April 10, 2023

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

Re: K223176
Trade/Device Name: Cleaner Plus™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: October 10, 2022
Received: October 11, 2022

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 (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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2023.04.10 12:42:19 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223176

Device Name
Cleaner Plus™ Thrombectomy System

Indications for Use *(Describe)*

The Cleaner Plus™ 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.

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510(k) Summary – K223176

Date Prepared: April 5, 2023

Company: Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, Texas 75751 USA
Facility Registration number: 1625425

Contact: Ana Jimenez-Hughes
Senior Regulatory Affairs Specialist
Phone: 903-676-4276
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Email: ana.hughes@argonmedical.com

Device Trade Name: Cleaner Plus™ Thrombectomy System

Device Common Name: Mechanical Thrombectomy Device

Device Classification: Embolectomy Catheter
Product code, QEW/KRA
21 CFR 870.5150
Class II
Review Panel: Cardiovascular Devices

Predicate Device(s): *Primary*: K211798 Cleaner Plus™ Thrombectomy System

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Description of the Device: The Cleaner Plus™ 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 system controls, and an integrated Maceration Wire, and a Peel-Away Introducer and (3) the Aspiration Canister.

The Aspiration Catheter with Dilator may be placed over-the-wire to navigate the device to the therapeutic site. The dilator and guidewire are removed, and the Maceration Wire, using the Peel-Away introducer is advanced through the hemostasis valve of the Aspiration Catheter to the therapeutic site and connected to the

	handpiece. To complete the system, the provided Aspiration Canister is connected to the handpiece to provide aspiration. The Handpiece provides controls to turn on/off maceration and/or the application of suction. Mechanical thrombectomy is achieved by rotating a flexible stainless-steel maceration wire powered by a motor inside the handpiece. The aspiration source is provided to aspirate macerated clot from the distal portion of the device through the handpiece and captures the macerated clot in the Aspiration Canister reservoir. The Aspiration Canister includes a switch to initiate the pump, and LEDs that indicate the level of the vacuum.
Indication for Use:	The Cleaner Plus™ 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.
Device Modification:	The device modification included in this submission is limited to the addition of a new helical component designed to assist the aspirate's movement through the Cleaner Plus™ Handpiece.

Substantial Equivalence:	There is no change of intended use or fundamental scientific technology between the proposed modified and predicate device. The proposed modified device has the same indication for use as the predicate, K211798.
	
	<u>Non-Clinical Testing</u>
	In accordance with the Design Failure Modes and Effects Analysis, supplemental verification testing was identified to support the substantial equivalence of the modified Cleaner Plus™ Thrombectomy System. The tests included:
	
	• Corrosion Resistance
	• Tensile Break
	• Simulated Use:
	  ○ Handpiece performance with Helical component
	  ○ Aspiration Performance
	• Torque Strength (Helical Component to Wire)
	• Wire Fatigue
	• Particulates
	
	Biocompatibility:
	• Cytotoxicity – MEM Elution
	• Sensitization – Guinea Pig Maximization
	• Irritation - Intracutaneous Reactivity
	• Sistemic Toxicity – Material Mediated Pyrogen
	• Systemic Toxicity – Acute Systemic Toxicity
	• Hemocompatibility – Hemolysis Indirect

	Animal testing was not required for the determination of substantial equivalence. Clinical testing was not required for the determination of substantial equivalence. Test results demonstrate that all acceptance criteria were met; therefore, the device meets the established product specifications.
Conclusion:	The proposed device modifications to the Cleaner Plus™ Thrombectomy System do not change its intended use or principles of operation. Based on the Indication for Use, design, and performance testing, the Cleaner Plus™ Thrombectomy System meets the requirements for its intended use and is substantially equivalent to the predicate device.