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K113124

NOV 9 2012

510(K) SUMMARY

ALN Optional Vena Cava Filter and Extraction Kit

1. General information

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Date of the summary preparation	May 22nd, 2012
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

Predicate device 3:

Trade Name	Gunther Tulip Vena Cava Filter
510(k) Number	K 090140
Common Name	Vena Cava Filter
Classification Name	Cardiovascular Intravascular filter
Class	II
Product Code	DTK
CFR Section	870.3375
Device Panel	Cardiovascular

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S.A.R.L. au capital de 1 000 000 €. - RCS BASTIA B 411 237 704 - SIRET 411 237 704 00019 - APE 3250A - N° TVA: FR.00 411 237 704
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Predicate device 4:

Trade Name	ALN Optional Vena Cava Filter and Retrieval Kit
510(k) Number	K 070514
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 with or without a retrieval hook 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.

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 Vena Cava Filter may be removed according to the instructions supplied in the Instruction for Use of the ALN Extraction Kit.
The ALN Optional Vena Cava Filter with Hook optional filter may be removed according to the instructions supplied in the Instruction for Use of the ALN Extraction Kit or with a Standard Gooseneck Snare.

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5. Technological Characteristics

The ALN Optional Vena Cava Filter and Extraction Kit has the same technological characteristics as the four predicate devices except for the items listed in the table below which all shown no additional risk for safety and effectiveness because it share each technological characteristic with at least one of the predicates.

Technological characteristic	Present	Predicate 1	Predicate 2	Predicate 3	Predicate 4
Brachial vascular approach	YES	NO	NO	NO	YES
Filter sheath introducer	7F	12F	-	7F	7F
Filter material	Stainless steel	Stainless steel	-	Conichrome	Stainless steel
Apical fixation of wires	Set	Welded	-	Welded	Set
Hook on the filter head	YES	NO	-	YES	NO
Filter configuration	9 wires	6 wires	-	4 wires	9 wires
Base diameter	28-32 mm	28 mm	-	30 mm	28-32 mm
Filter height	55 mm	50 mm	-	50 mm	55 mm
Extraction kit sheath introducer	9F	-	10F	-	9F
Plastic cone on the pincer	NO	-	YES	-	NO
Catheters material	PE	-	Pebax®	-	PE
Forceps design	8 wires	-	10 wires	-	8 wires
Forceps angulation of 90°	YES	-	YES	-	NO

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

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- 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 one the predicate device (results are similar for the two devices).

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)
- Gunther Tulip Vena Cava Filter (K 090140)
- ALN Optional Vena Cava Filter and Retrieval Kit (K 070514)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

ALN Implants Chirurgicaux
c/o Ms. Cynthia Couttereau
TWOKSA Conseil
2 Rue Quenot
Jarnac
France 16200

NOV 9 2012

Re: K113124
Trade/Device Name: ALN Optional Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: October 24, 2012
Received: October 26, 2012

Dear Ms. Couttereau:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram 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): K113124

Device Name: ALN Optional Vena Cava Filter and Extraction Kit

Indications for Use:

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

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

Extraction kit: The ALN Optional Vena Cava Filter Extraction Kit has been designed for the removal of an implanted ALN Optional Vena Cava Filter or ALN Optional Vena Cava Filter with Hook 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113124