

MAR 20 2002

510(k)
Summary of Safety and Effectiveness

K020316

Submitter: Bert Roossien, Ph.D.
Manager, Regulatory Affairs
Cordis Europa, N.V., a Johnson & Johnson Company
Oosteinde 8
NL-9301-LJ
The Netherlands

Contact Person: Karen Wilk
Manager, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powder Horn Drive
Warren, New Jersey 07059

Telephone: (908) 412-7257
Fax: (908) 412-3915

Date Prepared: January 29, 2002

General Provisions: Trade Name: Cordis TrapEase™ Permanent Vena Cava Filter with the
VisEase™ Angiographic Vessel Dilator

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 TrapEase Permanent Vena Cava Filter with the VisEase Angiographic Vessel Dilator is substantially equivalent to:

- Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (510(k) #K000062, #K003964 and #K010083)
- Cordis 5F Super Torque MB Angiographic Catheter (510(k) #K992347).
- Cordis 5.2 F Super Torque Plus Angiographic Catheter (510(k) #K914007)
- Cordis Brite Tip Catheter Sheath Introducer & Vessel Dilator (510(k) #K983023 and #K984500)

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 510(k) Sterility Review Guidance and Revision of November 16, 2001 (K90-1), and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions

For the Angiographic Catheter and vessel Dilator performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

[Unchanged from the predicate devices:] The Cordis **TrapEase™** 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.

[New:] 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.

Device Description

The subject TrapEase Permanent Vena Cava Filter with the VisEase Angiographic Vessel Dilator most notably differs from the predicate TrapEase Permanent Vena Cava Filter and Introduction Kit with regards to the vessel dilator that is included as a component in the Introduction Kit. In addition to its original function as a vessel dilator, which was featured with the predicate Cordis TrapEase Introduction Kits, the subject VisEase Angiographic Vessel Dilator features new intended uses involving angiographic visualization and linear measurement. These new intended uses of the subject VisEase Angiographic Vessel Dilator are addressed in updated product labeling herein and are identical to the intended uses of the predicate Cordis Super Torque MB Angiographic Catheter (reference K992347, determined substantially equivalent on October 8, 1999).

Besides the aforementioned changes in intended use for the VisEase Angiographic Vessel Dilator, the TrapEase Permanent Vena Cava Filter and all other components used with the subject device remain unchanged from that featured with the predicate devices (reference 510(k) Notifications #K000062, #K003964 and #K010083).

**Performance
Data:**

The safety and effectiveness of the Cordis TrapEase Permanent Vena Cava Filter and VisEase Angiographic Vessel Dilator have been demonstrated via data collected from non-clinical design verification tests and analyses. The design verification testing consisted of the following:

- Visual and Dimensional Inspection
 - Catheter Sheath Introducer Compatibility
 - Flow Rate Testing
 - Hydrodynamic Testing
 - Pull Strength Testing
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**Summary of
Substantial
Equivalence**

The design, material, components, fundamental technology and intended use featured with the Cordis TrapEase Permanent Vena Cava are substantially equivalent to those featured with the predecessor Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (reference 510(k) #K000062, #K003964 and #K010083). The design, material and new intended uses of the VisEase Angiographic Vessel Dilator are substantially equivalent to those featured with the predicate Cordis Super Torque MB Angiographic Catheter (reference 510(k) #K992347) and Cordis 5.2 F Super Torque Plus Angiographic Catheter (510(k) #K914007).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2002

Ms. Karen Wilk
Manager, Endovascular Regulatory Affairs
P. O. Box 4917
7 Powder Horn Drive
Warren, NJ 07059

Re: K020316
Cordis TRAPEASE™ Permanent Vena Cava Filter with the VISEASE™ Angiographic
Vessel Dilator
Regulation Number: 21 CFR 870.1200 and 21 CFR 870.1310
Regulation Name: Diagnostic Intravascular Catheter and Dilator for Percutaneous
Catheterization
Regulatory Class: Class II (two)
Product Code: DQO and DRE
Dated: January 29, 2002
Received: January 30, 2002

Dear Ms. Wilk:

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

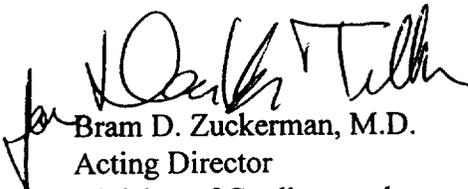
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

