January 5, 2021

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

Re: K200963
Trade/Device Name: Halo Single-Loop Microsnare Kit
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX, DQY
Dated: November 30, 2020
Received: December 2, 2020

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 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)*
K200963

Device Name
Halo™ Single-Loop Microsnare Kit

Indications for Use *(Describe)*
The Halo™ Single-Loop Microsnare Kit is intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy.

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 K200963

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| **Date Prepared:** | May 19, 2020 |
| **Company:** | Argon Medical Devices, Inc.<br>1445 Flat Creek Road<br>Athens, Texas 75751 USA<br>Facility Registration number: 1625425 |
| **Contact:** | Ana Jimenez-Hughes<br>Sr. Regulatory Affairs Specialist<br>Phone: 903-676-4276<br>Fax: 903-677-9396<br>Email: ana.hughes@argonmedical.com |
| **Device Trade Name:** | Halo™ Single-Loop Microsnare Kit |
| **Device Common Name:** | Percutaneous Retrieval Device |
| **Device Classification:** | Device, Percutaneous Retrieval<br>Product code, MMX<br>21 CFR 870.5150<br>Class II<br>Review Panel: Cardiovascular Devices |
| **Predicate Device(s):** | *Primary*: K970668 Amplatz Goose Neck Microsnare<br><br>*Reference*: K142265 ONE Snare Endovascular Microsnare System |
| **Description of the Device:** | Halo™ Single-Loop Microsnare Kit contains: (1) Microsnare, (1) Microsnare Catheter, (1) Introducer and (1) Torque Handle.<br><br>The microsnare is constructed of a flexible and radiopaque loop. The pre-formed microsnare loop can be introduced through the microsnare catheter without risk of microsnare deformation because of the snare's super-elastic construction. The microsnare catheter is constructed of flexible tubing and contains a radiopaque marker band. |
| **Indication for Use:** | The Halo™ Single-Loop Microsnare Kit is intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy. |

**Technological Characteristics:**

A comparison of the technological characteristics of the subject device and the predicate devices shows the Halo™ Single-Loop Microsnare Kit to be substantially equivalent to the current marketed predicate devices.

The proposed Halo™ Single-Loop Microsnare Kit is similar in materials of construction, dimensional specifications, design and sterilization process to the primary predicate device, the Amplatz Goose Neck Microsnare (K970668) and the reference predicate, the ONE Snare Endovascular Microsnare System (K142265). The Halo™ Single-Loop Microsnare Kit consist of (1) microsnare made of gold plated Tungsten coil and nitinol loop; (1) microsnare catheter made of Pebax tubing/Platinum Iridium marker band, (1) peel-away introducer and (1) torque handle.

The Halo™ Single-Loop Microsnare Kit has the same principle of operation and indications for use as the predicate devices. The system is advanced through a sheath proximal to the target under imaging. The system is then manipulated to grab and reposition or grab and remove a foreign body. The intended use of the proposed device and the predicate device is the same: *for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy*.

