December 15, 2025

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

Re: K253741
Trade/Device Name: V·Stick™ Vascular Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 24, 2025
Received: November 24, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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)*
K253741

Device Name

V•Stick™ Vascular Access Set

Indications for Use *(Describe)*

The V•Stick™ Vascular Access Set is intended for use in the introduction and placement of guidewires and/or catheters.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
V•Stick™ Vascular Access Set

Date Prepared:	November 24, 2025
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 Phone: 903-676-4276 Fax: 903-677-9396 Email: ana.hughes@argonmedical.com
Device Trade Name:	V•Stick™ Vascular Access Sets
Device Common Name:	Vascular Access Set
Device Classification:	Introducer, Catheter Product code, DYB 21 CFR 870.1340 Class II Review Panel: Cardiovascular Devices
Predicate Device(s):	Primary: K130730 V•Stick™ Vascular Access Set Reference: K223791 Talwire Guidewire
Description of the Device:	The V•Stick™ Vascular Access Set consists of a 4F or 5F coaxial introducer set (with a 3F standard or 3F stiff dilator), a 21ga entry needle (with an echogenic or non-echogenic tip), and a 0.018" x 40cm Nitinol core and with Stainless Steel coil vascular access guidewire with an articulatable tip.
Indication for Use:	The V•Stick™ Vascular Access Set is intended for use in the introduction and placement of guidewires and/or catheters.
Device Modification:	The device modification included in this submission is limited to the removal of the Nitinol with Palladium/Rhenium (Pd/Re) guidewire and replacing it with a 0.018" x 40cm Nitinol core with Stainless Steel coil tip guidewire. All other components remain unchanged.
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, K130730. Argon conducted a design change process to evaluate the impact of proposed change. The proposed change was evaluated through the Argon risk management process which is compliant with ISO 14971:2019.

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 V•Stick™ Vascular Access Set. The tests included:

- Simulated Use (including component compatibility)
- Shipping Qualification
- Sterilization Adoption

The following testing for the guidewire was leveraged from K223791:

- Performance Testing:
  - Dimensional Attributes
  - Kink resistance
  - Visual Inspection
  - Tip flexibility
  - Simulated use
  - Radiopacity
  - Tensile strength
  - Flex resistance
  - Torque strength
  - Fracture resistance
  - Torqueability
  - Prolapse force
  - Corrosion resistance

Needle testing leveraged from K130730:

- Dimensional
- Ultrasound Visibility
- Puncture Force
- Tensile (Hub retention force)

The following testing was leveraged from K130730 & K223791:

- Biocompatibility
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Irritation Intracutaneous Reactivity (ISO 10993-10)
  - Acute Systemic Toxicity (ISO-10993-11)
  - Hemocompatibility (ISO 10993-4)
  - SC5b-9 Complement Activation (ISO 10993-4)
  - Thrombogenicity (ISO 10993-4)
  - Material Mediated Pyrogenicity in Rabbits (ISO 10993-11)

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 V•Stick™ Vascular Access Set does not change its intended use or principle of operation. Based on the Indication for Use, design, and safety and performance testing, the V•Stick™ Vascular Access Set meets the requirements for its intended use and is substantially equivalent to the predicate device.