September 19, 2018

C. R. Bard, Inc.
Sharon Lambert, RAC
Regulatory Affairs Specialist II
8195 Industrial Blvd.
Covington, GA 30014

Re: K180781
Trade/Device Name: BARD® Vertus™ Foley Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: August 14, 2018
Received: August 16, 2018

Dear Sharon Lambert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -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)*
K180781

Device Name
BARD® Vertus™ Foley Catheter

Indications for Use *(Describe)*
The BARD® Vertus™ Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine in adult and pediatric patients of compatible anatomical size. 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® Vertus™ Foley 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 Blvd
Covington, GA 30014

Phone: (770) 784-6208
Fax: (770) 385-4706

Contact Person: Sharon Lambert, RA Specialist II
Date of Submission: August 14, 2018

Subject Device Name:

Name of Device:	BARD® Vertus™ Foley Catheter with product codes 0165B14, 0165B16, 0165B18
Common or Usual Name:	Urological Catheter
Classification Number	21 CFR 876.5130
Classification Name:	Urological Catheter and Accessories
Product Code	EZL
Product Code Name	Catheter, Retention Type, Balloon
Regulatory Class:	II

Predicate Device:

Name of Device:	Bard® LubriGuard™ Foley Catheter with product codes 0165B14, 0165B16, 0165B18
Common or Usual Name:	Urological Catheter
Classification Number	21 CFR 876.5130
Classification Name:	Urological Catheter and Accessories
Product Code	EZL
Product Code Name	Catheter, Retention Type, Balloon
Regulatory Class:	II
510(k)	K150699

Device Description:

The BARD® Vertus™ 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. The shaft has two lumens: one to allow 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 provided sterile via 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 a single use, prescription-only device.

Indications for Use of Device:

The BARD® Vertus™ Foley Catheter is indicated for use in the drainage and/or collection and/or measurement of urine in adult and pediatric patients of compatible anatomical size. Drainage is accomplished by inserting the catheter through the urethra and into the bladder.

Technological Comparison to Predicate Devices:

The BARD® Vertus™ Foley Catheter has identical technological characteristics and performance specifications as the predicate device, Bard® LubriGuard™ Foley Catheter (K150699). Both devices are manufactured from synthetic polyisoprene which has similar properties to natural rubber latex. Both subject and predicate devices are hydrogel-coated and possess the same design features and indications for use. In conclusion, the subject device is substantially equivalent to the predicate device and nonclinical test data demonstrate substantial equivalence.

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 *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 prolonged duration. The battery of testing included the following.

- Cytotoxicity (ISO 10993-5 and AS/NZS 2696:1996)
- Sensitization (ISO 10993-10)
- Vaginal Mucosal Irritation (ISO 10993-10)
- Systemic Toxicity (ISO 10993-11)
- Sub-Acute Systemic Toxicity (ISO 10993-11)
- Muscle Implantation (ISO 10993-6)
- Genotoxicity (ISO 10993-3)

Non-clinical functional performance testing

Non-clinical functional performance testing of the subject device was performed in accordance with ASTM F623-99/(R)2013, Standard Performance Specification for Foley Catheter. Coefficient of friction (CoF) was also conducted for lubricity evaluation.

Conclusions:

The BARD® Vertus™ Foley Catheter is substantially equivalent to the legally marketed predicate device, BARD® LubriGuard™ Foley Catheter, as demonstrated by the same intended use, indications for use, and technological characteristics. Non-clinical performance data demonstrates that the subject device is safe and effective.