September 7, 2023

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

Re: K232443
Trade/Device Name: Single-Loop Snare Retrieval Kit, Triple-Loop Snare Retrieval Kit
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: August 9, 2023
Received: August 14, 2023

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.09.07 11:13:13 -04'00'

Gregory O'Connell
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)*
K232443

Device Name
Single-Loop Snare Retrieval Kit
Triple-Loop Snare Retrieval Kit

Indications for Use *(Describe)*
Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are intended for the percutaneous removal of retrievable inferior vena cava (IVC) filters that are no longer medically required, via jugular approach.

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: August 9, 2023

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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Email: ana.hughes@argonmedical.com

Device Trade Name: Single-Loop Snare Retrieval Kit
Triple-Loop Snare Retrieval Kit

Device Common Name: Device, Percutaneous Retrieval

Device Classification: Device, Percutaneous Retrieval
Product code, MMX
21 CFR 870.5150
Class II
Review Panel: Cardiovascular Devices

Predicate Device(s): *Primary*: K191758 Single-Loop Snare Retrieval Kit, Triple-Loop Snare Retrieval Kit

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Description of the Device: The Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are single use devices.

The disposable system consists of: [A] 9F (ID) Inner Sheath, [B] 11F (ID) Outer Sheath, [C] 8F (OD) Dilator, [D] Hemostasis Valve with Sideport, [E] High Pressure Stopcock, [F] 7F [2.4mm] (OD) x 76cm Snare Catheter with Tuohy-Borst Y-Port Adapter, 20mm x 93cm Single-Loop Snare (fully expanded) or 30mm x 93cm Triple-Loop Snare (fully expanded) with Torque Handle.

The snares have radiopaque loops and are preloaded in the snare catheter. The snare catheter, inner sheath, and outer sheath have a radiopaque marker band at the distal tip for enhanced fluoroscopic visualization.

Indication for Use:	Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are intended for the percutaneous removal of retrievable inferior vena cava (IVC) filters that are no longer medically required, via jugular approach.
Device Modification:	The device modification included in this submission is limited to the change of inner layer material of the 11F (ID) Outer Sheath.
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, K191758.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, supplemental verification testing was identified to support the substantial equivalence of the modified Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit. Testing included:

- Outer Sheath – Visual
- Outer Sheath – Dimensional
- Outer Sheath – Tensile Strength
- Outer Sheath – Liquid Leakage
- Simulated Use
- Outer Sheath – Delamination

Biocompatibility:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or Intracutaneous Reactivity (ISO 10993-23)
- Material Mediated Pyrogen (ISO 10993-11)
- Acute Systemic Toxicity (ISO 10993-11)
- Hemocompatibility (ISO10993-4)
    - ASTM Hemolysis, Direct and Extract
    - Complement Activation, SC5b-9
    - Partial Thromboplastin (PTT)
    - Platelet and Leukocyte Count
    - *In vitro* Blood Loop

The following testing was leveraged from K191758:

- Visual/Dimensional (Inner Sheath, Dilator, Delivery Catheter Single-Loop Snare & Triple Loop Snare)
- Leak Test (Inner Sheath, Dilator and Delivery Catheter)
- Air Leak Test

- Burst Test
- Pull Test/Tensile Strength (Inner Sheath, Dilator, Delivery Catheter Single-Loop Snare & Triple Loop Snare)
- Corrosion Resistance (Single-Loop Snare & Triple Loop Snare)
- Torque Response (Snare Assembly)
- Radiopacity
- Luer Testing
- Contrast Medium Injection
- High Pressure Stopcock Testing
- Flexural Modulus and Tip Flexibility Testing
- Radial Force Testing
- Design Validation Testing and Summative Usability Testing

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 Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval kit do not change its intended use or principles of operation. Based on the Indication for Use, design, and performance testing, the Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit meet the requirements for its intended use and is substantially equivalent to the predicate device.