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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, Georgia 30014
Contact Person:	Frances E. Harrison, RAC
Contact Person's Phone:	(770) 784-6257
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	November 24, 2004

B. Device Name:

Trade Name:	Bard® InLayOptima™ Ureteral Stent with Suture
Common / Usual Name:	Bard Ureteral Stent
Classification Name:	Ureteral Stent

C. Predicate Device Name:

Trade Name:	Bard® InLayOptima™ Ureteral Stent with Suture #K022447

D. Device Description: The Bard® InLayOptima™ Ureteral Stent and Multi-Length Ureteral Stent is a coated, double pigtail ureteral stent with a monofilament suture loop attached to aid in stent removal. The stent is available in two forms: a single size or a customizable multi-length size. The following items are included with each stent:

1 Ureteral Stent with Suture
1 Push Catheter with Radiopaque Tip
1 Pigtail Straightener
1 Guidewire* *(Optional)*

**Note: a 4.7 Fr stent is compatible with a .035" guidewire and a 6,7,and 8 Fr stents are compatible with a .038" guidewire.*

In vitro testing conducted on the Bard® InLayOptima™ Ureteral Stents and Multi-Length Ureteral Stents indicate reduced accumulation of urine calcium salts as assayed by calcium when compared to a control. Correlation of *in vitro* data to clinical outcome has not been established.

Choong, SKS, Wood, S, Whitfield, HN. "A model to quantify encrustation on ureteric stents, urethral catheters, and polymers intended for urological use," BJU International (2000), 86, 414-421.

E. Intended Use: The Bard® InlayOptima™ Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.

F. Technological Characteristics Summary:

The table below provides a tabulated comparison summary of the technological characteristics of the Bard® InlayOptima™ Ureteral Stent with Suture versus the predicate device.

Comparison Summary of Technological Characteristics

Product Characteristics	Bard® Inlay Optima™ Ureteral Stent with Suture (this 510(k))	Bard® Inlay Optima™ Ureteral Stent with Suture (Predicate device - #K022447)	Difference
Stent			
Indications or Intended Use	The Bard® *Inlay* Optima™ Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.	The Bard® *Inlay* Optima™ Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.	None
Disposable	Yes	Yes	None
Sterile	Yes	Yes	None
Stent Base Material	Polycarbonate-based Polyurethane*	Polyether-based Polyurethane	Material change
X-Ray Opaque	Yes	Yes	None
Coating			
Double Pigtail	Hydrophobic polymer	Hydrophobic polymer	None
Multilength	Hydrophobic polymer	Hydrophobic polymer	None
Models and Sizes			
Fr. Sizes Available	4.7 Fr., 6 Fr., 7 Fr., and 8 Fr.	4.7 Fr., 6 Fr., 7 Fr., and 8 Fr.	None
Double Pigtail Lengths	14, 20-30 cm	14, 20-30 cm	None
Multilength Lengths	23-32cm (one overall adjustable length)	23-32cm (one overall adjustable length)	None
Pigtail Geometry			
Double Pigtail	360° curvature + 45° overlap (both ends)	360° curvature + 45° overlap (both ends)	None
Multilength	2 ½ Turns	2 ½ Turns	None
Suture Loop	Yes – USP Medical Grade black nylon monofilament; 3-0	Yes – USP Medical Grade black monofilament; 3-0	None
Guidewire Interface	4.7 Fr. = 0.035" diameter 6, 7, 8 Fr. = 0.038" diameter	4.7 Fr. = 0.035" diameter 6, 7, 8 Fr. = 0.038" diameter	None
Accessories			
Stent Clamp	No	No	Clamp Removed
Push Catheter			
Color	Orange	Orange	None
Material	High Density Polyethylene (HDPE)	High Density Polyethylene (HDPE)	None
Guidewire Interface	4.7 Fr. = 0.035" diameter 6, 7, 8 Fr. = 0.038" diameter	4.7 Fr. = 0.035" diameter 6, 7, 8 Fr. = 0.038" diameter	None
Radiopacity	Radiopaque marker band near distal end	Radiopaque marker band near distal end	None
Length	4.7, 6, 7, 8 Fr. = 17.75"	4.7, 6, 7, 8 Fr. = 17.75"	None

- New feature(s) or change this 510(k)

G. Performance Data Summary:

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The Bard® InlayOptima™ Ureteral Stent with Suture referenced in this submission is held to the same design, manufacture, and performance specifications as those stents currently manufactured by Bard. Performance and functional testing standards are based on the FDA draft "Guidance for the Content of Premarket Notifications for Ureteral Stents" dated February 10, 1993 and the draft ASTM F.04.70.01, "Standard Test Method for Ureteral Stents" dated July 9, 1997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2004

Frances E. Harrison, RAC
Director, Regulatory Affairs
C. R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K043193
Trade/Device Name: Bard® InlayOptima™ Ureteral Stent with Suture
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: 78 FAD
Dated: November 10, 2004
Received: November 18, 2004

Dear Ms. Harrison:

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) that do not require approval of a premarket approval application (PMA). 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 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043193

Device Name: Bard® InlayOptima™ Ureteral Stent

Indications for Use:

The Bard® InlayOptima™ Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 365 days. The stent is not intended as a permanent indwelling device.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

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

(Optional Format 1/2/96)

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043193