January 20, 2026

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

Re: K251318
Trade/Device Name: VariFuse Adjustable Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 28, 2025
Received: April 29, 2025

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.

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.01.20 23:09:52 -05'00'

for Lydia Glaw
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)*
K251318

Device Name
Varifuse Adjustable Infusion Catheter

Indications for Use *(Describe)*
The VariFuse Adjustable Infusion Catheter is indicated for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery 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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ARGON MEDICAL DEVICES

510(k) Summary
VariFuse™ Adjustable Infusion Catheter

Date Prepared: April 28, 2025

General Provisions	Submitter Name: Address: Facility Registration Number: Contact Name: Telephone Number: Email:	Argon Medical Devices, Inc 1445 Flat Creek Road Athens, Texas 75751 USA 1625425 Ana Jimenez-Hughes Sr. Regulatory Affairs Specialist (903) 676-4276 ana.hughes@argonmedical.com
Subject Device	Trade Name: Common/Usual Name: Classification Name: Device Classification: Product Code: Regulation: Review Panel:	VariFuse™ Adjustable Infusion Catheter Infusion Catheter Continuous Flush Catheter 2 KRA 21 CFR 870.1210 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	UNI*FUSE + ™ Infusion System with Cooper Wire Continuous Flush Catheter K202347 Angio Dynamics, Inc
Reference Device	Micro Therapeutics, Inc. DBA EV3 (Medtronic, Inc.) Cragg-McNamara™ Valved Infusion Catheter, K964868	

Device Description

The VariFuse™ Adjustable disposable Infusion Catheter System consists of:

- An adjustable infusion catheter is comprised of the outer and inner catheters pre-assembled coaxially and inseparable, set at the maximum infusion length (i.e. 50 cm) with a Touhy Borst Adapter for shipping.
  - The inner infusion catheter is designed with infusion holes spaced unevenly along the infusion length of 50 cm, a valve at the distal tip, and a radiopaque marker at the distal tip.
  - The outer infusion catheter is designed to set the infusion length by covering the infusion holes and contains a radiopaque marker at the distal tip.
- A 1cc Luer Lock Syringe is included in the packaging for flushing

Indications for Use

The VariFuse™ Adjustable Infusion Catheter is indicated for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature

Comparison to Predicate Device

A comparison of the technological characteristics of the subject device and the predicate device shows the VariFuse™ Adjustable Infusion Catheter 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.

The comparison between the subject and the predicate devices is based on the following:

- Same intended use
- Same indications for use
- Equivalent principle of operation

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510(k) Summary
VariFuse™ Adjustable Infusion Catheter

- Equivalent design
- Materials commonly used for medical devices that meet ISO 10993-1:2020.
- Same sterilization Method

