

MAY - 5 2005

K043509

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COOK[®]

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510(k) Summary

Submitted By:

COOK INCORPORATED
P.O. Box 489, 750 Daniels Way
Bloomington, IN 47402

Contact:

Earl E. Knight III, MPA
Regulatory Affairs
Phone: (812) 339-2235
Fax: (812) 322-0281

Date Prepared:

February 18, 2005

Device:

Trade Name: Günther Tulip Vena Cava Filter Set
Proposed Classification: 870.3375 DTK
Class II, Cardiovascular

Predicate Devices:

The Günther Tulip Vena Cava Filter Set is similar in terms of intended use, materials of construction and technological characteristics as the predicate Günther Tulip MReye™ Vena Cava Filter Set (K000855) and the Günther Tulip™ Vena Cava Filter and Retrieval Set (K032426).

Device Description:

The Günther Tulip Vena Cava Filter is crafted of an alloy consisting of Co, Cr, NI, Mo and Fe. The basic design of the filter is conical with four legs. The end of each leg is slightly hooked outward. "Webbed" wires (like tulip petals) between the legs are bent strands of the same alloy which maintain the shape of the filter by pressing outward toward the vein walls. These webs also increase the area into which the emboli can be trapped.

There are two types of Günther Tulip Vena Cava Filter Sets a femoral set which is introduced through the femoral vein and a jugular set which is introduced through the jugular vein.

The jugular set consists of: the Günther Tulip Vena Cava Filter with a protective sleeve, a 10 French Radiopaque Dilator, a 7 French Radiopaque Coaxial Introducer Sheath 65 centimeters long, a filter loading introducer with a pre-attached Günther Tulip Vena Cava Filter, a proximal protective sleeve to introducer, a Radiopaque polyethylene inner catheter, and a three-way stopcock.

The femoral set consists of: the Günther Tulip Vena Cava Filter with a protective sleeve, a 10 French Radiopaque Dilator, a 8.5 French Radiopaque Coaxial Introducer Sheath 65 cm long, a Radiopaque polyethylene inner catheter, a three-way stopcock and a 10 French filter loading introducer system preloaded with a Günther Tulip Vena Cava Filter.

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.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook Incorporated. This device will undergo sterilization similar to the devices currently marketed and distributed. Being similar with respect to indications for use, materials and physical construction to predicate devices, we believe this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The Günther Tulip Vena Cava Filter Set was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Simulated Transport Testing
2. Biocompatibility Testing
3. Deployment Testing
4. Package Testing
5. Lubricity 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 use as a vena cava filter set.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 5 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Incorporated
c/o Earl E. Knight III, MPA
Regulatory Affairs Specialist
750 N. Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K043509
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: April 4, 2005
Received: April 5, 2004

Dear Mr. Knight:

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.

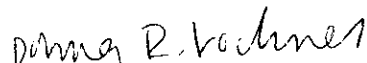
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



 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: K043509

Device Name: Günther Tulip™ Vena Cava Filter Set

Indications For 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 anticoagulation therapy is contraindicated;
- failure of anticoagulation therapy in thromboembolic diseases;
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- chronic, recurrent pulmonary embolism where anticoagulation 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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Anna R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

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