January 15, 2021

Argon Medical Devices, Inc.
Amy Clendening-Wheeler
Regulatory Affairs Manager
1445 Flat Creek Road
Athens, Texas 75751

Re: K202141
Trade/Device Name: Scorpion Stylet Portal Vein Access Set, Scorpion Needle Portal Vein Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 18, 2020
Received: December 21, 2020

Dear Amy Clendening-Wheeler:

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,

for

Misti Malone
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202141

Device Name
Scorpion Stylet Portal Vein Access Set and Scorpion Needle Portal Vein Access Set

Indications for Use *(Describe)*
The Scorpion Portal Vein Access Sets are intended for transjugular liver access in diagnostic and interventional procedures.

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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510(k) Summary

Date Prepared: December 30, 2020

Company: Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, Texas 75751 USA
Facility Registration number: 1625425

Contact: Amy Clendening-Wheeler
Regulatory Affairs Manager
Phone: 469-731-1413
Fax: 469-731-1480
Email: amy.wheeler@argonmedical.com

Device Trade Name: Scorpion™ Portal Vein Access Set

Device Common Name: Catheter Introducer

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

Predicate Device(s): *Primary*: K171820 Transjugular Liver Access Sets / Cook Incorporated

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Description of the Device: The Scorpion Portal Vein Access Sets have two models. One model has a Stylet as the puncture tool and the other model has a 17ga Needle as the puncture tool.

The Scorpion Stylet Portal Vein Access Set contains a 10F Introducer Sheath, a 10F Dilator, a 5F MPA catheter, a 14ga Stiffening Cannula, a 0.040" Nitinol Stylet with a 5Fr PEEK Catheter, and a 7F Cannula Sheath. The 14ga stiffening cannula with cannula sheath has a directional handle that indicates the direction of the curve. The 10F Introducer Sheath hemostatic valve is designed to be compatible with up to 13F (4.3mm/0.171") sleeve. These components are used to create a pathway through the liver parenchyma through which an endoprosthetic can be delivered. The Scorpion Stylet Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool (0.040" Stylet) through the parenchyma. The puncture tool (Stylet) is used

to make a pathway from the hepatic vein to the portal vein, and then the pathway is dilated to provide access for a larger sheath. The shunt is inserted through the sheath and deployed through the pathway. Then, all of the Scorpion Stylet Portal Vein Access Set components are removed.

The Scorpion Needle Portal Vein Access Set contains a 10F Introducer Sheath, a 10F Dilator, a 5F MPA Catheter, a 13ga Scorpion Stiffening Cannula, 17ga Nitinol Needle, a 6.2F PEEK Catheter, and 8F Sheath Introducer. The 13ga stiffening cannula with cannula sheath has a directional handle that indicates the direction of the curve. The 17ga Nitinol Needle has a directional handle that indicates the direction of the curve. The 10F Introducer Sheath hemostatic valve is designed to be compatible with up to 13F (4.3mm/0.171") sleeve. These components are used to create a pathway through the liver parenchyma through which an endoprosthetic can be delivered. The Scorpion Needle Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool (17ga Needle) through the parenchyma. The puncture tool (Needle) is used to make a pathway from the hepatic vein to the portal vein, and then the pathway is dilated to provide access for a larger sheath. The shunt is inserted through the sheath and deployed through the pathway. Then, all of the Scorpion Needle Portal Vein Access Set components are removed.

A Portal Vein Access Set is typically in use in procedures up to 4 hours.

Indication for Use:	The Scorpion Portal Vein Access Sets are intended for transjugular liver access in diagnostic and interventional procedures.
Technological Characteristics:	A comparison of the technological characteristics of the subject device and the predicate devices shows the Scorpion Portal Vein Access Set to be substantially equivalent to the current marketed predicate devices. Equivalence is based upon the product performance, design and intended use. The Scorpion Portal Vein Access Set and the predicate devices have similar materials of construction, dimensional specifications, designs and sterilization process.
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 guidances 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 Scorpion Portal Vein Access Set substantial equivalence.

