K983064

NOV 19 1998

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

510(k) Premarket Notification
IMPRA High Porosity Grafts

CONFIDENTIAL

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:	August 27, 1998

B. Device Name

Trade Name:	IMPRA High Porosity Grafts
Common/Usual Name:	Vascular Graft Prosthesis
Classification Names:	Vascular graft prostheses of greater than or equal to 6 mm diameter

C. Predicate Device Name

Trade Name(s): IMPRA ePTFE Vascular Graft
Atrium Hybrid PTFE Vascular Graft

D. Device Description

The IMPRA High Porosity Graft is an expanded polytetrafluoroethylene (ePTFE) vascular graft with a high porosity construction.

E. Intended Use

The IMPRA High Porosity Graft in Straight and IMPRA Flex configurations is indicated for use as a vascular prosthesis for bypass or reconstruction of arterial blood vessels. IMPRA Flex configurations have an external spiral bead support on the graft and can be used where resistance to compression or kinking is desired.

F. Technological Characteristics Summary

The IMPRA High Porosity Graft is an IMPRA ePTFE Vascular Graft with a high porosity construction.

G. Performance Data

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using methods recommended in ANSI/AAMI VP20-1994: Cardiovascular Implants - Vascular Prostheses and the 1993 FDA Draft Guidance: Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses.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

IMPRA High Porosity Grafts are substantially equivalent to the currently marketed IMPRA ePTFE Vascular Graft and the Atrium Hybrid PTFE Vascular Graft.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1998

Ms. Kristi M. Kistner
Manager, Regulatory Affairs
IMPRA, Inc.
1625 West 3rd Street
Tempe, AZ 85281

Re: K983064
IMPRA High Porosity Graft
Regulatory Class: II (Two)
Product Code: 74 DSY
Dated: August 27, 1998
Received: September 2, 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.

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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): K983064

Device Name: IMPRA High Porosity Grafts

Indications For Use: IMPRA High Porosity Grafts are indicated for use as vascular prosthesis 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 K983064

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

(Optional Format 1-2-96)