December 8, 2023

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

Re: K233432
Trade/Device Name: 10F Sheath and Dilator Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 12, 2023
Received: October 12, 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,

Misti L. Malone -S

Misti Malone, Ph.D.
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)*
K233432

Device Name
10F Sheath and Dilator Set

Indications for Use *(Describe)*
The 10F Sheath and Dilator Set is indicated for introduction of therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: October 10, 2023

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
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Device Trade Name: 10F Sheath and Dilator Set

Device Common Name: Introducer Sheath

Device Classification Name:
Introducer, Catheter
Class II
Product code DYB
21 CFR 870.1340
Review Panel: Cardiovascular Devices

Predicate Device(s): *Primary*: K142829 Flexor® Check-Flo® Introducer Set

Description of the Device:
The 10F Sheath and Dilator Set is designed for single use and intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

The 10F Sheath and Dilator Set consists of a 10F reinforced Introducer Sheath and a matching 10F radiopaque Dilator.

Indication for Use:
The 10F Sheath and Dilator Set is indicated for introduction of therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Technological Characteristics:
A comparison of the technological characteristics of the subject device and the predicate devices shows the 10F Sheath and Dilator Set 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.

	Subject Device	**Predicate Device**
	Argon 10F Sheath and Dilator Set	**Flexor® Check-Flo® Introducer Set**
Manufacturer	Argon Medical Devices, Inc.	Cook Inc.
FDA Clearance	TBD	K142829
Class	II	II

	Subject Device	Predicate Device
	Argon 10F Sheath and Dilator Set	**Flexor® Check-Flo® Introducer Set**
Device Classification Name	Introducer, Catheter	Introducer, Catheter
Regulation	21 CFR 870.1340	21 CFR 870.1340
Product Code	DYB	DYB
Intended Use	Vascular access	Vascular access
Principle of Operation	The 10F Sheath & Dilator Set is used to gain vascular access using the Seldinger technique within any vascular appropriate for a 10F sheath. It is used to introduce other therapeutic or diagnostic devices into the patient while hemostasis is maintained by the sheath.	SAME
Indication for Use	The 10F Sheath and Dilator Set is indicated for introduction of therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.	Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature
Contraindication	None known	None known
Single Use	Yes	SAME
Supplied Sterile	Yes	SAME
Device Description	The 10F Introducer sheath is a coil reinforced sheath with a Platinum Iridium radiopaque marker band. The sheath has a hemostasis valve and a side port with stopcock. The 10F dilator is made of radiopaque, non-reinforced material with an atraumatic tip to minimize blood loss. The device does not include any coating.	Flexor Introducers and Guiding Sheaths incorporate a Flexor shaft with a hemostasis valve and are provided with one or more dilators. These devices are available in various sizes, lengths and configurations. Configurations include differences in shaft construction, such as varying shaft stiffness and distal tip material and shape, dilator material, hydrophilic coating and/or distal radiopaque markers. *Flexor® Check-Flo® Introducer sheath is a coil reinforced sheath, incorporates a hemostasis valve and a side port tubing with stopcock.
Introducer Sheath		
Sheath Inner Diameter (F)	10.3F	10F
Sheath Outer Diameter (in)	0.158	0.157
Sheath Length (cm)	41.5	40
RO Marker	Platinum/Iridium	Platinum/Iridium
Materials	PTFE, Stainless Steel 304V, Nylon	PTFE, Stainless Steel 304V, Nylon
Dilator		
Outer Diameter (F)	10F	10F
Length (cm)	48.8	51.9
Material	Polyethylene, Barium Sulfate	Polyethylene (Radiopaque)

	Subject Device	Predicate Device
	Argon 10F Sheath and Dilator Set	**Flexor® Check-Flo® Introducer Set**
Dilator Tip Diameter Size (in)	Tip ID: Ø .041 Tip OD: Ø.068	Tip ID: Ø .041 Tip OD: Ø .062

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 10F Sheath and Dilator Set substantial equivalence:

- Radiopacity
- Visual
- Dimensional
- Simulative Use
- Leakage (Sheath and Dilator)
- Kink Test (System)
- Tensile (Sheath and Dilator)
- Luer testing
- Shipping Qualification

Non-Clinical Data Biocompatibility

Biocompatibility is established for the 10F Sheath and Dilator Set 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:

- 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)
  - 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)

Substantial Equivalence:	Based on the Indication for Use, design, and safety and performance testing, the 10F Sheath and Dilator Set meets the requirements for its intended use and is substantially equivalent to the predicate devices.
Conclusion:	Based on performance testing in vitro, and similarities in indications for use, materials, technological characteristics, principle of operation, design features and sterilization process; the 10F Sheath and Dilator Set is substantially equivalent to the predicate device.