May 22, 2023

Argon Medical Devices
Pratusha Kudumula
Senior Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K230631
Trade/Device Name: Kodiak™ Dual Port Coaxial Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 2, 2023
Received: March 7, 2023

Dear Pratusha Kudumula:

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,

Misti L. Malone -S

Misti Malone, PhD
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)*

K230631

Device Name
Kodiak™ Dual Port Coaxial Introducer Kit

Indications for Use *(Describe)*
The Kodiak™ Dual Port Coaxial Introducer Kit is indicated to introduce therapeutic or diagnostic devices into the 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date prepared	May 5th, 2023
Name	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number:1625425
Contact person	Pratusha Kudumula Sr. Regulatory Affairs Specialist 309-706-9488
Device Name	Kodiak™ Dual Port Coaxial Introducer Kit
Trade Name	Kodiak™ Dual Port Coaxial Introducer Kit
Common name	Catheter Introducer
Regulation name	Catheter Introducer
Classification number	21 CFR 870. 1340
Primary product code	DYB
Regulatory class	II
Predicate device	Performer Introducer (K171999) Cook, Inc.
Description of the Device:	The Kodiak™ Dual Port Coaxial Introducer Kit is intended to introduce therapeutic or diagnostic devices into the vasculature. The Kit Model 381416000 contains a coaxial 16F and 14F braided reinforced sheaths with a fluoropolymer coating, an embedded radiopaque marker band, and an over molded hub assembly containing two hemostasis valves and side port with stopcock. It also contains a removable Y-connector with two 7F (ID) ports with hemostasis valves, a 14F dilator, a 16ga blunt flushing needle, and a high-pressure Luer adapter. After percutaneous access is established and a working guidewire is placed, the introducer system is inserted over the guidewire and advanced under imaging. Therapeutic or diagnostic devices are inserted through the system. The Kodiak™ Dual Port Coaxial Introducer Kit is a single use device.
Indication for Use:	The Kodiak™ Dual Port Coaxial Introducer Kit is intended to introduce therapeutic or diagnostic devices into the vasculature.

Technological Characteristics:

A comparison of the technological characteristics of the subject device and the predicate devices shows the Kodiak™ Dual Port Coaxial Introducer Kit to be substantially equivalent to the current marketed predicate devices.

Equivalence is based upon the product performance, design and intended use. The Kodiak™ Dual Port Coaxial Introducer Kit and the predicate devices have similar materials of construction, dimensional specifications, design, and sterilization process.

SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**
Kodiak™ Dual Port Coaxial Introducer Kit	**Cook Performer Introducer**
Principle of Operation	
After percutaneous access is established and a working guidewire is placed, the introducer system is inserted over the guidewire and advanced under imaging. Therapeutic or diagnostic devices are inserted through the system.	After access is established and a working guidewire is placed, the introducer system is inserted over the guidewire and advanced under imaging. Therapeutic or diagnostic devices are inserted through the system.
Device Description	
The system consists of the following components: • 16F x 45cm outer sheath • 14F x 53cm inner sheath • 14F x 61cm dilator • 7F / 7F Y-connector • 16ga blunt flushing needle • High pressure Luer adapter	Performer® Introducers are designed to perform as a • Introducer sheath 6F-18F; 13cm – 85cm • 6F - 18F dilators of varying lengths
Guidewire Compatibility	
0.038”	0.035” or 0.038” depending on introducer size

Performance Tests (Non-Clinical):

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

testing below was shown to meet the acceptance criteria that was determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the Kodiak™ Dual Port Coaxial Introducer Kit substantial equivalence.

Performance Testing, including:

- System Leak
- Tensile Strength
- Tip Strength
- Radiopacity
- Kink Testing
- Dimensional
- Functional Fit
- Simulated Use
- Luer Testing
- Power Injection Testing
- Tip Buckling
- Particulate
- Packaging Integrity

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO10993-10)
- Irritation - Intracutaneous Reactivity (ISO10993-23)
- Acute Systemic Toxicity (ISO10993-11)
- Pyrogenicity (ISO 10993-11)
- Hemolysis Direct/Indirect (ISO 10993-4)
- Thromboresistance (ISO 10993-4)
- Partial thromboplastin time (ISO 10993-4)
- Complement Activation (ISO 10993-4)
- Platelet and Leukocyte Count (ISO 10993-4)

Substantial Equivalence: Based on the Indication for Use, design, and safety and performance testing, the Kodiak™ Dual Port Coaxial Introducer Kit meets the requirements for its intended use and is substantially equivalent to the predicate device.

Conclusion: The results of all testing demonstrate that the Kodiak™ Dual Port Coaxial Introducer Kit is substantially equivalent to the predicate device.