Table 1. Equivalency Table

	Subject Device	**Predicate Device**	**Comparison to Predicate**	**Reference Predicate**	**Comparison to Reference Device**
	VariFuse™ Adjustable Infusion Catheter	**UNI*FUSE + ™ Infusion System with Cooper Wire**		**Cragg-McNamara™ Valved Infusion Catheter**	
Manufacturer	Argon Medical Devices, Inc.	Angio Dynamics, Inc.	N/A	Micro Therapeutics, Inc. DBA EV3 (Medtronic, Inc.)	N/A
FDA Clearance	K251318	K202347, K192864	N/A	K964868	N/A
Class	II	II	Identical	II	Identical
Device Classification Name	Continuous Flush Catheter	Continuous Flush Catheter	Identical	Continuous Flush Catheter	Identical
Regulation	21 CFR 870.1210	21 CFR 870.1210	Identical	21 CFR 870.1210	Identical
Product Code	KRA	KRA	Identical	KRA	Identical
Intended Use	Infusion of fluids into the vasculature	Infusion of fluids into the vasculature	Identical	Infusion of fluids into the vasculature	Identical
Comparison of Clinical Characteristics					
Principle of Operation	The inner and outer catheter are inserted together over the wire using fluoroscopic guidance. The catheter is advanced through the thrombus until the tip of the inner catheter is placed at one end of the therapeutic area. The outer catheter is then adjusted by loosening the Touhy Borst adapter and pulling the outer catheter back until the tip is at the other end of the therapeutic area and then set by tightening the Touhy Borst adapter. The fluid is then infused into the inner catheter, manually and/or automatically (via an infusion pump). Infusion holes on the inner catheter allow for circumferential distribution of fluids.	An occluding wire is inserted to provide the proper force to activate pressure response outlets. The device is inserted over the wire. The catheter is directed to the thrombus in the vasculature. The guidewire is removed, and the occluding ball wire is introduced through the catheter and locked into place. The thrombolytic is infused using a syringe. When the thrombolytic agent reaches target pressure in the catheter, the pressure response outlets activate simultaneously, and the thrombolytic agent is distributed evenly into the undesirable material.	Substantially Equivalent	The single lumen catheter is inserted over the wire int the vasculature. One positioned in the thrombus area; various pharmacologic agents may be delivered through a standard luer lock adapter at the proximal end. The infusion area is indicated by distal and proximal radiopaque markers.	Substantially Equivalent
Indication for Use	The VariFuse™ Adjustable Infusion Catheter is indicated for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature.	The UNI*FUSE+™ Infusion System with Cooper Wire is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature.	Identical	The 2.9F Cragg-McNamara Valved Infusion Catheter is intended to be used for the controlled selective infusion of physician specified pharmacological agents and radiopaque contrast media into the general vasculature. It is not intended for coronary, neurological, pediatric or neonatal use.	Substantially Equivalent
Contraindication	The İnfusion catheter is contraindicated for the following: • For use in the coronary and neuro vasculature.	The infusion catheter is contraindicated for the following: • For use in the coronary vasculature	Substantially equivalent	Not intended for coronary, neurological, pediatric or neonatal use	Substantially equivalent

ARGON MEDICAL DEVICES

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VariFuse™ Adjustable Infusion Catheter

	• For use with pediatric or neonatal use. • For infusion of blood or blood products	• For infusion of blood or blood products			
Single Use	Yes	Yes	Identical	Yes	Identical
Supplied Sterile	Yes	Yes	Identical	Yes	Identical
Comparison of Technological Characteristics					
Device Description	The VariFuse™ Adjustable Infusion Catheter is composed of: • An adjustable infusion catheter is comprised of the outer and inner catheters pre-assembled coaxially and inseparable, set at the maximum infusion length (i.e. 50 cm) with a Touhy Borst Adapter for shipping. ▪ The inner infusion catheter is designed with infusion holes spaced unevenly along the infusion length of 50 cm, a valve at the distal tip, and a radiopaque marker at the distal tip. ▪ The outer infusion catheter designed to set the infusion length by covering the infusion holes and contains a radiopaque marker at the distal tip. • A 1cc Luer Lock Syringe is included in the packaging for flushing	UNI*FUSE™ Infusion System with Cooper Wire is composed of: • Single lumen 4F or 5F nylon catheter • Longitudinal slits located at 90° intervals around at distal end of the catheter • An occluding ball wire (or occlusion guidewire) • Overall lengths of 90cm and 135cm. • Multiple infusion segment lengths, 2cm and 5cm. • Radiopaque markers at the distal and proximal ends of the infusion segment.	Substantially Equivalent	Cragg-McNamara is composed of: • Valved-tip single lumen catheter (4F or 5F) with side holes in the distal portion. • Two radiopaque markers, • Tip occluded guidewire. • Proximal luer adapter.	Substantially Equivalent
Catheter Diameter	5.7F (6F nominal)	4F, 4.3 F, 5F	Substantially Equivalent	4F, 5F	Substantially Equivalent
Catheter Length (cm)	90-140cm	90cm, 135cm	Substantially Equivalent	40cm, 65cm, 100cm, 135cm	Substantially Equivalent
Catheter infusion length	0-50cm	2cm, 5cm, 10 cm, 15 cm	Substantially Equivalent	5cm, 10cm, 20cm, 30cm, 40cm, 50cm	Substantially Equivalent
Materials	All materials are commonly used for this type of medical device and are biocompatible in accordance with ISO 10993-1.	All materials are commonly used for this type of medical device and are biocompatible in accordance with ISO 10993-1.	Substantially Equivalent	Unknown	N/A
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical	Ethylene Oxide	Identical

