December 10, 2021

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

Re: K213638
Trade/Device Name: Traveler 0.038" Stylet Portal Vein Access (TPS001), Traveler 21ga Needle Portal Vein Access Set (TPS002), Traveler 16ga Needle Portal Vein Access Set (TPS003)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 17, 2021
Received: November 18, 2021

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 (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 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)*
K213638

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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510(k) Summary

Date Prepared: November 17, 2021

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

Contact: Ana Jimenez-Hughes
Senior Regulatory Affairs Specialist
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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*: K201489 Traveler™ Portal Vein Access Set

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Description of the Device: Each Portal Vein Access Set contains 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) or a 21ga Needle/5Fr Catheter or a 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 has a curved end, with a directional handle that indicates the direction of the curve.

Indication for Use: The Traveler™ Portal Vein Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

Device Modification:

The device modification included in this submission is limited to the removal of the following components from the Traveler™ 0.038" Stylet Portal Vein Access Set, the Traveler™ 21 ga Needle Portal Vein Access Set, and the Traveler™ 16 ga Needle Portal Vein Access Set:

- 10F Introducer sheath
- 10F Dilator

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, K201489.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification testing was identified to support the substantial equivalence of the modified Traveler Portal Vein Access Set. The tests included:

- Functional Fit
- Hemostasis Leak
- Simulative Use (including component compatibility)

The following testing was leveraged from K201489:

- 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

- Biocompatibility
  - 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)

Animal testing was not required for the determination of substantial equivalence.

Clinical testing was not required for the determination of substantial equivalence.

Test results demonstrate that all acceptance criteria were met; therefore, the device meets the established product specifications.

Conclusion: The proposed device modifications to the Traveler™ Portal Vein Access Set do not change its intended use or principles of operation. 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 device.