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Special 510(k): Device Modification
Günther Tulip™ Vena Cava Filter
COOK INCORPORATED
9 August 2007

510(k) SUMMARY

Submitted By:

Molly Busenbark
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN
(812) 339-2235 x 2162

NOV 0 8 2007

Device:

Trade Name:	Günther Tulip™ Vena Cava Filter
Proposed Classification:	Cardiovascular Intravascular Filter

Indications for Use:

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.

Retrieval Set

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

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.

Device Description:

The Günther Tulip™ Vena Cava Filter is available in femoral version, jugular version, or a universal set. The femoral set is introduced through the femoral vein, while the jugular

set is introduced through the jugular vein. The universal set includes both femoral and jugular vein versions. The device consists of a pre-loaded filter introducer, a coaxial introducer sheath system, a hydrophilic coated dilator, and a three-way stopcock. The filter is introduced and placed via an 8.5 French coaxial introducer sheath system. The introducer dilator is an 8.5 French power injectable dilator that is 71 centimeters long. The basic design of the filter is conical with four legs. The filter is supplied sterile in peel-open packages and intended for one-time use.

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.

Test Data:

The proposed Günther Tulip™ Vena Cava Filter was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

- Tensile Testing
- Flow Rate Testing
- Static Burst Testing
- Three-Point Bend Testing
- Drop Testing
- Biocompatibility Testing
- Accelerated Aging Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

Cook Incorporated
c/o Ms. Molly Busenbark
Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402

Re: K072240
Günther Tulip™ Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 4, 2007
Received: October 9, 2007

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 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochnes

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): K072240

Device Name: Günther Tulip™ Vena Cava Filter

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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. Vuchinich

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072240