DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 11, 2015

C.R. Bard, Inc.
William Heard
Regulatory Affairs Specialist I
8195 Industrial Blvd
Covington, GA 30014

Re: K150345
Trade/Device Name: Magic^3 Go^{TM} Intermittent Urinary Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: February 10, 2015
Received: February 11, 2015

Dear William Heard,

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,

Herbert P. Lerner -S

for 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)*
K150345

Device Name
Magic3 Go™ Intermittent Urinary Catheter

Indications for Use *(Describe)*
The Magic3 Go™ Intermittent Urinary Catheter is intended for urological use only. It is intended for use by adult female patients for bladder management including urine drainage, collection, and measurement. The device is passed to the urinary bladder via the urethra.

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 Magic³ Go™ Intermittent Urinary 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
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Contact:
William Heard
Regulatory Affairs Specialist I
Bard Medical Division
Ph: 770-784-6267
Fax: 770-385-4706

Submission Date: February 6, 2015

Subject Device:
Trade Name: Magic³ Go™ Intermittent Urinary Catheter
Common Name: Urological Catheter
Classification Name: Urological catheter and accessories
Regulation: 21 CFR §876.5130
Regulatory Classification: II
Product Code: EZD

Predicate Device: Legally marketed device to which substantial equivalence is claimed
- HydroSil, Magic, Personal Catheter – K122785

Device Description

Magic³ Go™ Intermittent Urinary Catheter is a ready-to-use silicone intermittent urinary catheter with a self-hydrating coating over a hydrophilic coating.

The device consists of an all silicone single lumen catheter with a thermoplastic elastomer (TPE) handle which does not contain DEHP and/or phthalates. The catheter has four drainage eyes located in the proximal tip and a tapered funnel located at the distal end. The outer surface of the all silicone catheter has two coatings. The first coating is a hydrophilic coating. Over the hydrophilic coating, a self-hydrating coating is applied. The additional coating does not require activation with water prior to use. The handle provides the user with an area for a secure grip and no-touch area with which to insert the catheter.

Indications for Use
The Magic^3 Go™ Intermittent Urinary Catheter is intended for urological use only. It is intended for use by adult female patients for bladder management including urine drainage, collection, and measurement. The device is passed to the urinary bladder via the urethra.

Comparison of Technological Characteristics with the Predicate Device
The Magic^3 Go™ Intermittent Urinary Catheter has similar technological characteristics as the predicate device, HydroSil, Magic, Personal Catheter cleared via K122785. The subject and predicate device are based on the following technological elements:

- Same intended use
- Same indications for use
- Same design features (tip, eyes, size)
- Provided sterile for single-use
- Composed of biocompatible materials
- Ergonomic handle design
- Same catheter materials
- Same hydrophilic coating

The subject device has a new self-hydrating coating.

Performance Data
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
The biocompatibility evaluation of the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices Part 1: Evaluation of Testing'"* May 1, 1995 and ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The subject device is considered as a mucosal contacting surface device with limited exposure. The battery of testing included the following:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Vaginal Mucosal Irritation (ISO 10993-10)

Nonclinical functional performance testing
Nonclinical functional performance testing of the subject device was performed in accordance with BS EN 1616: 1997 + A1:1999, *Sterile urethral catheters for single use.*

Coefficient of friction testing was also conducted on the subject device to determine the lubricity of the catheter surface and demonstrate substantial equivalence to the predicate device. The Magic^3 Go™ Intermittent Urinary Catheter has a low coefficient of friction resulting in low friction between the catheter and urethral mucosa.

Conclusions
The Magic^3 Go™ Intermittent Urinary Catheter is substantially equivalent to the legally marketed predicate device as demonstrated by the same intended use, same indications for use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.