APR - 3 2009

510(k) SUMMARY

Submitted By: Molly Busenbark
William Cook Europe ApS
Sandet 6, DK-4632
Bjaeverskov, Denmark
(812) 339-2235 x 2162

Device:

Trade Name: Günther Tulip® Vena Cava Filter and Cook® Celect® Vena Cava Filter

Proposed Classification: Cardiovascular Intravascular Filter

Indications for Use:

Günther Tulip® Vena Cava Filter

The proposed Günther Tulip® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism 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 pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Günther Tulip® Vena Cava Filter may be retrieved according to the instructions supplied in the section labeled: Optional Retrieval Procedure.

Cook® Celect® Vena Cava Filter

The proposed Günther Tulip® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism 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 pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Cook® Celect® Vena Cava Filter may be retrieved according to the instructions supplied in the section labeled: Optional Retrieval Procedure.

Predicate Device:

The Günther Tulip® Vena Cava Filter is similar in terms of intended use, materials of construction, and technological characteristics to the predicate Günther Tulip® Vena Cava Filter. The Cook Celect Vena Cava Filter is also similar to the predicate device in terms of intended use, materials of construction, and technological characteristics.

Device Description:

Günther Tulip® Vena Cava Filter

The Günther Tulip Vena Cava Filter is available in femoral vein and jugular vein access versions. A universal set is also available, which contains the components necessary for both the jugular and femoral filter delivery approach. The femoral set is introduced through the femoral vein, while the jugular set is introduced through the jugular vein. The device consists of a pre-loaded filter, a coaxial introducer sheath system, a hydrophilic coated dilator, and a three-way stopcock. The filter is introduced and placed via a 7.0 French coaxial introducer sheath system. The introducer dilator is a 7.0 French power injectable dilator that is 75 centimeters long.

The Günther Tulip Vena Cava Filter is constructed from conichrome. The basic design of the filter is conical with four primary legs. The end of each leg is hooked outward. The hooks are designed to secure the filter to the wall of the inferior vena cava. "Webbed" wires (like tulip petals) between the legs are bent secondary legs which maintain the shape of the filter by pressing outward toward the vein walls. These webs also increase the area into which emboli can be trapped.

Cook® Celect® Vena Cava Filter

The Cook® Celect® Vena Cava Filter is available in femoral vein and jugular vein access versions. A universal set is also available, which contains the components necessary for both the jugular and femoral filter delivery approach. The femoral set is introduced through the femoral vein, while the jugular set is introduced through the jugular vein. The device consists of a pre-loaded filter, a coaxial introducer sheath system, a hydrophilic coated dilator, and a three-way stopcock. The filter is introduced and placed via a 7.0 French coaxial introducer sheath system. The introducer dilator is a 7.0 French power injectable dilator that is 75 centimeters long.

The filter is compatible with placement in vena cavae with diameters between 15 and 30 mm and is constructed from conichrome. The design of the Cook® Celect® Vena Cava Filter allows the filter to anchor to the vena cava walls by means of the hooks at the ends of the primary legs. The secondary legs promote centering of the filter within the vena cava, and assist in caval filtering of sizeable thrombi in the bloodstream.

Substantial Equivalence:

Cook Incorporated currently markets the predicate Günther Tulip® Vena Cava Filter, which is substantially equivalent to the Günther Tulip® Vena Cava Filter, subject of this submission. The similar indications for use and technological characteristics of the Günther Tulip® Vena Cava Filter as compared to the predicate device support a determination of substantial equivalence.

William Cook Europe ApS currently markets the predicate Cook® Celect® Vena Cava Filter, which is substantially equivalent to the proposed Cook® Celect® Vena Cava Filter. The similar indications for use and technological characteristics of the Cook® Celect® Vena Cava Filter as compared to the predicate device support a determination of substantial equivalence.

Test Data:

The proposed Günther Tulip® and Cook Celect Vena Cava Filters were subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Flow Rate Testing
- Static Burst Testing
- Diameter Retention Testing
- Leak Testing
- Biocompatibility Testing
- Deployment 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
9200 Corporate Boulevard
Rockville MD 20850

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William Cook Europe ApS
c/o Ms. Molly Busenbark
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way
Bloomington, IN 47402

Re: K090140
Trade/Device Name: Günther Tulip and Cook Celect Vena Cava Filters
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: March 9, 2009
Received: March 10, 2009

Dear Ms. Busenbark:

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,

Donna R. Zuckerman

Bram 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): K090140

Device Name: Günther Tulip® Vena Cava Filter and Cook® Celect® Vena Cava Filter

Indications for Use for Günther Tulip® Vena Cava Filter:

The Günther Tulip® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism 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 pulmonary embolism when anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism when anticoagulant therapy has failed or is contraindicated.

Indications for Use for Cook® Celect® Vena Cava Filter:

The Cook® Celect® Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism 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 pulmonary embolism when anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism when anticoagulant therapy has failed or is contraindicated.

Prescription Use XX (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use ____ (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. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090140