

JUL 25 2003

K 031328

SECTION VIII

510(k) Summary of Safety and Effectiveness Information

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows:

A. Submitter Information:

Applicant: Bard Peripheral Vascular, a division of C.R. Bard, Inc.
1625 West 3rd Street
Tempe, Arizona 85280
Phone: 480-303-2640
Fax: 480-449-2546
Contact: Mary Edwards, Vice-President

B. Device Name:

Trade Name: Recovery Filter System
Common or Usual Name: Percutaneous Vena Cava Filter
Classification Name: Cardiovascular Intravascular Filter

C. Predicate

Device Name(s): Recovery Filter System

D. Device Description:

The Recovery Filter System consists of a nitinol vena cava filter and a delivery system. The filter has two levels of filtration and is prepackaged in a storage tube. The delivery system consists of a 7 Fr ID introducer sheath and dilator and a pusher system. Both components of the system are packaged in Tyvek/film pouches.

E. Statement of Intended Use:

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent 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.
- Recovery filter may be removed according to the instructions supplied in the Section labeled: **Optional Procedure for Filter Removal**. Data from removals in a 58 patient study suggests that the device can be safely removed (mean of 60 days; range 1-161 days).

F. Substantial Equivalence:

Recovery Filter is identical to the cited predicate device with the exception of the removal of labeling limitations and the addition of specific instructions to allow for safe removal of the device.

The safety of removal was addressed in a series of animal and clinical testing. The results of animal testing (including histology) and the confirmatory experience of 58 patients (mean 60 days to removal; range 1-161 days) show that the Recovery Filter may be safely retrieved and that the benefit of this procedure outweighs the potential associated risks.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Bard Peripheral Vascular
c/o Ms. Mary Edwards
Vice President, Regulatory & Clinical Affairs
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K031328

Bard® Recovery® Filter System RF-048F
Regulation Number: 21 CFR 870.3375
Regulation Name: Filter, Intravascular, Cardiovascular
Regulatory Class: Class II
Product Code: DTK
Dated: April 25, 2003
Received: April 28, 2003

Dear Ms. Edwards:

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.

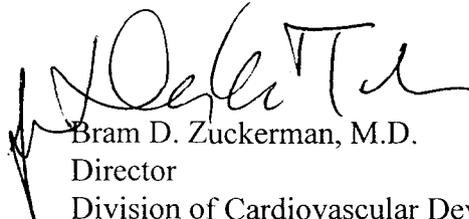
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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) 594-4692. 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,



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

Enclosure

ATTACHMENT A
INDICATIONS FOR USE STATEMENT

Device Name: **Recovery Filter System**

Indications for Use:

The Recovery Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent 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
- Recovery filter may be removed according to the instructions supplied in the Section labeled: **Optional Procedure for Filter Removal.**

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE
ON ANOTHER PAGE IF NEEDED.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

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


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031328