K070582

DEC

SECTION 5
BARDEX® TEMPERATURE-SENSING FOLEY CATHETER
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 INFORMATION:

Submitter's Name	C.R. Bard, Inc. Bard Medical Division 8195 Industrial Blvd. Covington, GA 30014
Contact Person:	Skip Rimer
Contact Person's Telephone Number:	770-784-6160
Contact Person's Fax:	770-784-6419
Date of Preparation:	January 10, 2007

B. DEVICE NAME:

Trade Name(s):	Bardex® Latex-Free Temperature-Sensing Foley Catheter, Bardex® Lubri-Sil® Temperature-Sensing Foley Catheter, and Bardex® Lubri-Sil® I.C. Temperature-Sensing Foley Catheter
Common/Usual Name:	Temperature-sensing Foley catheter
Classification Product Code:	EZL – Catheter, Retention Type, Balloon 21 CFR 876.5130
Subsequent Product Code:	MJC – Catheter, Urological (Antimicrobial) and Accessories 21 CFR 876.5130

C. PREDICATE DEVICE NAME:

Trade Name(s): Bardex® Latex-Free Temperature-Sensing Foley Catheter, Bardex® Lubri-Sil® Temperature-Sensing Foley Catheter, and Bardex® Lubri-Sil® I.C. Temperature-Sensing Foley Catheter

D. DEVICE DESCRIPTION:

The Bardex® Temperature-Sensing Foley Catheter is a two-way silicone Foley Catheter with a thermistor embedded in the third lumen. The catheters will be available uncoated, with a lubricious coating or with a silver and lubricious coating.

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E. INTENDED USE:

The Bardex® Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore® or Urotrack 224 Monitor, or other 400-Series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject device, Bardex® Temperature-Sensing Foley Catheter, has the same intended use, design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The Bardex® Temperature-Sensing Foley Catheter referenced in this submission is held to the same design, manufacture, and performance specifications as the predicate (#K003289). Performance and functional testing standards are based on the FDA "Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters" dated September 12, 1994 and ASTM F623-99, "Standard Performance Specification for Foley Catheter."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C.R. Bard, Inc.
% Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

DEC - 7 2007

Re: K070582
Trade/Device Name: Bardex® All-Silicone Temperature-Sensing Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: November 20, 2007
Received: November 21, 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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

SECTION 4
BARDEX® TEMPERATURE-SENSING FOLEY CATHETER
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Bardex® All-Silicone Temperature-Sensing Foley Catheter, Bardex® Lubri-Sil® Temperature-Sensing Foley Catheter, and the Bardex® Lubri-Sil® I.C. Temperature-Sensing Foley Catheter

Indications for Use:

The Bardex® Temperature-Sensing Foley Catheter, when connected to a Bard CritiCore® or Urotrack 224 monitor, or other 400-series Temperature Monitors, is intended for use in the drainage and/or collection and/or measurement of urine and in conjunction with an electronic urine monitor for the monitoring of core body temperature, in degrees Fahrenheit and degrees Celsius.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070582