February 5, 2026

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

Re: K260028
Trade/Device Name: CLEANER™ Vac Thrombectomy System, CLEANER™ Vac Aspiration Catheter with Handpiece, CLEANER™ Vac Aspiration Canister
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 5, 2026
Received: January 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

For GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.02.05 06:59:44 -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)*
K260028

Device Name
CLEANER™ Vac Thrombectomy System
CLEANER™ Vac Aspiration Catheter with Handpiece
CLEANER™ Vac Aspiration Canister

Indications for Use *(Describe)*
The CLEANER™ Vac 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™ Vac Thrombectomy System is not intended for use in the pulmonary vasculature for treating pulmonary embolism.

The CLEANER™ Vac Aspiration Canister is indicated as a vacuum source for the CLEANER™ Vac Thrombectomy 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date Prepared:	February 03, 2026

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 Fax: 903-677-9396 Email: ana.hughes@argonmedical.com

Device Trade Name:	CLEANER™ Vac Thrombectomy System CLEANER™ Vac Aspiration Catheter with Handpiece CLEANER™ Vac 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(s):	Primary – K232679, Cleaner Pro™ Thrombectomy System, Cleaner Pro™ Aspiration Canister, Cleaner Pro™ Aspiration Canister with Handpiece.

Description of the Device:

The CLEANER™ Vac Thrombectomy System is a single use device intended for 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:

- The CLEANER™ Vac Aspiration Catheter with Handpiece, and
- The CLEANER™ Vac Aspiration Canister (external vacuum reservoir with pump).

The Aspiration Catheter with handpiece includes a Dilator and 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™ Vac 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 Vac™ Thrombectomy System is not intended for use in the pulmonary vasculature for treating pulmonary embolism.

The CLEANER™ Vac Aspiration Canister is indicated as a vacuum source for the CLEANER™ Vac Thrombectomy System.

Device Modification:

The subject of this Special 510(k) is to incorporate a change to the CLEANER™ Vac Thrombectomy System (previously named, Cleaner™ Pro Thrombectomy System, 510(k) K232679).

Argon Medical Devices has identified the need of distributing the CLEANER™ Vac Aspiration Canister as part of the system and as a unit; therefore, Argon is incorporating a change to the shipping/distribution configuration of the CLEANER Vac™ Aspiration Canister and the addition of an indication for use for this component of the system. No changes to design, principle of operation or intended use are being implemented.

Substantial Equivalence:

There is no change of intended use or fundamental scientific technology between the proposed modified and predicate device K232679.

Argon conducted a design change process to evaluate the impact of proposed change. The proposed change was evaluated through the Argon risk management process which is compliant with ISO 14971:2019.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification testing was identified to support the substantial equivalence of the modified CLEANER Vac™ Thrombectomy System. The tests included:

- Shipping Qualification (including packaging integrity, simulated use and product integrity) for the CLEANER™ Vac Aspiration Canister.

The testing from K232679 listed below remains applicable for the CLEANER™ Vac Thrombectomy System and components. 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 (system)
- IEC-60601 Compliance
- Software Validation

The proposed change does not change the biocompatibility profile of the device; therefore, Biocompatibility testing was not required for the determination of substantial equivalence and the testing provided in K232679 is still applicable.

- 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)

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 modification to the CLEANER™ Vac Thrombectomy System does not change the intended use or principles of operation as the functionality and intended use (vacuum source) of the aspiration canister remains unchanged. Based on the indication for use, design, and performance testing, the CLEANER™ Vac Thrombectomy System meets the requirements for its intended use and is substantially equivalent to the predicate device.