K034050

MAR 2 2 2004

510(k)

Summary of Safety and Effectiveness

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Date Prepared: December 29, 2003

General Provisions:

Trade Name:	Cordis OptEase™ Vena Cava Filter
Common Name:	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 Vena Cava Filter is substantially equivalent to:

- Cordis OptEase Permanent Vena Cava Filter and Introduction Kit (#K023116)
- Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (#K000062 and #K020316)
- Recovery Filter System, Bard Peripheral Vascular, C.R. Bard, Inc. (#K031328)
- Günther Tulip™ Vena Cava Filter and Retrieval set, Cook Incorporated (#K032426)
- Cordis VISTA BRITE TIP® Guiding Catheter (#K965211)

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 Guidance for Industry and FDA, August 30, 2002, and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions, dated November 26, 1999.

Indications for Use for Filter:

The Cordis OptEase 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,
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The OptEase Filter may be removed according to the instructions supplied in the Section labeled: Optional Procedure for Filter Retrieval.

The 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.

Indications for Use for Retrieval Catheter:

The Cordis OptEase Retrieval Catheter is indicated for the retrieval of the Cordis OptEase Vena Cava Filter from the inferior vena cava. Retrieval of the OptEase Filter is possible only from the femoral vein approach.

Device Description

The subject OptEase Filter is identical to the predicate OptEase Permanent Vena Cava Filter with the exception of the addition of the retrievability option to the labeling. The OptEase Vena Cava Filter is packaged with a filter introduction kit that includes the Angiographic Vessel Dilator, a directional filter storage tube, catheter sheath introducer and obturator for safe and accurate deployment of the filter.

The subject OptEase Filter is substantially equivalent to the predicate devices (i.e., OptEase Permanent Vena Cava Filter, TrapEase Permanent Vena Cava Filter, Recovery Filter System, and Günther Tulip™ Vena Cava Filter and Retrieval Set).

Device Description (continued)

The subject OptEase Retrieval Catheter is an 80 cm long, 10F catheter with radiopaque tip. The subject device is packaged separately and is intended for the percutaneous retrieval of the OptEase Filter from the inferior vena cava when used with an appropriate Endovascular snare. The subject device is substantially equivalent to the predicates devices (i.e., the Günther Tulip™ Vena Cava Filter and Retrieval Set and the VISTA BRITE TIP® Guiding Catheter).

Performance Data:

The safety and effectiveness of the Cordis OptEase Vena Cava Filter and the OptEase Retrieval Catheter have been demonstrated via data collected from *in-vitro*, animal and clinical testing and analyses. The safety of retrieval of the OptEase Filter was evaluated in a prospective clinical study (n = 21 retrieval patients) and in a retrospective clinical experience (n = 40 retrieval patients). In the prospective clinical study, the time to retrieval ranged from 5 – 14 days (mean implantation time of 11.1 ± 1.8 days). In the retrospective clinical experience, the time to retrieval ranged from 3 – 48 days in 29 patients (mean implantation time of 16.4 ± 7.2 days). Eleven patients in the retrospective clinical experience had their filter captured from the vessel wall and then redeployed at the different location within the inferior vena cava (capture time ranged from 4 – 30 days, mean of 13.8 ± 6.1 days). The OptEase Filter was subsequently retrieved from this subset of patients.

Summary of Substantial Equivalence

The design, material, components, and fundamental technology featured with the Cordis OptEase Vena Cava are substantially equivalent to those featured with the predecessor Cordis OptEase Permanent Vena Cava Filter and Introduction Kit and the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit. In addition, the intended use for the OptEase Vena Cava Filter is substantially equivalent with the Recovery Filter System and the Günther Tulip Vena Cava Filter and Retrieval Set.

The design and materials of the OptEase Retrieval Catheter are substantially equivalent to the VISTA BRITE TIP Guiding Catheter. The intended use for OptEase Retrieval Catheter is substantially equivalent to the Günther Tulip Vena Cava Filter and Retrieval Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2004

Cordis Corporation
c/o Ms. Donna Marshall
Regulatory Affairs Associate II
7 Powder Horn Drive
Warren, NJ 07059

Re: K034050
Trade Name: Cordis OptEase™ Vena Cava Filter and Optease ™ Retrievable Catheter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: II (two)
Product Code: DTK
Dated: December 29, 2003
Received: December 30, 2003

Dear Ms. Marshall:

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,

Donna R. Marshall

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): K034050

Device Name: Cordis OptEase™ Vena Cava Filter and OptEase™ Retrieval Catheter

Indications For Use:

The **OPTEASE** Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy for thromboembolic disease,
- Emergency treatment following massive pulmonary embolism where anticipated,
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed, or is contraindicated

The **OPTEASE** Filter may be retrieved according to the instructions supplied in the Section labeled: **Optional Procedure for Filter Retrieval.**

The 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.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Donna R. Vodnel

(Division Sign-Off)
Division of Cardiovascular Devices

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