K121629

JUL 3 2012

510(k) Summary

Date Prepared: 31 May 2012

Submitted By:

William Cook Europe ApS
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Contact: Camilla Wamberg Munkesoe
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Device:

Trade Name: Cook Celect® Platinum Vena Cava Filter Set For Femoral Approach

Cook Celect® Platinum Vena Cava Filter Set For Jugular Approach

Cook Celect® Platinum Vena Cava Filter Set For Femoral and Jugular Approach

Common Name: Inferior Vena Cava Filter

Classification Name: Cardiovascular Intravascular Filter

(21 CFR 870.3375, Product Code DTK)

Classification: Class II

Indications for Use:

The Cook Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;

- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Cook Celect Platinum Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Filter Retrieval Set (not included in the filter set).

The product is intended for percutaneous placement via a femoral or jugular vein for filtration of inferior vena cava (IVC) blood to prevent pulmonary embolism.

Predicate Devices:

The Cook Celect Platinum Vena Cava Filter Sets are substantially equivalent to the predicate Cook Celect Vena Cava Filter Sets (K073374, K090140, K121057). The femoral introducer is identical to the femoral introducer of the predicate Cook Celect Vena Cava Filter Set with Flexible Tip (K121057), and the jugular introducer is identical to the jugular introducer of the predicate Cook Celect Vena Cava Filter Set (K090140). The Cook Celect Platinum Vena Cava Filter implant is substantially equivalent to the Cook Celect Vena Cava Filter implant of the predicate Cook Celect Vena Cava Filter Sets (K073374, K090140, K121057). Compared to the predicate devices, the Cook Celect Platinum Vena Cava Filter Sets have identical indications for use, the same fundamental technological characteristics, and similar materials of construction.

Device Description:

The Cook Celect Platinum Vena Cava Filter is an inferior vena cava filter intended for use in prevention of recurrent pulmonary embolism. The filter is intended for percutaneous placement via either the jugular vein or femoral vein for filtration of inferior vena cava (IVC) blood. The Cook Celect Platinum Vena Cava Filter Set is available in a Femoral Set and a Jugular Set. Each Set consists of a preloaded filter, a coaxial introducer sheath system, a hydrophilically coated pre-dilator, and a three-way stopcock. The filter is introduced and placed via a 7.0 French coaxial introducer sheath system with a Check-Flo® valve. The femoral filter introducer has a flexible tip. The introducer dilator is a 7.5 French injectable dilator with 8 sideports. The Cook Celect Platinum Vena Cava Filter Set is also available in a universal vein access version consisting of components for both femoral and jugular vein approaches. The Cook Celect Platinum Vena Cava Filter is constructed from a cobalt chromium alloy. The radiopaque marker

on each primary leg is constructed from a platinum tungsten alloy; the radiopaque markers enhance filter visibility on procedural imaging. The filter is approximately 49 mm long along its main axis when compressed to a diameter of 30 mm.

Technological Characteristics:

The Cook Celect Platinum Vena Cava Filter Sets have the same intended use, the same fundamental technological characteristics, and similar materials of construction as the predicate Cook Celect Vena Cava Filter Sets. The jugular and femoral introducers of the filter sets are physically identical to the predicate devices. The filter implant has a radiopaque marker on each primary leg to enhance filter visibility on procedural imaging.

Non-clinical Performance Data:

The Cook Celect Platinum Vena Cava Filter Sets were subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Bend Strength Testing
- Force Measurement Testing
- Fatigue Testing
- Radiopacity Testing
- Deployment Testing
- Corrosion Testing
- MRI Testing
- Biocompatibility Testing
- Animal Testing
- Shipping Testing

The results of these tests provide reasonable assurance that the devices have been designed and tested to assure conformance to the requirements for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

William Cook Europe ApS
C/O Ms. Jennifer Brown
MED Institute Inc.
1 Geddes Way
West Lafayette, IN 47906

JUL 3 2012

Re: K121629
Trade/Device Name: Cook Celect® Platinum Vena Cava Filter Sets
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: June 1, 2012
Received: June 4, 2012

Dear Ms. Brown:

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

Enclosure

Indications for Use

510(k) Number (if known): K121629

Device Name: Cook Celect® Platinum Vena Cava Filter Set For Femoral Approach
Cook Celect® Platinum Vena Cava Filter Set For Jugular Approach
Cook Celect® Platinum Vena Cava Filter Set For Femoral and Jugular Approach

The following Indication for Use statement is identical to the predicate devices:

The Cook Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

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

The Cook Celect Platinum Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Filter Retrieval Set (not included in the filter set).

The product is intended for percutaneous placement via a femoral or jugular vein for filtration of inferior vena cava (IVC) blood to prevent pulmonary embolism.

Prescription Use XX 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 K121629