

DEC 16 1998

K983769

**IMPRA**

A Subsidiary of C. R. Bard, Inc.  
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**IMPRA**

**CONFIDENTIAL**

**510(k) Premarket Notification**  
***DISTAFLO™ Bypass Graft***

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**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: October 22, 1998

**B. Device Name**

Trade Name: *Distaflo™ Bypass Graft*  
Common/Usual Name: Vascular Graft Prosthesis  
Classification Names: Vascular graft prostheses of less than 6 mm diameter

**C. Predicate Device Name**

Trade Name(s): *IMPRA Carboflo*<sup>®</sup> Vascular Graft  
*Venaflo*<sup>®</sup> Vascular Graft (*Venaflo* ePTFE Vascular Graft  
and *Venaflo* Graft with Carbon)

**D. Device Description**

The *Distaflo* Bypass Graft is an expanded polytetrafluoroethylene (ePTFE) vascular graft with a cuffed distal end. The *Distaflo* Bypass Graft can be manufactured with or without Flex beading and with or without a carbon lining.

**E. Intended Use**

The *Distaflo* Bypass Graft is intended for bypass or reconstruction of peripheral arterial blood vessels.

**F. Technological Characteristics Summary**

The *Distaflo* Bypass Graft is manufactured using the same materials and processes as the predicate devices. The shape of the distal cuff is modeled after the Miller Vein Cuff.

**G. Performance Data**

Device testing was performed on the cuffed portion of the *Distaflo* Bypass Graft and compared to the results of testing performed on the *IMPRA Carboflo* Vascular Graft and the *Venaflo* Graft with Carbon. 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using methods recommended in ANSI/AAMI VP20-1994: Cardiovascular Implants - Vascular Prostheses and the 1993 FDA Draft Guidance: Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses.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 *Distaflo* Bypass Graft is suitable for bypass or reconstruction of peripheral arterial blood vessels and the anticipated conditions of use imposed on the device. The results demonstrated that the *Distaflo* Bypass Graft has been adequately designed to perform in a manner substantially equivalent to that of the predicate devices.

*Distaflo* Bypass Grafts are substantially equivalent to the currently marketed *IMPRA* *Carboflo* Vascular Graft and the *Venaflo* Vascular Graft.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kristi M. Kistner  
Manager, Regulatory Affairs  
IMPRA, Inc.  
1625 West 3<sup>rd</sup> Street  
P.O. Box 1740  
Tempe, AZ 85281-1740

Re: K983769  
IMPRA Distaflo™ Bypass Graft  
Regulatory Class: III (Three)  
Product Code: 74 DYF  
Dated: October 22, 1998  
Received: October 26, 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 (for the indications for use stated in the enclosure) to 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.

Page 2 - Ms. Kristi M. Kistner

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) 594-4648. 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/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

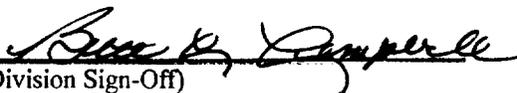
510(k) Number (if known): K983769 and K983861

Device Name: Impra Distaflo™ Bypass Graft

Indications For Use: Distaflo™ Bypass Grafts are intended for bypass or reconstruction of peripheral arterial blood vessels.

(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 K983769/K983861

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)