November 30, 2023

Argon Medical Devices
Scott Bishop
Director, Regulatory Affairs
1445 Flat Creek Road
Athens, Texas 75751

Re: K230669
Trade/Device Name: L-Cath™ Single and Dual Lumen Catheters, L-Cath™ Midline Catheters
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, FOZ
Dated: October 31, 2023
Received: October 31, 2023

Dear Scott Bishop:

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,

Porsche Bennett
For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K230669

Device Name
L-Cath™ Single and Dual Lumen Catheters, L-Cath™ Midline Catheters

Indications for Use *(Describe)*
The L-Cath Single and Dual Lumen Catheters and the L-Cath Midline Catheters are indicated for short or long term peripheral access to the central venous system for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

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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K230669 510(k) Summary

Date Prepared:	November 30, 2023

Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
Contact:	Scott Bishop Director, Regulatory Affairs Phone: 469.430.0546 Email: Scott.Bishop@argonmedical.com

Device Trade Name:	L-Cath™ Single and Dual Lumen Catheters, L-Cath™ Midline Catheters
Device Common Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Primary Product Code:	LJS
Secondary Product Code:	FOZ
Regulation:	21 CFR 880.5970
Classification:	Class II
Review Panel:	General Hospital

Predicate Device(s):	K091670 BD L-Cath™ Midline Catheter BD Cath™ Single Lumen BD Cath™ Dual Lumen Peripherally Inserted Central Catheters PICC
Description of the Device:	The L-Cath™ Single and Dual Lumen and L-Cath™ Midline Catheters are sterile, single use devices, sold as standalone devices which includes the following accessories: • Trim Tool • Tape measure • Stylet (include in the final catheter assembly as applicable) • Polyurethane catheter

These catheters are also sold as a component in a Basic Kit (catheter and introducer packaged together) which includes the following:

- BD Introsyte Autoguard Introducer or Splittable Introducer
- Stylet (include in the final catheter assembly as applicable)
- Trim Tool
- Tourniquet
- Tape measure

Indication for Use:

The L-Cath Single and Dual Lumen Catheters and the L-Cath Midline Catheters are indicated for short or long term peripheral access to the central venous system for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

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, *K091670*.

	Predicate Device L-Cath™ Single and Dual Lumen and L-Cath™ Midline Catheter	**Modified Proposed Device (Subject of This Submission) & Discussion**
Manufacturer	Argon Medical Devices, Inc	SAME
FDA Clearance	K091670	K230669
Class	II	SAME
Device Classification Name	Percutaneous, implanted, long-term intravascular catheter.	SAME
Regulation	21 CFR 880.5970	SAME
Product Code	LJS/FOZ	SAME
Technological Characteristics: Technological characteristics of the Subject device are substantially equivalent to those of the cited predicate device with respect to intended use, indications for use, target patient population, operating principle, fundamental scientific technology, packaging configurations, sterility assurance level and method of sterilization. The differences of the Subject device from the Predicate device are limited to the materials used in the Luer Lock assembly. Additionally, contraindications have been added based on review of similar devices. The following table provides a summary comparison between the subject and predict device.		
Intended Use	The L-Cath Single and Dual Lumen Catheters and the L-Cath Midline Catheters are indicated for short or long term peripheral access to the central venous system for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.	SAME

Principle of Operation	The L-Cath Single and Dual Lumen Catheters and the L-Cath Midline Catheters are a family of surgically Invasive, long-term, polyurethane catheters that are in direct contact with the central circulatory system. • For proper use, clinicians must be familiar with and trained in the placement, maintenance, and use of PICC and/or midline catheters. Their use should be preceded by an established institutional protocol and accepted professional standards and guidelines and performed by persons trained in the procedure and knowledgeable of the inherent risks. • PICC catheters shall have the distal tip dwelling in the lower one third of the	SAME
	superior vena cava to the junction of the superior vena cava and the right atrium. Lower extremity placement shall have the distal tip dwelling in the thoracic inferior vena cava above the level of the diaphragm. • Midline catheters shall have the distal tip residing in the basilic, cephalic, or brachial vein at or below the axillary level and distal to the shoulder. Infusates should be at or near normal serum osmolality. • Follow sterile technique per institutional policy. Sterile technique and proper skin preparation are essential for proper use. The use of maximal barrier precautions during catheter insertion is recommended to help reduce the risk of catheter-related infection, including the use of sterile gown, mask, cap, sterile gloves, and large sterile drapes to cover the body. Observe Standard/Universal precautions for all patients to reduce the potential exposure to bloodborne pathogens.	
Mechanism of Action	The polyurethane PICC and Midline Catheter Systems transport medicines and nutritional therapies into the bloodstream of the patient by providing an enclosed fluid pathway that connects other catheters and then creates a seal at the connections and junctions with the other enclosed fluid pathways (catheters).	SAME
Indication for Use	The L-Cath Single and Dual Lumen Catheters and the L-Cath Midline Catheters intended use shall be for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.	SAME

