COOK®

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APR 20 2007

510(k) Summary

510(k) Owner:	William Cook Europe, ApS
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Contact:	Thalia Brine
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Contact Phone Number:	812-339-2235
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Date 510(k) Summary Prepared:	26 June 2006
Trade name:	Cook Celect™ Vena Cava Filter
Common name:	Inferior Vena Cava Filter
Classification name:	Cardiovascular intravascular filter 21 CFR 870.3375, Product Code DTK

Substantial Equivalence:

The Cook Celect Vena Cava Filter is substantially equivalent to the Günther Tulip Vena Cava Filter (#K000855, cleared on 18 October 2000), which is currently marketed. The Cook Celect Vena Cava Filter, the subject of this submission, is based on the design of the Günther Tulip Vena Cava Filter, with key similarities to the Tulip design. The similar indications for use, principles of operation, technological characteristics and results of performance testing of the Cook Celect Vena Cava Filter as compared to the predicate device support a determination of substantial equivalence.

Device Description:

The Cook Celect Vena Cava Filter is an inferior vena cava filter, intended for use in prevention of 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 filter is compatible with placement in vena cavae with diameters between 15 and 30 mm. The Cook Celect Vena Cava Filter is constructed from a biocompatible alloy. The filter is 46 mm long along its main axis, and, when unrestrained, the legs will expand radially to a base diameter of over 32 mm. 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 are the filter wires, distributed to catch thrombi in the caval bloodstream and they are shaped to assist in promote centering of the filter within the vena cava.

Intended Use:

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

The filter is intended for percutaneous placement via either the jugular vein or femoral vein. The filter is compatible with placement in vena cava with measured diameters in the range of 15 mm to 30 mm. The filter is intended for one time use.

Technological Characteristics:

Key Similarities:

The majority of the Cook Celect Vena Cava Filter components are identical to the predicate device and the design of the filter is substantially similar.

Key Differences:

The design of the secondary legs of the Cook Celect filter has been modified.

Non-clinical Testing:

The testing that has been conducted on the Cook Celect Vena Cava Filter has demonstrated that this device is substantially equivalent to the predicate device. Bench and animal testing has been performed using the Cook Celect Vena Cava

Filter, and the results have been compared with the predicate device. Both devices were tested for mechanical properties as well as the safety and performance of these devices, *in vitro* and *in vivo*. All the testing conducted demonstrates that the Cook Celect Vena Cava Filter exhibits the same safety and performance qualities of the predicate device.

The following bench testing has been performed:

1. Mechanical characteristics
2. Performance characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2007

Cook Incorporated
c/o Ms. Thalia Brine
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402-0489

Re: K061815
Trade/Device Name: Cook Celect™ Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: April 10, 2007
Received: April 11, 2007

Dear Ms. Brine:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K061815

Device Name: Cook Celect™ Vena Cava Filter

Indications for Use:

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

The filter is intended for percutaneous placement via either the jugular vein or femoral vein for filtration of inferior vena cava (IVC) blood to prevent pulmonary thromboembolism. The filter is compatible with placement in vena cava diameters between 15 and 30 mm.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use_____ (Per 21 CFR 807 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 K061815