



Food and Drug Administration
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July 28, 2015

C.R. Bard, Inc.
Michele Davis
Regulatory Affairs Project Manager
Bard Medical Division
8195 Industrial Blvd
Covington, GA 30014

Re: K150699
Trade/Device Name: Bard LubriGuard Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: June 19, 2015
Received: June 22, 2015

Dear Michele Davis,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K150699

Device Name

Bard LubriGuard Foley Catheter

Indications for Use (Describe)

The Bard LubriGuard Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Drainage is accomplished by inserting the catheter through the urethra and into the bladder.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014



510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Bard LubriGuard Foley Catheter 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014
Establishment Registration Number: 1018233

Contact: Michele Davis, RAC
Regulatory Affairs Project Manager
Bard Medical Division
Tel: 770-784-6274
Fax: 770-385-4706

Date: March 17, 2015

Subject Device: Trade Name: Bard® LubriGuard™ Foley Catheter
Common Name: Urological Catheter
Classification Name: Urological catheter and accessories
Regulation: 21 CFR 876.5130
Classification: II
Product Code: EZL

Legally marketed device to which substantial equivalence is claimed:

- Bard Hydrogel-Coated Foley Catheters, K910195

Device Description

The LubriGuard Foley Catheter is a biocompatible, hydrogel-coated, synthetic polyisoprene Foley catheter used in the drainage of urine. The catheter consists of a shaft with eyelets near the tip, balloon, drainage funnel and inflation arm with cap and valve. The eyelets allow for drainage of urine from the tip of the catheter through the drainage lumen. The balloon once inflated retains the catheter within the bladder. There are two lumens: one for urine drainage and the second for balloon inflation. The two-way valve, upon activation, permits flow in either direction and allows for inflation and deflation of the balloon. The cap retains the valve and provides identification for the catheter.

The catheter will be offered in multiple French sizes to accommodate differing patient anatomies. The product is ethylene oxide sterilized (per ISO 11135:2014, *Sterilization of health care products – ethylene oxide – Requirements for development, validation and routine control of a sterilized process for medical devices*). The catheter is for single use.

Indications for Use

The Bard LubriGuard Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Drainage is accomplished by inserting the catheter through the urethra and into the bladder.

Technological Characteristics

The Bard LubriGuard Foley Catheter has similar technological characteristics as the predicate device. The subject device is manufactured from synthetic polyisoprene which has similar properties as the predicate device that is manufactured from natural rubber latex. Both the subject and predicate device are hydrogel-coated.

Performance Data

Nonclinical functional performance testing was performed per ASTM F623-99 (2006), *Standard Performance Specification for Foley Catheter* and Coefficient of Friction testing. Nonclinical biocompatibility testing was conducted in accordance with ISO 10993-1:2009/(R)2013, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993 “Biological Evaluation of Medical Devices Part 1: Evaluation of Testing.”

Substantial Equivalence

The Bard LubriGuard Foley Catheter has similar design features and indications for use as the predicate device, Bard Hydrogel-Coated Foley Catheters, K910195. The subject device is substantially equivalent to the predicate device and nonclinical test data demonstrates that the subject device is safe and effective.