December 22, 2020

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

Re: K201489
Trade/Device Name: Traveler Portal Vein Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 20, 2020
Received: November 23, 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,

Finn Donaldson
Assistant Director (Acting)
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)*
K201489

Device Name
Traveler™ Portal Vein Access Set

Indications for Use *(Describe)*
The Traveler™ Portal Vein Access Set is 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.

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:	December 18, 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:	Traveler™ 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 Reference: K152913 GORE TIPS Set / Creganna Medical
Description of the Device:	The Traveler™ 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: 0.038" Stylet with a 5Fr Stylet Catheter (separated with a removable spacer clip), a 21ga Needle/5Fr Catheter or 16ga Needle/7Fr Catheter (both are separated with a removable spacer clip) and a bending tool. The 14ga stiffening cannula with cannula sheath and the 16ga needle have a curved end, with a directional handle that indicates the direction of the curve. The 10F Introducer Sheath hemostatic valve is designed to allow entry of a 13F (4.3mm/0.171") access sleeve but taper down to a 10F inner diameter.

	These components are used to create a pathway through the liver parenchyma through which an endoprosthetic can be delivered. The Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool toward the parenchyma. The puncture tool is used to make a pathway from the hepatic vein to the portal vein, and then the pathway is dilated to provide access for the 10F Introducer Sheath. The shunt is inserted through the sheath and deployed through the pathway. Then, all of the Portal Vein Access Set components are removed. The Portal Vein Access Set is typically in use in procedures up to 4 hours.
Indication for Use:	The Traveler™ Portal Vein Access Set is 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 Traveler™ 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 Traveler™ 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 Traveler™ Portal Vein Access Set substantial equivalence. <u>Performance Testing, including:</u> • Dimensional & Functional Fit • Surface Inspection

- Component Compatibility
- Tensile Strength
- Torque Strength Test
- Liquid Leakage
- Air Leakage
- Burst Pressure
- Flow Rate
- Corrosion Resistance
- Simulative Use
- Radiopacity
- Echogenicity
- Luer Connector Functional Testing
- 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 (ISO10993-4)
  - ASTM Hemolysis – Direct and Indirect Contact
  - Complement Activation, SC5b-9
  - *In Vivo* Thrombogenicity
  - Platelet and Leucocyte Counts
  - Partial Thromboplastin Time (PTT)

Substantial Equivalence:

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

Substantial Equivalence Table

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
	Traveler™ Portal Vein Access Set	**Transjugular Liver Access Sets**	**GORE® TIPS Set**
Manufacturer	Argon Medical Devices, Inc.	Cook Incorporated	Creganna Medical
510(k)	TBD	K171820	K152913
Class	II	**SAME**	**SAME**
Classification Name	Catheter Introducer	**SAME**	**SAME**
Regulation	21 CFR 870.1340	**SAME**	**SAME**
Product Code	DYB	**SAME**	**SAME**

Clinical Comparison			
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 puncturing tool and guide catheter is inserted into the introducer sheath and the puncturing tool is used to puncture the hepatic vein, liver parenchyma and access the portal vein.	**SAME**	**SAME**
Indication for Use	The Portal Vein Access Set is intended for transjugular liver access during diagnostic and interventional procedures.	Intended for transjugular liver access in diagnostic and interventional procedures.	Intended to be used together for percutaneous transjugular liver access during diagnostic and interventional procedures in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.
Contraindication	None Known	Unknown	Unknown
Single Use	YES	**SAME**	**SAME**
Supplied Sterile	YES	**SAME**	**SAME**
Sterilization	EtO	**SAME**	**SAME**
Technical and Biological Comparison			
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: 0.038" Stylet with a 5Fr Stylet Catheter (separated with a removable spacer clip), a 21ga Needle/5Fr Catheter or 16ga Needle/7Fr Catheter (both are separated with a removable spacer clip) and a bending tool. The 14ga stiffening cannula with cannula sheath and the 16ga needle have a curved end, with a directional handle that indicates the direction of the curve. The 10F Introducer	The Transjugular Liver Access Sets are comprised of various components that facilitate transjugular access to the liver for the purpose of performing diagnostic and 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 a core component comprised of a combination of either a stiffening cannula/Teflon catheter or needle stylet/Teflon catheter that facilitates access into the hepatic vasculature and the creation of a pathway into the portal vein. Other components included in	The GORE® TIPS Set consists of the GORE® TIPS Sheath and the GORE® TIPS Needle, which may be supplied together or individually. The GORE® TIPS Sheath consists of an introducer sheath with a hemostatic valve and a dilator. The GORE® TIPS Needle consists of a stainless steel hollow shaft with a Needle tip and a guiding catheter.

	Sheath hemostatic valve is designed to allow entry of a 13F (4.3mm/0.171") access sleeve but taper down to a 10F inner diameter.	some of these sets are a Check-Flo Introducer Set, selective catheters, and wire guides.	
Introducer Sheath	10F	**9F or 10F**	**10F**
Introducer Sheath, working length (cm)	42	38.5, 40	40
Sheath, composition	Pebax or PTFE Inner Layer Stainelss Steel Coil Pebax Outer Layer	PTFE liner Stainless Steel Coil Nylon Jacket	PTFE Liner Stainless Steel Coil Pebax 6333 Jacket Pt/IR markerband Grilamid hub Hemostatis seal
Dilator Length (cm)	49	40, 51	47
Dilator end hold size (in)	0.040	0.035, 0.038	0.035
Guidewire Compatibility (in)	0.035, 0.038	**SAME**	≤ 0.035
Dilator, composition	HDPE with barium sulfate	Polyethylene	HDPE Extrusion
Stiffening Cannula	14ga	**SAME**	**Not Available**
Puncturing Tool Assembly	**16ga Stainless Steel Needle** - 57 cm in length 7F Peek Catheter - 51cm in length OR **0.038" Stainless Steel Stylet** - 69 cm in length 5F Peek Catheter - 66 cm in length OR **21ga Needle** - 72 cm in length 5F Peek Catheter - 67 cm in length	**16ga Stainless Steel Needle** - 50.5 cm in length 9F or 10F Teflon Catheter - 45.5 cm in length OR **0.038" Stainless Steel Needle** **Stylet** - 62.5 cm in length 5.2F Teflon Catheter - 62 cm in length 14ga Stainless Steel Stiffening Access Cannula - 54.5 cm in length 10F Teflon Catheter - 51.8 cm in length	**16ga Stainless Steel Needle** - 56 cm in length 10F MDPE catheter - 49 cm in length
Puncturing Tool, composition	304 Stainless Steel	**SAME**	**SAME**
Puncturing Tool Catheter, composition	PEEK	Teflon/nylon	MDPE Extrusion HDPE Hub
Bending Tool	**New**	**Not Available**	**Not Available**
Bending Tool, composition	302 Stainless Steel	**Not Available**	**Not Available**
Performance Testing	• Radiopacity • Echogenicity • Corrosion Resistance	• Radiopacity • Corrosion Resistance • Tensile Strength	• 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	• Torque Strength Test • Liquid leakage • Air Leakage • Burst Pressure • Flexibility & Fracture • Simulative Use – performance testing including dimensional, surface and compatibility of components	• 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) o ASTM Hemolysis – Direct and Indirect Contact o Complement Activation, SC5b-9 o *In Vivo* Thrombogenicity o Platelet and Leucocyte Counts o 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	• 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 pouches components	Tyvek/Polyethylene-polyester Film
Intended Shelf Life	3 years	3 years	1 year

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