AUG 26 2011

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

BARD | MEDICAL

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR §807.92 for the ComfortGlide™ Intermittent Catheter 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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

Contact:
Stacci Cronk, RAC
Regulatory Affairs Specialist II
Bard Medical Division
C. R. Bard, Inc.
Ph: 770-784-6994
Fax: 770-385-4706
E-mail: stacci.cronk@crbard.com

Date Prepared:
June 22, 2011

Subject Device:
Trade Name: ComfortGlide™ Intermittent Catheter
Common/Usual Name: Urological Catheter
Classification Name: Urological catheter and accessories
Regulation: 21 CFR §876.5130
Classification: II
Product Code: KOD

Predicate Device(s): The ComfortGlide™ Intermittent Catheter is substantially equivalent with respect to the following predicate devices:

Product	Company	510(k) Number
Bard® Red Rubber All-Purpose Urethral Catheter	C. R. Bard, Inc.	Pre-amendment Device
Urinary Intermittent Catheter with and without Hydromer® Hydrophilic Lubricant (InterGlide™ Catheter)	Biosearch Medical Products, Inc.	K951260
InCare Intermittent Catheter	Hollister, Inc.	K013345

Device Description: The ComfortGlide™ Intermittent catheter is a hydrophilic coated, synthetic polyisoprene, urinary catheter used for temporary drainage of urine from the bladder. The catheter is a tube consisting of a funnel, shaft, drainage eyes and tip. The tip of the catheter enters the bladder to allow urine to drain into the drainage eyes and then through the catheter. The catheter will be offered in multiple French sizes (10-18 Fr), lengths (6", 10" and 16") and two stiffnesses (soft and firm). Product offerings include the catheter with water sachet in a pouch as a standalone product or the catheter with water sachet in a kit configuration. The kit configuration includes two gloves, drape, benzalkonium chloride (BZK) towelette, povidone-iodine (PVI) prep pad and bag. The product is Ethylene Oxide sterilized (per ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices) and for single use.

Intended Use: The ComfortGlide™ Intermittent Catheter is intended for use by adult and pediatric, male and female patients for draining urine from the bladder.

Technological Characteristics: The ComfortGlide™ Intermittent Catheter has the same technological characteristics as the predicate devices. The subject device is made using synthetic polyisoprene, where the soft option is similar in stiffness to the natural rubber latex predicate device (Bard® Red Rubber All-Purpose Urethral Catheter) and the firm option is similar in stiffness to the PVC predicate device (InterGlide™ Catheter, K951260). The ComfortGlide™ Intermittent Catheter utilizes a water sachet inside the package for patient convenience. Water is required to activate the hydrophilic coating for the ComfortGlide™ Intermittent Catheter and the InterGlide™ Catheter (K951260).

Performance Data: Nonclinical functional performance testing included (1) testing per BS EN 1616:1997 + A1:1999 Sterile Urethral Catheters for Single Use and (2) Coefficient of Friction Testing. Nonclinical biocompatibility testing in accordance with ISO 10993-1:2009, 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" was conducted.

Substantial Equivalence: The ComfortGlide™ Intermittent Catheter has the same intended use as the predicate devices. Nonclinical test data demonstrate that the device is safe and effective and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bard Medical Division
C.R. Bard, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 26 2011

Re: K112137
Trade/Device Name: ComfortGlide™ Intermittent Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: August 15, 2011
Received: August 16, 2011

Dear Mr. Job:

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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

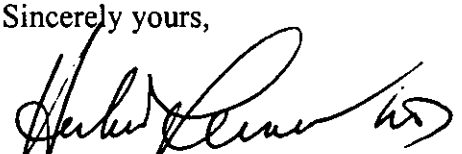
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Section 4: Indications for Use Statement

510(k) Number: K112137

Device Name: ComfortGlide™ Intermittent Catheter

Indications for Use: The ComfortGlide™ Intermittent Catheter is intended for use by adult and pediatric, male and female patients for draining urine from the bladder.

Prescription Use: ☒ **or** **Over the Counter Use** ☐

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112137

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