Performance Testing, including:

- Dimensional and Functional Fit
- Surface Inspection
- Component Compatibility
- Tensile Strength
- Torque Strength Test
- Liquid Leakage
- Air Leakage
- Corrosion Resistance
- Simulative Use
- Radiopacity
- Echogenicity
- Luer Connector Functional Testing
- Burst Pressure
- Flow Rate
- Resistance to Fracture Testing

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous Irritation (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material Mediated Pyrogen (ISO 10993-11)
- Hemocompatibility (ISO 10993-4)
  - ASTM Hemolysis – Direct and Indirect Contact
  - Complement Activation, SC5b-9
  - Thrombogenicity
  - Platelet and Leucocyte Counts
  - Partial Thromboplastin Time (PTT)

Substantial Equivalence:

Based on the Indication for Use, design, and safety and performance testing, the Scorpion Portal Vein Access Set meets the requirements for its intended use and is substantially equivalent to the predicate devices.

Substantial Equivalence Table

	SUBJECT DEVICE	PREDICATE DEVICE
	SCORPION	**Transjugular Liver Access Sets (Rosch-Uchida and Ring) K171820**
Manufacturer	Argon Medical Devices, Inc.	Cook Incorporated
510(k)	K202141	K171820

	Class	II	**SAME**
	Classification Name	Catheter Introducer	**SAME**
	Regulation	21 CFR 870.1340	**SAME**
	Product Code	DYB	**SAME**
	Indication for Use	The Scorpion Portal Vein Access Set is intended for transjugular liver access during diagnostic and interventional procedures.	**SAME**
	Principle of Operation	Access to the jugular vein using standard access techniques. The Introducer sheath and dilator are inserted over the guidewire, advanced, and positioned in the hepatic vein and the dilator is removed. The stiffening cannula and cannula sheath, followed by the puncturing tool and guide catheter, are inserted into the introducer sheath and the puncturing tool is used to puncture the hepatic vein, liver parenchyma and access the portal vein.	**SAME (In the case of the Ring set, the puncturing tool and guide catheter are inserted without use of a stiffening cannula and cannula sheath)**
	Contraindication	None Known	None Known
	Single Use	YES	**SAME**
	Device Description	Each Portal Vein Access Set contains a 10F wall-reinforced Introducer Sheath with radiopaque tip, a 10F Dilator, a 5F MPA catheter, a puncturing tool that comes in the following variations: 0.040" Stylet with a 5Fr Stylet Catheter (separated with a removable spacer clip) and a 14ga Stiffening Cannula with a 7F Cannula Sheath or 17ga Needle/6.2Fr Catheter (separated with a removable spacer clip) and a 13ga Stiffening Cannula with an 8F Cannula Sheath. The stiffening cannulas and the stylet/needle puncturing tools have curved distal ends, with directional handles that indicate the direction of the curves, which facilitate access into the hepatic vasulature and the creation of a pathway into the portal vein. The 10F Introducer Sheath hemostatic valve is designed to allow entry of a 13F (4.3mm/0.171") access sleeve	The Transjugular Liver Access Sets are comprised of various components that facilitate transjugular access to the liver for the purpose of performing interventional procedures. The sets are grouped into two basic types: the Ring Transjugular Intrahepatic Access Set and the Rösch- Uchida Transjugular Liver Access Set. Each set includes core components comprised of an introducer sheath and dilator. The Ring Transjugular Intrahepatic Access Set includes a 16ga stainless steel needle with 9F or 10F guiding catheter. The Rösch-Uchida Transjugular Liver Access Set includes a 14ga stainless steel stiffening cannula with 10F catheter and a 0.038" stainless steel stylet with 5F guiding catheter. Both the 16ga needle in the Ring set and the 14ga stiffening cannula in the Rösch- Uchida set have curved distal ends, with directional handles that indicate the direction of the curves, which facilitate access into the hepatic vasulature. Other components included in some of

