MAR - 7 2014

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA of 1990 and 21 CFR 807.92 in order to gain clearance to market the OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter. The OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter are identical in design and intended use to the predicate OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter. The change is to provide unique catalog numbers for the femoral-only, jugular-only, and jugular/antecubital-only approaches with dedicated OPTEASE® Vena Cava Filter packaged within a unidirectional storage tube according to the site specific deployment approach.

APPLICANT	Cordis Corporation A Johnson & Johnson Company 6500 Paseo Padre Parkway Fremont, CA 94555 Tel.: 510-248-2961 Fax: 510-248-2533
OFFICIAL CORRESPONDENT	Shamsa Karimi Manager, Regulatory Affairs Phone:(510) 248-2896 Fax: (510) 248-2533 e-mail: SKarimi@ITS.JNJ.com
DATE PREPARED	February 04, 2014
TRADE NAME	OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter
COMMON NAME	Vena Cava Filter and Introduction Kit
CLASSIFICATION NAME	Filter, Intravascular, Cardiovascular
DEVICE CLASSIFICATION	21 CFR §870.3375
PRODUCT CODES	DTK
PREDICATE DEVICE	OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter Previously cleared under K034050 and again under K091077

SUBSTANTIALLY EQUIVALENT TO:

The Cordis OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter are substantially equivalent to the predicate Cordis OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter, previously cleared under K034050 and again under K091077.

- The OPTEASE® Vena Cava Filter (Filter) is identical in design and intended use to the predicate OPTEASE® Filter.
- The packaging components of the Cordis OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter are substantially equivalent to the predicate packaging components.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Cordis OPTEASE® Vena Cava Filter (Filter) is designed for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava (IVC). The self-centering OPTEASE® Filter is laser cut from nickel titanium alloy (Nitinol) tubing. The proximal and distal baskets of the OPTEASE® Filter, consisting of struts in a six-diamond shape configuration, are designed for optimal clot capture. The constrained filter is supplied in a unidirectional storage tube that is loaded as a system into the hemostasis valve of the sheath introducer. The subject device is comprised of the filter packaged within a unidirectional storage tube, introduction kit that includes angiographic vessel dilator, catheter sheath introducer and obturator. The OPTEASE® Retrieval catheter is packaged separately.

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 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 the radiopaque contrast media to the vena cava.

TECHNICAL CHARACTERISTICS:

The self-centering OPTEASE® Filter is laser cut from nickel titanium alloy (Nitinol) tubing. The proximal and distal baskets of the OPTEASE® Filter, consisting of struts in a six-diamond shape configuration, are designed for optimal clot capture. Six straight struts connect the baskets. A single row of fixation barbs is present at the cranial end of the struts. These barbs are intended for the fixation to the vessel wall, and are extensions of the parallel struts. A hook is centrally

located at the caudal basket extremity. The constrained filter is supplied in a unidirectional storage tube that is to be loaded as a system into the valve of the sheath introducer. The constrained filter is flexible and achieves its unconstrained diameter upon deployment in the inferior vena cava (IVC). Upon deployment, the filter imparts an outward radial force on the luminal surface of the Vena Cava to ensure proper positioning and stability.

The OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter is packaged with an Introduction Kit that contains the following components:

- Filter packaged within unidirectional storage tube (containing the constrained OPTEASE Filter)
- 6F BRITE TIP® Catheter Sheath Introducer
- VisEase™ Angiographic Vessel Dilator
- Obturator.

The OPTEASE® Retrieval catheter is packaged separately.

PERFORMANCE DATA:

Design verification and validation testing data confirms that the Optease® Vena Cava Filter in a unidirectional storage tube performs according to its intended use and is equivalent in performance to the predicate device. Specifically, the following tests were performed on the proposed device to demonstrate substantial equivalence with the predicate device.

Test	Conclusion
Human Factor Assessment	The proposed product configuration was safer to use and better at mitigating the risk of incorrect insertion.
Transfer filter into CSI	Meets Acceptance Criteria
Filter release from storage tube	
Fixation on mounting card	
Fixation in storage tube	
Dimensional Analysis	
Visual inspection and verification of packaging and labeling	

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technical comparison and design verification and validation testing demonstrate that the subject OPTEASE® Vena Cava Filter and OPTEASE® Retrieval Catheter are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Cordis Corporation, A Johnson & Johnson Co.
Ms. Shamsa Karimi
Manager, Regulatory Affairs
6500 Paseo Padre Parkway
Fremont, CA 94555 US

Re: K140286
Trade/Device Name: OPTEASE Vena Cava Filter and OPTEASE Retrieval Catheter
Regulation Number: 21 CFR 870.3375
Regulation Name: Vena Cava Filter and Introduction Kit, Filter, Intravascular, Cardiovascular
Regulatory Class: Class II
Product Code: DTK
Dated: February 4, 2014
Received: February 5, 2014

Dear Ms. Karimi,

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. 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kenneth J Cavanaugh -S

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): K140286

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 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 the radiopaque contrast media to the vena cava.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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