| | **SUBJECT DEVICE** | **PRIMARY PREDICATE DEVICE** | **REFERENCE PREDICATE DEVICE** |
|---|---|---|---|
| | Halo™ Single-Loop Microsnare Kit | Amplatz Goose Neck Microsnare | ONE Snare Endovascular Microsnare System |
| **Manufacturer** | Argon Medical Devices | ev3 Inc. | Merit Medical Systems, Inc. |
| **510(k)** | TBD | K970668 | K142265 |
| **Class** | II | **SAME** | **SAME** |
| **Classification Name** | Device, Percutaneous Retrieval | Catheter, Percutaneous | **SAME** |
| **Regulation** | 21 CFR 870.5150 | 21 CFR 870.1250 | **SAME** |
| **Technical Characteristics Comparison** | | | |
| **Device Description** | Each Halo Single-Loop Microsnare kit consists of (1) microsnare, (1) microsnare catheter, (1) introducer and (1) torque handle. The microsnare is constructed of a flexible and radiopaque loop. The pre-formed microsnare loop can be introduced through the microsnare catheter without risk of microsnare deformation because of the microsnare's super-elastic construction. The microsnare catheter is constructed of flexible tubing and contains a radiopaque marker band. | The Amplatz "GOOSE NECK" Microsnare is a percutaneous retrieval and manipulation device with a uniquely shaped retriever loop. The "GOOSE NECK" Microsnare component consists of a core wire, with the "beak-like" retriever loop mounted at a right angle to the axis of shaft at its distal tip. The device is primarily comprised of a nickel-titanium alloy allowing virtual kink-resistance performance during navigation and retrieval of a foreign object. | ONE Snare Endovascular Microsnare System contains: (1) Snare, (1) Snare Catheter, (1) Insertion Tool and (1) Torque Device. The snare is constructed of nitinol cable and a gold-plated tungsten loop. The pre-formed snare loop can be introduced through catheters without risk of snare deformation because of the snare's super-elastic construction. The snare catheter is constructed of polyether block amide and contains a platinum/iridium radiopaque marker band. |

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| **Catheter, French Size** | 3F | 2.3-3F | 2.3-3F |
| **Catheter, working length (cm)** | 150 & 175 | **SAME** | **SAME** |
| **Catheter, composition** | Pebax tubing with<br>Platinum Iridium Marker Band | HDPE<br>Barium Sulfate<br>Platinum/Iridium Marker Band<br>LDPE<br>TPXRT 18X B resin | Polyether block amide (Pebax) |
| **Catheter Tip Flexibility** | Equivalent per Characterization Testing | Equivalent per Characterization Testing | Not available |
| **Snare Loop Diameter (mm)** | 2, 4 & 7 | **SAME** | **SAME** |
| **Snare Length (cm)** | 175 & 200 | **SAME** | **SAME** |
| **Snare Tip Flexibility** | Equivalent per Characterization Testing | Equivalent per Characterization Testing | Not available |
| **Snare composition** | Gold plated Tungsten coil<br>Nitinol Loop<br>Nitinol shaft<br>PTFE heat shrink | Gold plated Tungsten coil<br>Nitinol Loop<br>Nitinol shaft<br>PTFE heat shrink | Gold plated tungsten coil<br>Nitinol Loop<br>Nitinol shaft |
| **Torque Handle** | **YES** | **SAME** | **SAME** |
| **Introducer Style** | Peel-Away Introducer | Introducer | **SAME** |
| **Single Use** | YES | **SAME** | **SAME** |
| **Supplied Sterile** | YES | **SAME** | **SAME** |
| **Sterilization** | 100% EtO | **SAME** | **SAME** |

The Halo™ Single-Loop Microsnare Kit was subject to applicable testing to demonstrate equivalence, based upon the product performance, design and intended use.

**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 Halo™ Single-Loop Microsnare Kit substantial equivalence.

<u>Performance Testing, including:</u>

- Tensile strength
- Liquid leakage
- Air leakage
- Corrosion Resistance
- System Tip Flexibility

- Tip Flexibility – Microsnare & Microsnare Catheter
- Snare Flexing & Fracture Test
- Catheter Flexural Modulus
- Catheter Kink Test
- Marker Band Pull Test
- Torque Strength Test
- Simulative Use
- Radiopacity
- Particulate
- Luer Testing
- Shipping Test

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
  - Platelet and Leucocyte Counts
  - Partial Thromboplastin Time (PTT)

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| **Substantial Equivalence:** | Based on the Indication for Use, design, and safety and performance testing, the Halo™ Single-Loop Microsnare Kit meets the requirements for its intended use and is substantially equivalent to the predicate devices. |
| **Conclusion:** | The results of all testing demonstrate that the Halo™ Single-Loop Microsnare Kits are substantially equivalent to the predicate devices. |