September 10, 2024

Argon Medical Devices, Inc.
Scott Bishop
VP Regulatory Affairs
1445 Flat Creek Road
Athens, Texas 75751

Re: K242612
Trade/Device Name: Option ELITE Vena Cava Filter System and Option™ELITE Vena Cava Filter 100cm System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: August 30, 2024
Received: September 3, 2024

Dear Scott Bishop:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.09.10 14:57:48 -04'00'

For

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242612

Device Name
Option™ELITE Vena Cava Filter System and Option™ELITE Vena Cava Filter 100cm System

Indications for Use *(Describe)*
The Option™ELITE Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava (IVC) in the following conditions:
• Pulmonary thromboembolism when anticoagulants are contraindicated
• Failure of anticoagulant therapy in thromboembolic disease
• Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
• Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated
The Option™ELITE Filter may be removed according to the instructions supplied in the Section IX, entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can only be performed by the jugular approach.

The Option™ELITE Vena Cava Filter 100cm System is indicated for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:
• Pulmonary thromboembolism when anticoagulants are contraindicated
• Failure of anticoagulant therapy in thromboembolic disease
• Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
• Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Option™ELITE Filter may be removed according to the instructions supplied in the Section IX, entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can only be performed by the 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.

Option Elite Vena Cava Filter System
510(k) Summary

Date Prepared: August 28, 2024

Submitted By:

Argon Medical Devices Inc.
1445 Flat Creek Road
Athens, TX 75751

Contact: Scott Bishop
Phone: (469) 430-0546
Email: Scott.Bishop@argonmedical.com

Device:

Trade Name:	Option™ELITE Vena Cava Filter System
	Option™ELITE Vena Cava Filter 100cm System
Common Name:	Inferior Vena Cava Filter
Classification Name:	Filter, Intravascular, Cardiovascular
Regulation/Product Code:	21 CFR Part 870.3375 / DTK
Classification / Panel:	Class II / Cardiovascular

Predicate Devices:
The Option™ELITE Vena Cava Filter System (K133243, cleared Dec. 17, 2013) and the Option™ELITE Vena Cava Filter 100cm System (K143405, cleared April 16, 2015).

Summary of Change:
No changes have been made to the subject Option Elite Vena Cava Filter System or 100cm System. The purpose of the submission is to incorporate results from the PRESERVE study summary data into the IFU.

Device Description:
The Option™ELITE Vena Cava Filter is designed for the prevention of recurrent pulmonary embolism via percutaneous delivery in the inferior vena cava (IVC).

The Option™ELITE Vena Cava Filter 100cm System is designed for IVC filter insertion, delivery, deployment and placement via the popliteal and antecubital approach.

The self-centering Option™ELITE Filter is laser cut from nickel – titanium alloy (Nitinol) tubing. The Option™ELITE Filter consists of shape memory Nitinol struts emanating from a central location and is designed for optimal clot capture. Retention anchors (retention hooks) are located at the caudal portion of the filter. These anchors are intended for filter fixation to the

vessel wall. The Option™ELITE Filter is intended to be used in caval diameters up to 30mm. A retrieval hook is centrally located at the cranial extremity.

The constrained Option™ELITE Filter is flexible and expands to the internal diameter of the IVC upon deployment. The Option™ELITE Filter imparts an outward radial force on the luminal surface of the vena cava to ensure proper positioning and stability. The Option™ ELITE Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (5F ID), Angiographic Vessel Dilator with an open end, and a Pusher with deployment marker.

The Angiographic Vessel Dilator has side holes and 2 radiopaque markers, separated by 32mm (between the marker bands), that provide linear measurement of the inferior vena cava and assists in angiographic visualization when radiopaque contrast is delivered. The pusher advances the filter through the Catheter Sheath Introducer up to the deployment marker, and is then used to fix the filter in place during uncovering. The location of the distal end of the Catheter Sheath Introducer can be controlled by rotating the entire device to position the Catheter Sheath Introducer in the center of the vena cava. The Filter Cartridge houses the Option™ELITE Filter. The body of the Cartridge has text and colored arrows printed on it that identify assembly orientation, femoral is printed in green and jugular is printed in blue. The arrow of the desired access site will point into the Catheter Sheath Introducer hub. The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

Intended Use:

Option™ELITE Vena Cava Filter

The Option™ELITE Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava (IVC) in the following conditions:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Option™ELITE Filter may be removed according to the instructions supplied in the Section IX, entitled “Optional Procedure for Filter Retrieval” in patients who no longer require a filter. Retrieval of the filter can only be performed by the jugular approach.

Option™ELITE Vena Cava Filter (100cm)

The Option™ELITE Vena Cava Filter 100cm System is indicated for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Option™ELITE Filter may be removed according to the instructions supplied in the Section IX, entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can only be performed by the jugular approach.

Comparison to Predicate Device:

Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices, the Option™ ELITE Vena Cava Filter System & the Option Elite Vena Cava Filter 100cm System, are identical to the predicate devices, specifically:

- Intended Use = Identical
- Indication for Use = Identical
- Target Population = Identical
- Delivery System Design = Identical
- Filter Design and Material = Identical
- Fundamental scientific technology = Identical
- Packaging Configuration = Identical
- Method of Sterilization and SAL level = Identical

Performance Testing Summary:

No new operating principles have been introduced with the subject device. The subject device operates using the identical fundamental scientific technology as the predicate device; therefore, no performance testing was necessary nor was any performed. The clinical testing was previously provided to FDA under the Investigational Device Exemption and the PRESERVE study.

Conclusion:

The Option™ ELITE Vena Cava Filter System & the Option Elite Vena Cava Filter 100cm System are substantially equipment to the legally marketed predicate devices. No changes have been made to the Option Elite Filter or delivery system. The purpose of the submission is to incorporate results from the PRESERVE study summary data into the IFU.