
- System – Simulated Use
- Shipping Qualification
- IEC-60601 Compliance
- Software Validation

Non-Clinical Data Biocompatibility

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

All studies were performed following the approved protocol under Good Laboratory Practices (GLP) in compliance to FDA GLP, 21 CFR Part 58.

Biocompatibility Testing included:

- 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)

Non-Clinical - Animal Study

An animal study was performed to assess substantially equivalent safety and performance outcomes of the Cleaner Pro Thrombectomy System when used in the target vasculature 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, and safety and performance testing, the Cleaner Pro Thrombectomy System meets the requirements for its intended use and is substantially equivalent to the predicate devices.

Conclusion:	The Cleaner Pro Rotational Thrombectomy System introduces no additional clinical risk, based on its comparable indication for use and mechanism of action. Based on performance testing in vitro and in vivo, and similarities in indications for use, materials, technological characteristics, principle of operation, design features and sterilization process; the Cleaner Pro Thrombectomy System is substantially equivalent to the predicate devices.