Performance Testing Comparison

	Subject Device	**Predicate Device**
	VariFuse™ Adjustable Infusion Catheter	**UNI*FUSE + ™ Infusion System with Cooper Wire**
Performance Testing (In-Vitro)	-Visual & Dimensional -Leak Test -Tensile Strength -Kink test -Flow Rate -Valve Flow Performance -Infusion Catheter, 24hr Study	-Dimensional Verification -Length Sufficiency -Catheter Hub-to-Catheter Shaft Connection Compatibility -Catheter-to-Guidewire Compatibility -Catheter-to-Introducer Sheath Compatibility -Catheter Tip Radius -Catheter Infusion

ARGON MEDICAL DEVICES

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VariFuse™ Adjustable Infusion Catheter

	-Luer Compatibility -Particulate Testing -Radiopacity -Torque Testing -Corrosion Resistance -Simulated Use -Shipping Qualification - Design Validation and Summative Usability - Chemical Compatibility	-Slit Pattern Radiopacity -Catheter Degradation -Catheter Pressure -Catheter-to-Occlusion Wire Configuration (Slow Infusion Compatibility) -Catheter/Accessory Compatibility -Catheter/Fluid Compatibility -Catheter Hub-to-Shaft Joint Kink Resistance -Occlusion Wire Flexibility -Occlusion Wire Flow -Occlusion Wire Seal -Hub-to-Wire Bond/Connection -Distal Spring Tip-to-Mandrel Connection -Occlusion Wire Withdrawal -Human Factors Testing

Non-Clinical Data (Bench-top Testing)

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 VariFuse™ Adjustable Infusion Catheter substantial equivalence:

- Visual
- Dimensional
- Simulated Use
- Leak Test
- Tensile Strength
- Kink test
- Flow Rate
- Valve Flow Performance
- Infusion Catheter, 24hr Study
- Luer Compatibility
- Particulate Testing
- Radiopacity
- Torque Testing
- Corrosion Resistance
- Shipping Qualification
- Design Validation and Summative Usability

Non-Clinical Data Biocompatibility

Biocompatibility is established for the VariFure™ Adjustable Infusion Catheter according to ISO 10993-1:2018 as an external communicating device, 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.

<u>Biocompatibility Testing included:</u>

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization
- ISO 10993-23 Irritation or Intracutaneous Reactivity
- ISO 10993-11 Material Mediated Pyrogenicity
- ISO 10993-11 Acute Systemic Toxicity
- ISO 10993-4 Hemocompatibility
  - *In-vitro* Blood Loop Assay with Comparison Article
  - Complement Activation Assay, SC5b-9 Method with Comparison Article (ISO)

510(k) Summary
VariFuse™ Adjustable Infusion Catheter

- Heparinized Platelet and Leukocyte Count Assay with Comparison Article (ISO)
- Partial Thromboplastin Time (PTT) Assay with Comparison Article (ISO)
- ASTM Hemolysis Assay, Direct and Extract Methods (ISO)

Literature Search	A literature review was conducted by Argon Clinical Affairs that resulted in 3 articles on the predicate device encompassing at least 55 cases. One article had 2 devices within the CDT group without breaking down how many cases were actually UNI*FUSE™. Based on the bench testing performed, Argon Medical Devices asserts that the subject and predicate device possess substantially equivalent technological characteristics such as principle of operation and in-vitro performance testing. The subject and predicate device both adhere to ISO 10993-1 and have the same sterilization method. A systematic literature search was conducted to support the use of the subject device for catheter-directed thrombolysis, which resulted in 9 articles.
Substantial Equivalency Conclusion	The VariFuse™ Adjustable Infusion Catheter is comparable to the predicate in its indication for use, intended use and principle of operation. Based on performance testing in vitro and similarities on indications for use, intended use, principle of operation, materials, technological characteristics, design features and sterilization process; the VariFuse™ Adjustable Infusion Catheter system is substantially equivalent to the predicate device.