DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 20, 2017

C.R. Bard, Inc.
Nancy Underwood
Regulatory Affairs Specialist
8195 Industrial Blvd
Covington, GA 30014

Re: K172247
Trade/Device Name: Magic3 Go® Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: July 25, 2017
Received: July 26, 2017

Dear Nancy Underwood:

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 (DICE) 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 (DICE) 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,

Charles Viviano -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172247

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 and pediatric patients of all ages 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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Magic3 Go® Intermittent Urinary Catheter

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Boulevard
Covington GA 30014
Phone: 770-784-6284
Fax: 770-385-4706
Contact Person: Nancy Underwood, Regulatory Affairs Specialist
Date of Submission: July 25, 2017

Subject Device Name:

Name of Device:	*Magic3 Go® Intermittent Urinary Catheter*
Common or Usual Name:	Urological Catheter
Classification Name:	Urological catheter and accessories
FDA Pro Code:	EZD
Regulatory Class:	II
Regulation Number:	21 CFR §876.5130

Predicate Devices:

Primary Predicate

Name of Device:	Magic3 Go® Intermittent Urinary Catheter, K150345
Common or Usual Name:	Urological Catheter
Classification Name:	Urological catheter and accessories
Regulatory Class:	II
Regulation Number:	21 CFR §876.5130

Name of Device:	Hydrophilic Personal Catheter®, K000723
Common or Usual Name:	Urological Catheter
Classification Name:	Urological catheter and accessories
Regulatory Class:	II
Regulation Number:	21 CFR §876.5130

Device Description:

The *Magic3 Go® Intermittent Urinary Catheter* is a ready-to-use silicone intermittent catheter with a self-hydrating coating over a hydrophilic coating. The device is provided sterile and is for single use.

The device consists of an all silicone single lumen catheter with a polyethylene insertion sleeve (Sure-Grip™) which is not made from natural rubber latex, DEHP and/or other phthalates. The catheter has four drainage eyes located in the proximal tip and a tapered funnel located at the distal end. The catheter will be offered in multiple French sizes (6 – 20Fr), multiple lengths (10" & 16") and two tip designs (straight and coudé).

The outer surface of the 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 Sure-Grip™ insertion sleeve provides the user with an ergonomically designed area for a secure grip and no-touch area with which to insert the catheter.

Indications for Use of Device:

The *Magic3 Go® Intermittent Urinary Catheter* is intended for urological use only. It is intended for use by adult and pediatric patients of all ages for bladder management including urine drainage, collection, and measurement. The device is passed to the urinary bladder via the urethra.

Technological Comparison to Predicate Devices:

The *Magic3 Go® Intermittent Urinary Catheter* has similar technological characteristics as the predicate device, Magic3 Go® Intermittent Urinary Catheter previously cleared via K150345 and the Hydrophilic Personal Catheter® previously cleared via K000723. The subject and predicate devices are based on the following technological elements:

- Same intended use
- Similar indications for use
- Same drainage eye position

- Similar tip configurations
- Provided sterile for single-use
- Composed of biocompatible materials
- Same catheter materials
- Same self-hydrating coating
- Similar design features
- Similar product offerings

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 Use of International Standard ISO 10993-1, *Biological evaluation of medical devices and testing within a risk management process* – July 21, 2016. The subject device is considered 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)

Non-clinical functional performance testing

Non-clinical 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 (CoF) testing was previously conducted on the cleared predicate device K150345. Since the subject device is identical to the predicate device K150345, in terms of catheter material and coatings, it has been determined that lubricity testing was not necessary on the subject device. The lubricity of the subject device is determined to be equivalent to the predicate device, K150345.

Conclusions:

The *Magic3 Go*® *Intermittent Urinary Catheter* is substantially equivalent to the legally marketed predicate devices as demonstrated by the same intended use, similar indications for use, similar technological characteristics and performance data, and does not raise different questions of safety and effectiveness