	but taper down to a 10F inner diameter.	these sets are a Check-Flo Introducer Set, selective catheters, and wire guides.
Introducer Set		
Sheath Materials	Pebax or PTFE Inner Layer Stainless Steel Coil Pebax Outer Layer	PTFE liner Stainless Steel Coil Nylon Jacket
Sheath Marker Band	Pebax with 80% Tungsten black Pebax	Platinum/Iridium
Sheath hub material	Polycarbonate (Makrolon)	Nylon
Sheath Inner Diameter (Fr)	10	9 or 10, 10
Sheath Length (cm)	42	38.5, 40
Dilator		
Outer diameter (F)	10	9 or 10 (Rosch-Uchida), 10 (Ring)
Material	HDPE w/ Barium Sulfate	Polyethylene
Hub material	HDPE	HDPE
Length (cm)	49	40, 51
Dilator Endhole Size (in)	.041	0.035, 0.038
Catheter (MPA/MPB)		
Outer diameter (F)	5	5
Length (cm)	80	80
Endhole size (in.)	.041	0.035
Shaft materials	Nylon, Barium Sulfate, stainless steel	Teflon, Nylon
Tip material	Pebax, Bismute subcarbonate, Titanium dioxide	N/A
Hub material	Polycarbonate	Polycarbonate
Puncturing Tool Assembly	**Stylet Set**: 14ga Stiffening Cannula -Stainless steel 7F Cannula Sheath - HDPE 0.040" x 73 cm Nitinol Stylet reinforced with stainless steel hypotube with a 5Fr Stylet PEEK Catheter HDPE Spacer clip OR **Needle Set:** 13ga Stiffening Cannula- Stainless steel 8F Cannula Sheath - HDPE 17ga x 73 cm Stainless Steel / Nitinol composite Needle 6.2F x 64 cm PEEK Catheter HDPE Spacer clip	**Rosch-Uchida Set (Stylet and catheter assembly)** 14ga Stiffening Access Cannula-Stainless Steel 10F Teflon Catheter 0.038" Stainless Steel Needle Stylet x 62.5cm with 5.2F Teflon Catheter OR **Ring Set (Colapinto Needle and catheter assembly)** 16ga Stainless Steel Needle 9F or 10F x 45.5 cm Teflon Catheter
Puncturing Tool, composition	Proximal: 304 Stainless Steel Distal: Nitinol	Needle/Stylet: 304 Stainless Steel

Puncturing Tool Catheter, composition	PEEK	Teflon/nylon
Bench Testing		
Performance Testing	• Radiopacity • Echogenicity • Corrosion Resistance • Dimensional & Functional Fit • Tensile Strength • Torque Strength Test • Liquid Leakage • Air Leakage • Burst Pressure • Flow Rate • Simulative Use - performance testing including dimensional, surface and compatibility of components • Luer Functional Testing • Shipping Test • Resistance to Fracture Testing	• Radiopacity • Corrosion Resistance • Tensile Strength • Torque Strength Test • Liquid leakage • Air Leakage • Burst Pressure • Flexibility & Fracture • Simulative Use – performance testing including dimensional, surface and compatibility of components
Biological Comparison	• Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous Irritation (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material Mediated Pyrogen (ISO 10993-11) • Hemocompatibility (ISO10993-4) ○ ASTM Hemolysis – Direct and Indirect Contact ○ Complement Activation, SC5b-9 ○ *In Vivo* Thrombogenicity ○ Platelet and Leucocyte counts ○ Partial Thromboplastin Time (PTT)	• Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous Reactivity/Irritation (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material Mediated Pyrogenicity • Hemocompatibility (ISO10993-4) - Hemolysis Direct/Indirect - Complement Activation (ISO Direct Contact) -In Vivo Thrombogenicity
Packaging Configuration	PETG Tray in a Tyvek/poly pouch	Individually pouched components
Sterilization	Minimum SAL 10^{-6} EtO	**SAME**
Intended Shelf Life	3 years	**SAME**

Conclusion: The results of all testing demonstrate that the Scorpion Portal Vein Access Set are substantially equivalent to the predicate device.