K022236

NOV 27 2002

IMPRA
A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740
TEL: 800-321-4254
480-894-9515
FAX: 480-966-7062

IMPRA

510(k) SUMMARY OF SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Impra
Submitter's Address: 1625 West 3rd Street
Contact Person: Kay Fuller
Contact Person's Telephone Number: (480) 303-2539
Contact Person's FAX Number: (480) 449-2546
Date of Preparation: July 8, 2002

B. Device Name:

Recovery™ Filter System

C. Predicate Devices:

Simon Nitinol Filter/Straightline™ System
Titanium Greenfield® Vena Cava Filter

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. Intended Use:

The Recovery Filter is indicated for use in the prevention of pulmonary embolism via placement in the 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.

F. Technological Characteristics Summary:

The filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. The wires form two levels of filtration: six arms and six legs. The delivery system is used to place the filter into the inferior vena cava.

G. Performance Data:

Bench testing was performed per the FDA guidance document, "Guidance for Cardiovascular Intravascular Filter 510(k) Submission". Testing showed that the Recovery Filter is substantially equivalent to the Bard predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2002

Ms. Kay Fuller
Senior Regulatory Affairs Specialist
C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281

Re: K022236/S2
Trade/Device Name: Bard® Recovery™ Filter System, Model RF-048F
Regulation Number: 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: II
Product Code: DTK
Dated: October 25, 2002
Received: October 29, 2002

Dear Ms Fuller:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling and in promotional materials:

> The safety and effectiveness of the Recovery™ Filter for use as a retrievable or temporary filter have not been established.

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.

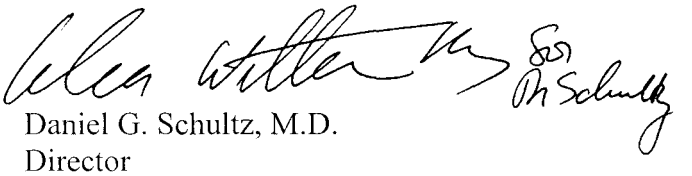
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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"(21 CFR 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,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022236

Device Name: Bard® Recovery™ Filter System, Model RF-048F

FDA's Statement of the Indications For Use for device:

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 anticoagulation 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.

Division of Cardiovascular & Respiratory Devices
510(k) Number K022236

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