DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 22, 2016

Cook Incorporated
Jessica Swafford
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K161218
Trade/Device Name: Gianturco-Roehm Bird's Nest Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: April 28, 2016
Received: April 29, 2016

Dear Ms. Jessica Swafford:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161218

Device Name
Gianturco-Roehm Bird's Nest® Vena Cava Filter

Indications for Use *(Describe)*
The Gianturco-Roehm Bird's Nest® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:
1. Pulmonary thromboembolism when anticoagulants are contraindicated;
2. Failure of anticoagulant therapy in thromboembolic diseases;
3. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
4. Prophylactically in patients with chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

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.

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510(k) SUMMARY K161218

Submitted By:

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P.O. Box 489
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Phone: (812) 335-3575 x104260
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Date Prepared: April 28, 2016

Device:

Trade Name:	Gianturco-Roehm Bird's Nest® Vena Cava Filter
Common Name:	Vena Cava Filter
Classification Name:	Filter, Intravascular, Cardiovascular DTK (21 CFR §870.3575)

Indications for Use:

The Gianturco-Roehm Bird's Nest® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

1. Pulmonary thromboembolism when anticoagulants are contraindicated;
2. Failure of anticoagulant therapy in thromboembolic diseases;
3. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
4. Prophylactically in patients with chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Predicate Devices:

The device subject of this submission is substantially equivalent to the predicate devices, the Gianturco-Roehm Bird's Nest® Vena Cava Filters approved under PMA number P850049 (down classified on May 1, 2000 under 65 FR 17144) and cleared under K073528 on February 27, 2008.

Comparison to Predicate Devices:

It has been demonstrated that the Gianturco-Roehm Bird's Nest® Vena Cava Filter is comparable to the predicate devices. The Gianturco-Roehm Bird's Nest® Vena Cava Filter is identical in

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terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate devices. The labeling of the device is being modified to include MRI information from recent testing as well as to align with current standards.

Device Description:

The Gianturco-Roehm Bird's Nest® Vena Cava Filter is a permanent cardiovascular intravascular filter intended for percutaneous insertion into the inferior vena cava and positioning below the renal veins and above the iliac veins. The Gianturco-Roehm Bird's Nest® Vena Cava Filter utilizes a fine-wire stainless steel multiplane filtering system. The Gianturco-Roehm Bird's Nest® Vena Cava Filter is placed via standard percutaneous entry (Seldinger) technique with fluoroscopic control.

Access sites for filter delivery include both left and right femoral veins, and left and right internal jugular veins. The 11.0 French delivery catheters are available in a 40 and 45 centimeter length for femoral vein approach and a 75 centimeter length for jugular vein approach.

The Gianturco-Roehm Bird's Nest® Vena Cava Filter is designed for use in venae cavae measuring up to 40 millimeters in diameter. Caval measurements should be performed prior to filter insertion, and care should be taken to ensure proper strut fixation.

Test Data:

The following testing was performed to demonstrate that the Gianturco-Roehm Bird's Nest® Vena Cava Filter, subject of this submission, met applicable design and performance requirements and support a determination of substantial equivalence:

- MRI Testing – MRI testing verifies the marking of the implant as *MR Conditional* with the applicable parameters described in the Instructions for Use.

In conclusion, the testing results provide reasonable assurance to support a determination that the device is substantially equivalent to the predicate devices