4/22/99

K991027

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

IMPRA

**510(k) Premarket Notification**
**Bi-Directional Tunneler**

**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: | (480) 894-9515 |
| Fax: | (480) 966-7062 |
| Contact Person: | Kristi M. Kistner |
| | Manager, Regulatory Affairs |
| Date of Preparation: | March 26, 1999 |

### B. Device Name

| | |
|---|---|
| Trade Name: | Bi-Directional Tunneler |
| Common/Usual Name: | Vascular Tunneler |
| Classification Name: | An accessory to a vascular graft prosthesis |

### C. Predicate Device Name

| | |
|---|---|
| Trade Name(s): | Kelly-Wick Tunneler |

## D. Device Description

The Bi-Directional Tunneler is a stainless steel device composed of a knurled handle, shafts in different lengths and curvatures, bullet tips from 4mm to 12 mm diameter, and a vein tip with a luer adapter. Each tunneler shaft is manufactured with internal threaded ends and a locking mechanism on each end for interchangeable tip and handle attachment. Each tip is manufactured with an external threaded end for luer adapter and shaft attachment.

The Bi-Directional Tunneler is supplied non-sterile to the user in a stainless steel perforated case. The perforations are intended to facilitate steam sterilization.

## E. Intended Use

The Bi-Directional Tunneler is indicated for use in creating subcutaneous tunnels for the placement of vascular prostheses or autogenous grafts for arteriovenous access, peripheral vascular and extra-anatomic bypass procedures.

## F. Technological Characteristics Summary

The Bi-Directional Tunneler has the same indications for use as the predicate device. All components for both the Bi-Directional Tunneler and the predicate device are made from stainless steel, are equivalent in size and configuration, and are provided non-sterile to the user. The only significant difference between the Bi-Directional Tunneler and the Kelly-Wick Tunneler is the bi-directional feature. This bi-directionality is a change in the operating principle of the tunneler and does not affect safety or effectiveness of the device.

## G. Summary of Substantial Equivalence

The Bi-Directional Tunneler is substantially equivalent in intended use, design, technology/operating principles, materials and performance to the Kelly-Wick Tunneler. Differences between the two devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1999

Ms. Kristi Kistner
IMPRA, Inc.
A Subsidiary of C.R. Bard, Inc.
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K991027
Impra Bi-Directional Tunneler
Regulatory Class: II (Two)
Product Code: 74 DSY
Dated: March 26, 1999
Received: March 29, 1999

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 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) 594-4648. 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" (21CFR 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

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): K991027

Device Name: Impra Bi-Directional Tunneler

Indications For Use: The Bi-Driectional Tunneler is indicated for use in creating subcutaneous tunnels for the placement of vascular prostheses or autologous grafts for arteriovenous access, peripheral vascular and extra—anatomic bypass procedures.

(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 K991027

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

(Optional Format 1-2-96)