Contraindication	There are no Contraindications	• The devices are contraindicated whenever there is presence of device related infections or presence of thrombosis in the intended insertion vessel or catheter pathway. • The devices are contraindicated when the patient's body size is insufficient to accommodate the size of the device. • The patient is known or is suggested to be allergic to materials contained in the device. • Clinical assessment of the patient must be completed to ensure no contraindications exist.
Single Use	Yes	SAME
Supplied Sterile	Yes, EO	SAME
Device Description	All Argon L-Cath PICC and Midline polyurethane catheters are sold as standalone devices which includes the following accessories: • Trim Tool • Tape measure • Stylet (include in the final catheter assembly as applicable) • Polyurethane catheter These catheters are also sold as a component in a Basic Kit (catheter and introducer packaged together) which includes the following: • BD Introsyte Autoguard Introducer • Stylet (include in the final catheter assembly as applicable) • Trim Tool • Tourniquet • Tape measure	SAME
PICC & Midline Catheter Outer Diameter	Single Lumen: 16, 18, or 20-gauge Dual Lumen: 16, 18, and 20-gauge Small vein access (SVA) Single Lumen: 26 and 28-gauge Midline: 18 and 20-gauge	SAME
PICC & Midline Catheter Length	Single Lumen: 60 cm Dual Lumen: 60 cm SVA Single Lumen: 25 and 30 cm Midline: 20 cm	SAME

Luer Lock Material	Gamma Stable Polycarbonate	PEBAX 7433 SA01 MED NATURAL/CLEAR • Biocompatibility and performance testing demonstrated that the difference between the subject and predicate devices does not raise new or different questions to safety and effectiveness
Catheter Material	Polyurethane	SAME
Strain Relief Material	Silicon	SAME
Tubing Material	Polyurethane	SAME
Stylet Material	304V Stainless Steel ABS	SAME
Y Site Assembly Material	Makrolon	SAME
Discussion: The technological difference in the Luer Lock Material was evaluated using industry consensus standards and as determined in the risk assessment. The technological differences between the subject and predicate device do not raise new or different questions of safety or effectiveness.		

Performance Testing: In accordance with the Design Failure Modes and Effects Analysis, supplemental verification testing was identified to support the substantial equivalence of the Subject Device.		
Performance Testing	• Catheter – Joint Leak Test • Catheter – Dimensional • Catheter – Pressure Burst • Catheter – Durometer • Catheter - Radiopacity • Stylet – Retaining force • Luer Functional • Mechanical Bonds – Pull force • Particulates • Material Durability	SAME as K091670 Supplemental testing to support the design change: Report 2023-039-RPT • Luer Integrity (Functional) Report 2023-042-RPT • ISO 80369-7 Compliance Testing Report 2023-134-RPT • Luer Integrity (Functional); Functional Leak Test
Biological Comparison	• Pyrogenicity (ISO 10993-11) • Cytotoxicity (ISO 10993-5) • Hemocompatibility (ISO 10993-4) • Irritation/Sensitization (ISO 10993-10) • Systemic Toxicity (ISO 10993-11) • Ethylene oxide Residuals (ISO 10993-7) • Local effects after implantation (ISO 10993-7)	Supplemental testing to support the material change: Report 2022-026-RPT • Systemic Toxicity (10993-17) • Genotoxicity (10993-3)
Sterilization	100% EtO SAL 10^{-6}	ISO 11135:2014 AAMI TIR28:2016 SAME
The subject device met all the predetermined acceptance criteria derived from the above listed reference standards and internal test protocols and demonstrated substantially equivalent performance compared to the predicate device. This included evaluation of biocompatibility endpoints and assessment of impact of the design changes on the SAL.		
Clinical Testing	Clinical testing was not required for the determination of substantial equivalence.	
Animal Testing	Animal testing was not required for the determination of substantial equivalence.	

Conclusion: The proposed device modifications to the L-Cath™ Single and Dual Lumen and L-Cath™ Midline Catheters do not change its intended use or principles of operation. Based on the Indication for Use, design, and safety and performance testing, L-Cath Single-Lumen and Dual-Lumen Catheters and the L-Cath Midline Catheters, K230669 meet the requirements for its intended use, the differences do not raise new or different questions of safety and effectiveness and is therefore substantially equivalent to the predicate device, K091670.