



December 17, 2019

Argon Medical Devices, Inc.  
Jo Huang  
Sr. Regulatory Specialist  
1445 Flat Creek Road  
Athens, Texas 75751

Re: K191758

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: November 15, 2019  
Received: November 18, 2019

Dear Jo Huang:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

## Indications for Use

510(k) Number (if known)

K191758

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

<b>Date Prepared:</b>	December 17, 2019
<b>Company:</b>	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
<b>Contact:</b>	Jo Huang Senior Regulatory Specialist Phone: 972-677-9327 Fax: 903-677-9396 Email: <a href="mailto:jo.huang@argonmedical.com">jo.huang@argonmedical.com</a>
<b>Device trade name:</b>	Single-Loop Snare Retrieval Kit Triple-Loop Snare Retrieval Kit
<b>Device Common Name:</b>	Device, Percutaneous Retrieval
<b>Device classification:</b>	Device, Percutaneous Retrieval Product code, MMX 21 CFR 870.5150 Class II Review Panel: Cardiovascular Devices
<b>Predicate Device(s):</b>	<i>Primary:</i> K152560 Bard Retrieval Kit <i>Reference:</i> K021606 Atrieve Vascular Snare Kit (formerly known as EnSnare Endo-vascular Snare and Catheter) K073374 Cook Günther Tulip Vena Cava Filter Retrieval Set
<b>Description of the device:</b>	The Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit consist of a 9F inner sheath, 11F outer sheath, 8F dilator, hemostasis valve with sideport, high pressure stop-cock, 20mm single-loop snare (fully expanded) or 30mm triple-loop snare (fully expanded), 7F snare catheter, Tuohy-Borst Y-port adapter, and 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. This product does not contain natural rubber latex. The maximum recommended infusion rate is 15mL/sec for power injection of contrast.
<b>Indications for Use:</b>	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.

**Technological  
Characteristics:**

Comparisons of Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

The Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are similar in design – device dimensional specifications, intended use, shelf life, materials and sterilization process of that of the predicate devices.

**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 guidance's and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use.

The device design has been subjected to and have passed the following tests to ensure reliable design and performance under the specified testing parameters:

Performance Testing, including:

- Tensile strength
- Liquid leakage
- Air leakage
- Corrosion Resistance
- Snare Assembly Torque Response
- Simulated Use
- Radiopacity
- Luer Testing
- Contrast medium injection
- High Pressure Stopcock Testing
- Flexural modulus and tip flexibility testing
- Design validation testing and summative usability testing
- Radial force testing

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)

- Sensitization (ISO 10993-10)
- Irritation-Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material Mediated Pyrogenicity (ISO 10993-11)
- Hemocompatibility (ISO 10993-4)
- Hemolysis (ISO 10993-4)
- Thromboresistance (ISO 10993-4)
- Complement Activation (ISO 10993-4)

**Substantial  
Equivalence:**

Based on the Indication for Use, design, safety and performance testing, the Single Loop Snare Retrieval Kit and Triple Loop Snare Retrieval Kit meet the requirements for its intended use and are substantially equivalent to the predicate devices.

**Conclusion:**

The results of all testing demonstrates that Single-Loop Snare Retrieval Kit and Triple-Loop Snare Retrieval Kit are substantially equivalent to the predicate devices