C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209

DEC 15 1998

K983498

BARD

SECTION VI

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:	Georgia C. Abernathy
Contact Person's Phone:	(770) 784-6454
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	September 30, 1998

B. Device Name:

Trade Name:	Bard® InLay™ Lubricious Double Pigtail Ureteral Stent with Suture
Common / Usual Name:	Bard Lubricious Ureteral Stent
Classification Name:	Ureteral Stent

C. Predicate Device Name:

Trade Name:	Bard Lubricious-Coated Ureteral Stent with Suture

D. Device Description:

The Bard Lubricious Ureteral Stent is a polyurethane stent with a hydrophilic (lubricious) coating which is intended to aid in stent insertion/removal and which has the potential to enhance patient comfort while indwelling; the stent also incorporates a monofilament suture loop which aids in stent removal.

E. Intended Use:

The Bard Lubricious Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma 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.

F. Technological Characteristics Summary:

Table VI-1 provides a tabulated comparison summary of the technological characteristics of the Bard Lubricious Ureteral Stent versus the predicate device.

Table VI-1
Comparison Summary of Technological Characteristics

Product Characteristic	Bard Lubricious Ureteral Stent (this 510(k))	Bard Lubricious-Coated Ureteral Stent with Suture (Predicate device) (#K903345)	Difference
Stent			
Indications or Intended Use	The Bard Lubricious Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma 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.	The Bard Lubricious-Coated Ureteral Stent with Suture is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma 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.	None
Disposable	Yes	Yes	None
Sterile	Yes	Yes	None
Stent Base Material	Polyurethane	Polyurethane	None
X-Ray Opaque	Yes	Yes	None
Coating			
Double Pigtail	Hydrophilic polymer (lubricious)*	Hydrophilic polymer (lubricious)	Different formula, different supplier
Multilength	Hydrophilic polymer (lubricious)	None	Not previously coated
Fr. Sizes Available	4.7**, 6, 7 and 8 Fr.	4.7, 6, 7 and 8 Fr.	4.7 Fr. stent will have a taper on the kidney-end tip
Double Pigtail Lengths	14, 20-30cm*	14-30cm	16 and 18cm lengths deleted
Multilength Lengths	22-32cm (one overall adjustable length)	22-32cm (one overall adjustable length)	None
Pigtail Geometry			
Double Pigtail	360° curvature + 45° overlap (both ends)	"J" curl configuration (no overlap)	Additional curl length
Multilength	2 ½ turns	2 ½ turns	None
Suture Loop	Yes-USP Medical Grade black nylon monofilament; 3-0	Yes-USP Medical Grade dark blue nylon monofilament; 3-0	Color change, both biocompatible
Guidewire Interface	4.7 Fr. = .035" diameter* 6, 7, 8 Fr. = .038" diameter*	4.7 Fr. = .025" diameter 6, 7, 8 Fr. = .038" diameter*	4.7 Fr. interfaces with larger diameter guidewire
Stent Clamp?	Yes	Yes	None

Product Characteristic	Bard Lubricious Ureteral Stent (this 510(k))	Bard Lubricious-Coated Ureteral Stent with Suture (Predicate device) (#K903345)	Difference
Push Catheter			
Color	Orange*	Green	Color change
Material	High Density Polyethylene (HDPE)	High Density Polyethylene (HDPE)	None
Guidewire Interface	4.7 Fr. = .035" diameter* 6, 7/8 Fr. = .038" diameter*	4.7 Fr. = .025" diameter 6/7/8 Fr. = .038" diameter	4.7 Fr. interfaces with larger diameter guidewire
Radiopacity	Radiopaque marker band near distal end*	N/A	Add radiopaque band
Length	4.7, 6, 7, 8 Fr. = 17.75"*	4.7 Fr. = 22" 6/7/8 Fr. = 16"	Length changed, OD on new push catheter same as stent

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

** 4.7 Fr. stent will have a taper on the kidney-end tip

G. Performance Data Summary:

The Bard Lubricious Ureteral Stent referenced in this submission is held to the same design, manufacture, and performance specifications as those stents currently manufactured. 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 15 1998

Georgia C. Abernathy
Regulatory Affairs Associate
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209

Re: K983498
Bard® Inlay™ Lubricious Double Pigtail Ureteral Stent
Dated: September 30, 1998
Received: October 5, 1998
Regulatory Class: II
21 CFR 876.4620/Procode: 78 FAD

Dear Ms. Georgia:

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) 594-4613. 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I - D

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K983498

Device Name: Bard Lubricious Ureteral Stent

Indications for Use:

The Bard Lubricious Ureteral Stent is indicated to relieve obstruction in a variety of benign, malignant and post-traumatic conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma 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.

(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. Lazarus

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983498