COOK® MEDICAL

MAR - 7 2008

WILLIAM COOK EUROPE ApS
SANDET 6
4632 BJAEVERSKOV, DENMARK
PHONE +45 56 86 86 86
WWW.COOKMEDICAL.COM

Cook Celect™ Vena Cava Filter and
Günther Tulip™ Vena Cava Filter Retrieval Set
510(k) Summary
21 CFR 807.92

1. Submitter Information:

Applicant:	William Cook Europe ApS
Address:	Sandet 6, DK-4632 Bjaeverskov, Denmark
Phone Number:	011-45-56-86-86-86
Fax Number:	011-45-56-86-86-96
Contact:	Molly Busenbark, Regulatory Affairs Specialist
Contact Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	812-339-2235 Ext. 2162
Contact Fax Number:	812-332-0281

2. Device Information:

Filter -	
Trade name:	Cook Celect™ Vena Cava Filter
Common name:	Inferior Vena Cava Filter
Classification:	Class II
Regulation:	21 CFR 870.3375
Product Code:	DTK
Retrieval Set -	
Trade name:	Günther Tulip™ Vena Cava Filter Retrieval Set
Common name:	Percutaneous Retrieval Device
Classification:	Class II
Regulation:	21 CFR 870.5150
Product Code:	MMX

3. Predicate Device:
The Cook Celect Vena Cava Filter Set with its expanded indications for use statement is substantially equivalent (identical) to the Cook Celect Vena Cava Filter (D.C.# K061815, cleared on 20 April 2007).

The Günther Tulip Vena Cava Filter Retrieval Set with its expanded indications for use statement is substantially equivalent (identical) to the Günther Tulip Vena Cava Filter Retrieval Set (D.C.# K032426, cleared on October 31, 2003).

4. 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 Cook Celect Vena Cava Filter is constructed from a biocompatible alloy. The filter is 48 mm long along its main axis when compressed to a diameter of 30 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 Günther Tulip Vena Cava Filter Retrieval Set consists of a retrieval loop system with a braided platinum wire loop, a coaxial retrieval sheath system, an entry needle, a wire guide, and a dilator. The outer sheath is provided with a radiopaque band on the distal tip for assisting in positioning of the sheath.

There have been no changes in the design, dimensions, or materials of either device.

5. 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 may be retrieved according to the instructions supplied in the section labeled "Optional Retrieval Procedure."

The Günther Tulip Vena Cava Filter Retrieval Set has been designed for retrieval of implanted Günther Tulip and Cook Celect Vena Cava Filters in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach. The Günther Tulip Vena Cava Filter Retrieval Set is supplied sterile in peel-open packages and intended for one-time use.

6. Technological Characteristics:

The Cook Celect Vena Cava Filter described in this submission is physically identical to the predicate deployment system and filter (Cook Celect Vena Cava Filter) in terms of technological characteristics (design, dimensions, and materials).

The Günther Tulip Vena Cava Filter Retrieval Set described in this submission is physically identical to the predicate device (Günther Tulip Vena Cava Filter Retrieval Set) in terms of technological characteristics (design, dimensions, and materials).

7. Reason for Filing:

This submission is for an expansion in the indications for use – a change in labeling only - in the Celect Vena Cava Filter and Günther Tulip Vena Cava Filter Retrieval Set.

This expansion is supported by bench testing on the devices demonstrating that the Celect filter can be retrieved. This expansion is supported by the results of a clinical study on 43 patients demonstrating that the Celect filter can be retrieved with a 95% success rate. A Kaplan-Meier analysis of the data predicts an 89% probability of a successful retrieval at 52 weeks.

There has been no change to the design, dimensions, or materials of the existing, cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2008

William Cook Europe ApS
c/o Ms. Molly Busenbark
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K073374
Trade/Device Name: Cook Celect™ Vena Cava Filter and Günther Tulip™ Vena Cava Filter Retrieval Set
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: February 11, 2008
Received: February 12, 2008

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. Lechner

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

Indications for Use

510(k) Number (if known): K073374

Device Name: Cook Celect™ Vena Cava Filter and Günther Tulip™ Vena Cava Filter Retrieval Set

Indications for Use for Cook Celect™ Vena Cava Filter:

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 may be retrieved according to the instructions supplied in the section labeled "Optional Retrieval Procedure."

Indications for Use for Günther Tulip™ Vena Cava Filter Retrieval Set:

The Günther Tulip™ Vena Cava Filter Retrieval Set has been designed for retrieval of implanted Günther Tulip™ and Cook Celect™ Vena Cava Filters in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/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)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073374