K091077

FEB - 4 2010

510(k) Summary

Applicant

Cordis Corporation, a Johnson & Johnson Company
430 Rt. 22 East
Bridgewater, New Jersey 08807
Telephone: 908-541-4888
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Contact

Joan Martin, Manager, Regulatory Affairs

Date

April 13, 2009

Subject Device

Trade Name:	**OPTEASE® Vena Cava Filter** and **OPTEASE® Retrieval Catheter**
Common or Usual Name:	Cardiovascular Intravascular Filter (per 21 CFR 870.3375)
Classification:	Class II
Classification Panel	Cardiovascular

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis OPTEASE® Vena Cava Filter **and** OPTEASE® Retrieval Catheter (ref. 510(k) K034050)
- G2 EXPRESS Filter System, Bard Peripheral Vascular, Inc. (ref. 510(k) K082305)

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 OPTEASE Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in thromboembolic disease,
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced,
- 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.

Indications for Use for Retrieval Catheter

The Cordis OPTEASE Retrieval Catheter is has been designed for retrieval of an implanted OPTEASE Filter in patients who no longer require a filter. Retrieval of the filter can be performed only by femoral approach.

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 Angiographic Vessel Dilator, a directional filter storage tube, catheter sheath introducer and obturator for safe and accurate deployment of the filter.

Summary of Substantial Equivalence

The subject OPTEASE Vena Cava Filter is substantially equivalent to the predicate devices, the OPTEASE Vena Cava Filter and the G2 EXPRESS Filter System in terms of intended use, application and user application. The change to the predicate devices, OPTEASE Vena Cava Filter and OPTEASE Retrieval Catheter, only affects the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 4 2010

Cordis Corporation
c/o Ms. Joan Martin
430 Rt. 22 East
Bridgewater, NJ 08807

Re: K091077
OPTEASE Vena Cava Filter and OPTEASE Retrieval Catheter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: January 4, 2010
Received: January 5, 2010

Dear Ms. Martin:

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 use in the prevention of recurrent pulmonary embolism 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram 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): K091077

Device Name: **OPTEASE® Vena Cava Filter and OPTEASE Retrieval Catheter**

Indication for Use:

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

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091077