K023116

OCT 18 2002

510(k)

Summary of Safety and Effectiveness

Submitter:

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Date Prepared: September 18, 2002

General Provisions:

Trade Name	Cordis OptEase™ Permanent Vena Cava Filter
Common Name	Permanent Vena Cava Filter and Introduction Kit
Classification Name	Cardiovascular Intravascular Filter (per 21 CFR 870.3375)
Device-classification	Class II

Predicate Devices:

The subject Cordis OptEase Permanent Vena Cava Filter is substantially equivalent to:

- Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit,
- Cordis TrapEase Permanent Vena Cava Filter with the VisEase Angiographic Vessel Dilator,
- Günther Tulip Vena Cava MReye™ Filter set, Cook Incorporated,
- Vena Tech LGM 30 CJ/U & 30 D/U Vena Cava Filter.

Performance Standards

As per 21 CFR 870.3375, the following special controls were established for cardiovascular intravascular filters:

- Use of International Standards Organization's ISO-10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,
- FDA's Updated 510(k) Sterility Review Guidance (K90-1); Final Guiance for Industry and FDA, August 30, 2002 , and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions

Indications for Use

The Cordis **OptEase** Permanent Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are 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.

This is the same intended use as for the filter featured with the predicate devices: TrapEas, Günther Tulip Vena Cava MR*eye* Filter set, and Vena Tech LGM Vena Cava Filter.

The **VisEase** Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the Vena Cava.

This is the same intended use as for the VisEase Angiographic Vessel Dilator featured with the predicate device.

Device Description

The subject device is a system that consists of a flexible, self-expanding vena cava filter to be deployed in the infra-renal inferior vena cava via a 6F sheathed introduction kit. The filter is designed to trap large, life threatening emboli and therefore prevent recurrent pulmonary embolism, while maintaining caval patency. The OptEase Permanent Vena Cava Filter is packaged with a filter introduction kit that includes the VisEase Angiographic Vessel Dilator, a directional filter storage tube, catheter sheath introducer and obturator for safe and accurate deployment of the filter.

The modification to the design of the OptEase Vena Cava Filter with respect to the number and configuration of the fixation hooks and the introduction of a filter extension at the caudal end of the filter basket, do not affect the intended use or basic fundamental technology of the device. The subject device is substantially equivalent to the predicate devices, i.e., TrapEase permanent Vena Cava Filter, Günther Tulip Vena Cava MR*eye* Filter and the Vena Tech LGM Vena Cava Filter.

Performance Data:

The safety and effectiveness of the Cordis OptEase Permanent Vena Cava Filter have been demonstrated via data collected from *in-vitro* and *in-vivo* testing and analyses conducted on the OptEase Permanent Vena Cava Filter.

The following *in-vitro* tests have been performed on the OptEase Permanent Vena Cava Filter:

- Visual Inspection: Storage Tube
- Visual Inspection: Filter position in Storage tube
- Visual Inspection: Filter
- Dimensional Inspection: Marker position obturator
- Dimensional Inspection Storage Tube
- Dimensional Inspection: Measurement of expanded filter diameter
- Suitability; Pull strength / Friction test Storage Tube
- Simulated Deployment & Introducer / sheath Suitability incl. Kink resistance
- Resistance to Migration – in-vitro-test – Subject and Predicate Devices

The following *in-vivo* have been performed:

- Animal Study - Part I: Filter implantation with simulated thrombo-embolic load.
- Animal Study - Part II: Filter implantation without simulated thrombo-embolic load.

Summary of Substantial Equivalence

The design, material, components, fundamental technology and intended use featured with the Cordis OptEase Permanent Vena Cava are substantially equivalent to those featured with the predecessor Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit and the Cordis TrapEase Permanent Vena Cava with the VisEase Angiographic Vessel Dilator. In addition, the design of the OptEase Permanent Vena Cava Filter is substantially equivalent with the Günther Tulip Vena Cava MR*eye* Filter set and the Vena Tech LGM Vena Cava Filter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

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NL-9301-LJ Roden
The Netherlands

Re: K023116
Trade/Device Name: Cordis OptEase™ Permanent Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II (two)
Product Code: DTK
Dated: September 18, 2002
Received: September 19, 2002

Dear Dr. Roossien:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and promotional materials:

> The safety and effectiveness of the OptEase™ Filter for use as a retrievable or temporary filter have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

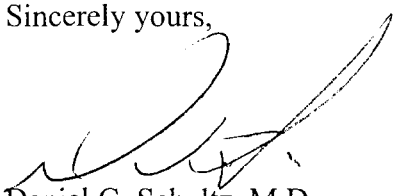
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). 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,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023116

Device Name: Cordis OptEase™ Permanent Vena Cava Filter

FDA's Statement of the Indications For Use for device: The OptEase™ is indicated for the prevention of recurrent pulmonary embolism via permanent, percutaneous placement in the inferior vena cava in the following situations: pulmonary thromboembolism when anticoagulants are 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.

Division of Cardiovascular & Respiratory Devices
510(k) Number K023116

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)