June 26, 2024

Aln S.a.r.l.
Alain Nigon
Managing Director
589 chemin du Niel
Bormes les Mimosas, 83230
France

Re: K241507
Trade/Device Name: ALN Optional Vena Cava Filter (FB.010500, FF.010995, FJ.120096, FB.HOOK, FF.HOOK, FJ.HOOK)
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: April 22, 2024
Received: May 28, 2024

Dear Nigon Alain:

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.

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: 2024.06.26 11:08:56 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241507

Device Name

ALN Optional Vena Cava Filter (FB.010500, FF.010995, FJ.120096, FB.HOOK, FF.HOOK, FJ.HOOK)

Indications for Use *(Describe)*
The ALN Optional Vena Cava Filter with Hook and without Hook are indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

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

ALN Optional Vena Cava Filters with Hook and without Hook, may be retrieved with the ALN Extraction and /or Repositioning Kits according to the Instructions For Use of these devices.

The ALN Optional Vena Cava Filter with Hook may be also retrieved with a standard GooseNeck Snare according to the the Instructions For Use of this medical device.

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.

Submitter

510(k) Submitter

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Date Prepared June 25, 2024

Device

Trade Name of the Device	ALN Optional Vena Cava Filter (FB.010500, FF.010995, FJ.120096, FB.HOOK, FF.HOOK, FJ.HOOK)
Common Name of the Device	Vena Cava Filter
Classification Name	Cardiovascular Intravascular Filter (CFR 870.3375)
Product code	DTK
Regulatory Class	II
Device Panel	Cardiovascular

Device Description

The device is unchanged in comparison to the predicate device.

The ALN Optional Vena Cava Filter is a conical-shaped structure made of 316LVM stainless steel and consisting of 9 legs (i.e., 9 filtering elements). The 6 shortest legs (i.e., anchoring legs) are ended with distal hooks and each leg has a different length to avoid intertwining when the filter is introduced into the sheath or released in the vessel. The 3 longest legs (i.e., centering legs) have no hooks and serve to line up the cone along the vena cava axis. The loop at the end of the longest one helps to push the filter during its implantation through the femoral vascular approach. All 9 legs are equally involved in capturing and breaking an embolus. The ALN Optional Vena Cava Filter is about 55 mm high and is suitable for vena cava diameters up to 32 mm. The implantation approaches may be jugular, brachial or femoral. The ALN Optional Vena Cava Filter with a Hook is the same ALN Optional Vena Cava Filter with an additional 4mm retrieval hook on the apex of the device.

Intended Use and Indications for Use

The intended use and the indications for Use are unchanged in comparison to the predicate device.

The ALN Optional Vena Cava Filter with Hook and without Hook are indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

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

ALN Optional Vena Cava Filters with Hook and without Hook, may be retrieved with the ALN Extraction and/or Repositioning Kits according to the Instructions For Use of these devices.

The ALN Optional Vena Cava Filter with Hook may be also retrieved with a standard GooseNeck Snare according to the Instructions For Use of this medical device.

Predicate Device for equivalence

The legally marketed device to which ALN S.A.R.L. is claiming equivalence is ALN Optional Vena Cava Filter:

Trade Name	ALN Optional Vena Cava Filter and ALN Extraction and/or Repositioning Kit
510(k) Number	K163699
Common Name	Vena Cava Filter and Extraction Kit
Classification Name	Cardiovascular Intravascular filter (870.3375)
Product Code	DTK
Regulatory Class	II
Device Panel	Cardiovascular

Important note: the predicate device ALN Optional Vena Cava Filter was FDA Cleared together with ALN Extraction and/or Repositioning Kit, under the trade name “ALN Optional Vena Cava Filter and ALN Extraction and/or Repositioning Kit”. The ALN Extraction and/or Repositioning Kit has been designed for the retrieval of an implanted predicate device ALN Optional Vena Cava Filter. This device modification submission concerns labeling changes only

for the ALN Optional Vena Cava Filter. The labeling for the Extraction and/or Repositioning kit, remains unchanged.

Technological Characteristics

The technological characteristics are unchanged in comparison to the predicate device.

- **Technological principle:** the technological principle is unchanged in comparison to the predicate device. The mechanical trapping of blood clots. It is based on the filtering legs constituting the conical-shaped filter and the compression movement in the inferior vena cava, preventing them from reaching the heart and lungs, and reducing the risk of pulmonary embolism.

- **Design:** The design is unchanged in comparison to the predicate device. The ALN Optional Vena Cava Filter is a conical-shaped structure consisting of 9 legs at two different levels: an upper level for anchoring (6 shorter legs) and a lower level for centering (3 longer legs). The legs are crimped inside the filter apex. The distal tip of the anchoring legs is curved in a hook shape allowing an active anchorage. Two centering legs with flaked to reduce traumatic risk on the vena wall. One centering leg with a loop allow to push the filter during femoral implantation. The implantation kit includes: the ALN filter in its filter-holder, an introduction system (dilator, introducer sheath, pushing catheter), a puncture needle and a J-guidewire.

- **Raw Materials:** The raw material is unchanged in comparison to the predicate device. The ALN Optional Vena Cava Filter is made of 316 LVM stainless-steel.

- **Manufacturing process:** the manufacturing process is unchanged in comparison to the predicate device .

- **Packaging and sterilization process:** the packaging and sterilization processes are unchanged in comparison to the predicate device.

Labeling

The product labels and the patient card are unchanged in comparison to the predicate device.

The Instructions for Use are updated in comparison to the predicate device.

The PRESERVE Study summary is included in the Instruction for Use of each model of ALN Optional Vena Cava Filter, at the FDA's request.

PRESERVE is an FDA-directed multicenter, prospective, open-label, non-randomized trial that studied the safety and efficacy of IVC filters from six manufacturers, including ALN. The study demonstrates inferior vena cava (IVC) filters are safe and effective way to treat venous thromboembolism (VTE).

Substantial Equivalence

The design, material, components, fundamental technology, intended use and indications for use are unchanged in comparison to the predicate device.

The reason for submitting this Special 510(k) notification is about a labeling change, requested by the FDA to all manufacturer following the PRESERVE study outcomes: inclusion of new clinical data (summary of the PRESERVE study) in the Instruction for Use of the ALN Optional Vena Cava Filter.

Conclusion

The comparison of design, material, components, technological characteristics, intended use, and indications for use demonstrate that the modification to the labeling does not raise new questions of safety and effectiveness and supports substantial equivalence of the subject device to the predicate device.