

K981079

MAY 7 1998

IMPRA

A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P. O. Box 1740
Tempe, AZ 85280-1740
TEL: 800-321-4254
602-894-9515
FAX: 602-966-7062



CONFIDENTIAL

**510(k) Premarket Notification
VENAFLO™ Vascular Grafts**

510(k) SUMMARY

A. Submitter Information

Submitter's Name: IMPRA, Inc.
A Subsidiary of C. R. Bard, Inc.
Address: 1625 West Third Street
Tempe, Arizona 85281
Telephone: (602) 894-9515
Fax: (602) 966-7062
Contact Person: Kristi M. Kistner
Manager, Regulatory Affairs
Date of Preparation: March 20, 1998

B. Device Name

Trade Name: *Venaflo™ Vascular Graft (Venaflo ePTFE Vascular Graft and Venaflo Graft with Carbon)*
Common/Usual Name: Vascular Graft Prosthesis
Classification Names: Vascular graft prostheses of greater than or equal to 6 mm diameter

IMPRA, Inc., A Subsidiary of C. R. Bard, Inc.
F:\510(k)\VenaCarb\VENACARBgt6.wpd**22**



000028

C. Predicate Device Name

Trade Name(s): *Venaflo* Vascular Graft
 Venaflo ePTFE Vascular Graft
 IMPRA Carboflo® Vascular Graft

D. Device Description

The *Venaflo* Graft with Carbon is an expanded polytetrafluoroethylene (ePTFE) vascular graft with a cuffed venous end and a carbon-lined luminal surface.

E. Intended Use

The *Venaflo* Graft with Carbon is indicated for use as a subcutaneous arteriovenous conduit for blood access only.

F. Technological Characteristics Summary

The *Venaflo* Graft with Carbon is an *IMPRA Carboflo* Vascular Graft with a cuffed venous end having the same shape and dimensions as the cuff on the *Venaflo* ePTFE Vascular Graft.

G. Performance Data

Device testing was performed on the cuffed portion of the *Venaflo* Graft with Carbon and compared to the results of testing performed on the *Venaflo* ePTFE Vascular Graft. The testing was conducted using methods recommended in ANSI/AAMI VP20-1994: Cardiovascular Implants - Vascular Prostheses and the 1993 FDA Draft Guidance: Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses. The results of all testing indicated that the *Venaflo* Graft with Carbon is suitable for use as a subcutaneous arteriovenous conduit for blood access and the anticipated conditions of use imposed on the device. The results demonstrated that the *Venaflo* Graft with Carbon has been adequately designed to perform in a manner substantially equivalent to that of the predicate devices.

Venaflo Grafts with Carbon are substantially equivalent to the currently marketed *Venaflo* ePTFE Vascular Graft and the *IMPRA Carboflo* Vascular Graft.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 7 1998

Ms. Kristi Kistner
Impra, Inc.
A Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K981079
Venaflor™ Vascular Graft
Regulatory Class: II (two)
Product Code: 74 DSY
Dated: March 20, 1998
Received: March 24, 1998

Dear Ms. Kistner:

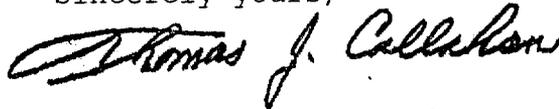
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971076 and K 971079

Device Name: Venaflo Grafts with Carbon

Indications For Use: The *Venaflo* Grafts with Carbon are indicated for subcutaneous arteriovenous conduit for blood access only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 971079

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)