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JAN 30 2008

510(K) SUMMARY

ALN Optional Vena Cava Filter and Extraction Kit

1. General information

510(K) Submitter	ALN Implants Chirurgicaux Mr Alain NIGON 589 chemine de Niel 93230 BORMES LES MIMOSAS FRANCE Tel.: +33 4 94 01 05 01 Fax: +33 4 94 01 09 01 Alain.nigon@aln2b.com
Contact	NAMSA Advisory Services Mrs Julianne Slaughter 900 Circle 75 Parkway Suite 1240 ATLANTA GEORGIA 30339 USA Tel.: 770 563 1665 Fax: 770 563 1661 jslaughter@namsa.com
Date of the summary preparation	January 4th, 2007
Common Name of the Device	Optional Vena Cava Filter and Retrieval Kit
Trade Name of the Device	ALN Optional Vena Cava Filter and Extraction Kit
Classification Name	Cardiovascular Intravascular Filter (21 CFR 870.3375, Product Code DTK)
Class	II
Device Panel	Cardiovascular

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2. Predicate Devices

Predicate device 1:

Trade Name	Stainless Steel Greenfiled® Vena Cava Filter With 12F Introducer System
510(k) Number	K 912035
Common Name	Permanent Vena Cava Filter
Classification Name	Cardiovascular Intravascular filter
Class	II
Product Code	DTK
CFR Section	870.3375
Device Panel	Cardiovascular

Predicate device 2:

Trade Name	Recovery Cone® Removal System
510(k) Number	K 031328
Common Name	Vena Cava Filter
Classification Name	Cardiovascular Intravascular filter
Class	II
Product Code	DTK
CFR Section	870.3375
Device Panel	Cardiovascular

3. Device Description

The ALN Optional Vena Cava Filter and Extraction Kit consists of a 9 legs 316L stainless steel vena cava filter sold with a delivery kit, and an extraction kit with an 8 arms 316L stainless steel forceps. The filter is prepackaged in a filter holder designed to facilitate the insertion of the filter in the introducer catheter. The filter and the delivery kit are packaged together in Tyvek/film pouches and the extraction kit is packaged alone in the same type of pouches.

The ALN Optional Vena Cava Filter is designed to stop free thrombus in the vena cava in high risk patients. The insertion of the filter can be made by jugular, brachial or femoral approach and are very little traumatic, as the sheath has a 7F diameter. The extraction can be made only by jugular approach.

Siège Social : Route de la Gare 20240 Ghisonaccia
Bureaux : 589, Chemin du Niel 83230 Bormes les Mimosas -Tél : 33 (0) 4.94.01.05.01 - Fax : 33 (0) 4.94.01.09.01
S.A.R.L. au capital de 255000 €. - RCS BASTIA B 411 237 704 - SIRET 411 237 704 00019 - APE 331 B - N° TVA: FR.00 411 237 704
Adresse Email : **contact@aln2b.com** - Home page : **www.aln2b.com**

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4. Intented Use

The ALN Optional Vena Cava Filter is 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.

The ALN optional filter may be removed according to the instructions supplied in the Instruction for Use of the ALN Extraction Kit.

5. Technological Characteristics

The ALN Optional Vena Cava Filter has the same technological characteristics as the two predicate devices except for the items listed below which all shown no additional risk for safety and effectiveness:

- 7F Sheath introducer (present) vs 12F or 10F Sheath introducer (predicate)
- BRACHIAL Vascular approach (present)
- Apical fixation of wires: set (present) vs welded (predicate)
- Filter configuration: 9 wires (present) vs 6 wires (predicate)
- No plastic cone on the extraction kit (present) vs urethane cone (predicate)
- Polyethylene catheters (present) vs Pebax® catheters (predicate)
- Forceps design: 8 wires (present) vs 10 wires (predicate)

6. Non-clinical Performances

The ALN Optional Vena Cava Filter and Extraction Kit passed all the tests required to demonstrate its non clinical performances:

- Simulated deployment
- Introducer / sheath suitability
- Clot trapping ability
- Filter fracture
- Caval perforation / filter migration
- Thrombogenicity
- MRI compatibility

Moreover, the filtering performances were assessed by a bench test in comparison with the predicate device (results are similar for the two devices).

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7. Clinical Performances

The safety and effectiveness of the ALN Optional Vena Cava Filter and Extraction Kit have been demonstrated via clinical data collected for 14 years. Every clinical investigation is in conformance with the FDA guidance for cardiovascular intravascular filter and a review of the literature underlines that clinical performances of ALN Optional Vena Cava Filter and Extraction Kit are similar to the clinical performances of the two predicates. The last clinical study about ALN Optional Vena Cava Filter and Extraction Kit was published in chest in 2006. It includes 220 patients who receive an ALN Optional Vena Cava Filter for prevention of venous thromboembolism. Results show low rates of complication. On the 220 filters, 55 were retrieved after a mean period of 51 days (range: 6 – 352 days) without any complication.

8. Substantial Equivalence

The design, material, components, fundamental technology, intended use, non clinical and clinical performances of the ALN Optional Vena Cava Filter and Extraction Kit are identical and therefore substantially equivalent to the predicates :
- Stainless steel Greenfield® vena cava filter with 12F introducer system (K 912035)
- Recovery Cone® Removal System (K 031328)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

ALN Implants Chirurgicaux
c/o Ms. Julianne Slaughter
NAMSA Advisory Services
900 Circle 75 Parkway
Suite 1240
Atlanta, GA 30339

Re: K070514
Trade/Device Name: ALN Optional Vena Cava Filter and Extraction Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: November 5, 2007
Received: November 13, 2007

Dear Ms. Slaughter:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indication for Use Statement

510(k) Number (if know): K070514

Device Name: ALN Optional Vena Cava Filter and Extraction Kit

Indications for Use:

The ALN Optional Vena Cava Filter is 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.

The ALN Optional Vena Cava Filter may be retrieved according to the instructions supplied in the Instruction For Use of the ALN Extraction Kit.

Extraction kit: The ALN Optional Vena Cava Filter Extraction Kit has been designed for the removal of an implanted ALN Optional Vena Cava Filter in patients who no longer require a filter. The retrieval of the filter can be performed only by jugular approach.

Prescription Use ☑ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochaver
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070514