K032426

OCT 3 1 2003

510(k) SUMMARY

Submitted By:	Cook Incorporated
Contact:	Jennifer Bosley, MBA Regulatory Affairs Coordinator Tel: (812) 339-2235 Fax: (812) 332-0281
Date Prepared:	October 31, 2003

Device:

Trade Name:	Günther Tulip™ Vena Cava Filter and Retrieval Set
Common/Usual Name	Inferior Vena Cava Filter and Retrieval Set
Proposed Classification: & Product Code	Filter, Intravascular, Cardiovascular 21 CFR §870.3375, Class II, DTK—Cardiovascular

Intended Use:

Filter Set:

The Günther Tulip™ Vena Cava Filter Set is indicated 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 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 jugular approach.

Predicate Devices:

The subject devices are substantially equivalent to predicate devices: Günther Tulip™ Vena Cava MR*eye*® Filter, #K000855 (Cook Incorporated); Amplatz Goose Neck Snare, #K972511 (Microvena Corp.); and the Radius Microsnare, #K022201 (Radius Medical Technologies).

K032476

Device Description:
The Günther Tulip™ Vena Cava Filter and Retrieval Set is an inferior vena cava filter with a radiopaque band at the tip, which can be introduced via either femoral or jugular vein. The radiopaque retrieval catheter has a braided platinum loop at the distal end.

Substantial Equivalence:
The subject device is similar with respect to intended use, materials and functional characteristics of commercially available predicate devices in terms of section 510(k) substantial equivalence; any differences that may exist do not significantly affect the safety and effectiveness of the device.

Test Data:
The Günther Tulip™ Vena Cava Filter and Retrieval Set have been subjected to and have passed the following tests to ensure reliable design and performance under the specified testing parameters:

Filter Set:
- Biocompatibility
- Material and stress analysis tests
- Clinical experience

Retrieval Set:
- Biocompatibility
- Tensile
- Clinical evaluation

Clinical Experience:
To evaluate the safety of retrieving the Günther Tulip™ Vena Cava Filter, a clinical study was conducted in which 41 patients [female (n=19); male (n=22)] were enrolled for possible retrieval of the filter. Indications for placement of retrievable filter in the study included: bleeding while anticoagulated (n=2), recent bleeding not anticoagulated (n=0), prophylactic pre-op (n=12), prophylactic post-op (n=3), failure of anticoagulation resulting in recurrent PE (n=1), failure of anticoagulation resulting in extension of DVT (n=0), prophylaxis following PE (n=3), prophylaxis with extensive DVT (n=3), trauma (n=13) and other (n=4).

Retrieval was not attempted in 15 patients due to the continued need for permanent implantation of the filter. A total of 26 attempted retrievals in 26 patients were successful. [n= number of filters retrieved] Retrieval of filter immediately after deployment at Day 0 (n=1), Day 2 (n=1), Day 7 (n=1), Day 9 (n=3), Day 10 (n=6), Day 11(n=2), Day 12 (n=1), Day 13 (n=4), Day 14 (n=6), Day 20 (n=1). No adverse events were reported in the retrieved filter group. 23 patients in whom a filter was retrieved were followed for three months post retrieval with no abnormalities reported. Results from the clinical study showed that the filter could be safely retrieved up to 14 days or longer in patients who no longer required an inferior vena cava filter. Time to retrieval ranged from 2-20 days with a mean implantation time of 11.4 days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Cook Incorporated
c/o Ms. Jennifer J. Bosley
Regulatory Affairs Coordinator
P.O. Box 489
Bloomington, IN 47402-0489

Re: K032426
Günther Tulip™ Vena Cava MR*eye*® Filter and Retrieval Set
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: August 5, 2003
Received: August 6, 2003

Dear Ms. Bosley:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Ashley B. Boam

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 Statement

510(k) Number (if known): K032426

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

Filter Set

The Günther Tulip™ Vena Cava Filter Set is indicated 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 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 jugular approach.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Ashley B. Boam

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032426