K070508

5.0 510(k) Summary of Safety and Effectiveness

MAR 0 9 2007

Product :	Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr
Preparer/Contact	Michelle Gudith Senior Regulatory Affairs Manager Bard Medical Division C.R. Bard Inc. 8195 Industrial Blvd. Covington, Georgia 30014 USA Phone (770) 784-6722, Fax (770) 784-6722 E-mail michelle.gudith@crbard.com
Manufacturer	C.R. Bard Inc.
Date summary was prepared:	January 03, 2007
Name(s) of the device:	Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr
Identification of predicate device(s):	Rochester Medical Silicone Hydrophilic Coated Foley Catheter Bardex® All-Silicone Lubri-Sil® Lubricious Coated Foley Catheter, 2 and 3-way. Bardex® Lubri-Sil® I.C. All-Silicone Lubricious Coated Foley Catheter, 3-way.

5.1 ESTABLISHMENT REGISTRATION NUMBER

Owner/Operator: C.R. Bard Inc.

C.R. Bard Manufacturing Locations:

The device will be lubricious-coated at Moncks Corner, South Carolina, USA, Establishment Registration Number, 1030583.

Device packaging will occur at the Nogales, Sonora, Mexico, Establishment Registration Number, 9611950.

The device will be sterilized/distributed Covington, Georgia, USA, Establishment Registration Number, 1018223.

Qualified Suppliers/Contract Manufacturers:

Uncoated catheters will be extruded and assembled at Degania Silicone, Ltd. in Tel Aviv, Israel. Registration Number, 8030107.

5.2 OFFICIAL CORRESPONDENT

Michelle Gudith
Senior Manager, Regulatory Affairs
Bard Medical Division
C.R. Bard Inc.
8195 Industrial Blvd.
Covington, Georgia 30014 USA
Phone (770) 784-6722,
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5.3 CLASSIFICATION

21 CFR 876.5130
Regulation Name: Urological Catheter
Regulatory Class: Class II
Product Code: EZL

5.4 CLASSIFICATION NAME

Urological Catheter/Catheter, Retention Type, Balloon

5.5 COMMON OR USUAL NAMES

Urological Foley Catheter

5.6 PROPRIETARY NAME

Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr

5.7 INTENDED USE

The Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr is indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as nephrostomy tract.

5.8 PREDICATE DEVICES

K000723 - Rochester Medical Silicone Hydrophilic coated Foley catheters

K984084 - Bardex® All-Silicone Lubri-Sil® Lubricious coated Foley catheter, 2-way.

K002868 - Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley catheter, 3-way.

Bardex® Lubri-Sil® I.C. All-Silicone Lubricious Coated Foley catheter, 3-way.

5.9 DESCRIPTION OF THE DEVICE:

Intended Use:

The Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr is indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as nephrostomy tract.

Device Description

The Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr is a single use, sterile, 2-way, latex-free, hydrogel-coated Foley catheter and represents a product line extension to the current Bard Medical Division product line range of silicone Foley catheters found substantially equivalent in K984084 and K002868.

Technological Characteristics

The catheters described in this 510(k) have similar technological and performance characteristics to the predicate devices. The catheters are manufactured from silicone and have a lubricious/hydrophilic coating, just as the predicate devices from C.R. Bard Inc. and Rochester Medical.

Evaluation of Substantial Equivalence:

The device is a line extension of the C.R. Bard Foley Catheter product line of lubricious-coated silicone catheters. The 6 Fr size adds another pediatric size in addition to the 8 and 10 Fr sizes currently commercially available. In addition, Rochester Medical's 510(k) includes a 6 Fr size made of silicone with a hydrophilic coating.

The new device was tested to meet C.R. Bard Inc. dimensional requirements, coefficient of friction test and ASTM F623-99 Standard Performance Specification for Foley Catheter for flow rate, balloon integrity, inflated balloon response to pull out, balloon volume maintenance, balloon and shaft size, and balloon deflation reliability. Biocompatibility testing has also been performed successfully. Additional testing established by C.R. Bard Inc. for a silicone-coated pediatric catheter are also provided within this 510(k).

Conclusion

The proposed Bard® Lubri-Sil® All-Silicone Lubricious coated Foley Catheter 6 Fr is substantially equivalent to commercially available devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 0 9 2007

C. R. Bard, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K070508
Trade/Device Name: Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catherer 6 Fr
Regulation Number: 21 CFRT §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: February 21, 2007
Received: February 22, 2007

Dear Mr. Mosenkis:

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/industry/support/index.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): ~~Unknown~~ K070508

Device Name: Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr

Indications for Use: The Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6 Fr is indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as nephrostomy tract.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jegerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070509