



February 23, 2026

C. R. Bard, Inc.
Cameron Boyd
Regulatory Affairs Specialist
8195 Industrial Boulevard
Covington, Georgia 30014

Re: K251864
Trade/Device Name: Rubber Utility Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: January 30, 2026
Received: February 2, 2026

Dear Cameron Boyd:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSICA K. NGUYEN -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K251864

Device Name

Rubber Utility Catheter

Indications for Use (Describe)

The BD Rubber Utility Catheter is indicated for intermittent catheterization of the urethra to drain urine from the bladder by patients who are not capable of voluntary urination.

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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510(k) Summary
K251864

In accordance with 21 CFR 807.92, the following information is provided for the BD Rubber Utility Catheter Traditional 510(k) Premarket Notification. This submission was prepared in accordance with 21 CF 807.90 Subpart E and the FDA’s electronic submission template eSTAR.

510(k) Owner/Submitter Information

C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014
Phone: 1-844-823-5433
Contact Person: Cameron Boyd, Regulatory Affairs Specialist
Contact Email: Cameron.Boyd@BD.com
Date Prepared: 20 February 2026

Subject Device

Trade Name:	Rubber Utility Catheter
Common Name(s):	Red Rubber Catheter, Urological Catheter
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	KOD
Device Classification Name:	Catheter, Urological
Review Panel:	Gastroenterology/Urology
Basis for Submission:	Modified Device

Predicate Device

Trade Name:	Dover Red Rubber Robinson Catheter
Predicate 510(k) Number:	K041243
Common Name(s):	Urinary Drainage Catheter
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	KOD
Device Classification Name:	Catheter, Urological
Review Panel:	Gastroenterology/Urology

Additionally, a reference device was selected within the 510(k) to provide a clinically, commercially, and legally marketed comparator as an additional benchmark to ensure the subject device does not raise different questions of safety or effectiveness.



Reference Device

Trade Name:	Intermittent Nelaton Catheter for Single Use
Predicate 510(k) Number:	K222677
Common Name:	Urethral Catheter
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	EZD
Device Classification Name:	Catheter, Straight
Review Panel:	Gastroenterology/Urology

Device Description

The BD Rubber Utility Catheter is an uncoated, latex, intermittent urethral catheter that is provided sterile and intended for single use. It is intended for the drainage of urine from the bladder via intermittent urethral catheterization. The device is intended for use in adult and pediatric patients 2 years of age or older. Selection of the appropriate catheter size should be determined by the patient’s healthcare provider based on clinical judgement.

Indications for Use

The BD Rubber Utility Catheter is indicated for intermittent catheterization of the urethra to drain urine from the bladder by patients who are not capable of voluntary urination.

Non-Clinical Data

The following data is provided in support of the substantial equivalence determination and the safety and effectiveness claims of the subject device based on FDA recognized consensus standards and others at the time of submission.

Biocompatibility:

The biocompatibility evaluation was conducted in accordance with FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* and applicable sections of

- ISO 10993-1 – *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5 – *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-6 – *Biological evaluation of medical devices - Part 6: Tests for local effects after implantation*
- ISO 10993-10 – *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*
- ISO 10993-11 – *Biological evaluation of medical devices - Part 11: Tests for systemic toxicity*
- ISO 10993-12 – *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*
- ISO 10993-23 – *Biological evaluation of medical devices - Part 23: Tests for irritation*

Non-Clinical Functional Performance Testing:

Non-clinical performance testing of the subject device was performed in accordance with applicable sections of

- ISO 20696 – *Sterile urethral catheters for single use*
- ASTM F623-19 (2023) – *Standard Performance Specification for Foley Catheter*
- ASTM D8389-21 – *Standard performance specification for urinary intermittent catheters*

Non-clinical performance testing of the subject device's primary packaging was performed in accordance with applicable sections of

- ASTM F88/F88M-21 – *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F2096-11 – *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*

To demonstrate device and packaging functionality over time, accelerated aging was performed to simulate aging in accordance with

- ASTM F1980-21 – *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

Sterilization validation was performed according to

- ISO 11135 Second Edition 2014-07-15 – *Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]*

All tests met the requirements of the pre-determined acceptance criteria.

Technological Characteristic Comparison

The subject device is substantially equivalent to the predicate device cited above. The differences between the subject device and the predicate device are minor, and all associated risks have been appropriately mitigated through testing. These differences in technological characteristics do not raise different questions of safety or effectiveness. Table 1 below provides a comparison of the technological characteristics of the subject device and predicate device.

Conclusion

The BD Rubber Utility Catheter has the same intended use and similar technological characteristics as the predicate device. The subject device is substantially equivalent to the legally marketed predicate device as demonstrated by the substantial equivalence comparisons and performance data, and the subject device does not raise different questions of safety and effectiveness for its intended use.



Table 1. Technological Characteristic Comparison

Characteristic	Subject Device	Predicate Device (K041243)
Regulation Number	21 CFR 876.5130	21 CFR 876.5130
Regulation Description	Urological Catheter and Accessories	Urological Catheter and Accessories
Product Code	KOD	KOD
Classification	II	II
Intended Use	Urine drainage from the bladder via intermittent urethral catheterization	Urine drainage from the bladder via intermittent urethral catheterization
Indications for Use	The BD Rubber Utility Catheter is indicated for intermittent catheterization of the urethra to drain urine from the bladder by patients who are not capable of voluntary urination.	The proposed device is intended for use in the drainage of urine from the urinary bladder. The product is intended for intermittent catheterization on patients who are not capable of voluntary urination. This product is not designed for use as an indwelling catheter.
Target Population	Adult and Pediatric	Not stated
Sterile State	Provided sterile	Provided sterile
Condition of Use	Single Use	Single Use
Principle of Operation	Device is passed to the urinary bladder via the urethra.	Device is passed to the urinary bladder via the urethra.
Where Used	Hospital, nursing home, rehabilitation facilities, restrooms, or home use environment	Hospital, nursing home, rehabilitation facilities, restrooms, or home use environment
Catheter Design	Single lumen catheter with eyelets to funnel urine	Single lumen catheter with eyelets to funnel urine
Catheter Material	Natural Rubber Latex	Natural Rubber Latex
Catheter Coating	None	None
Tip Configuration	Straight tip	Straight tip
Diameter French Sizes	8-18	12 inch length: 8-10 16 inch length: 12-30
Catheter Length	Effective Length: 385 mm	Overall Lengths: 12 inches (305 mm) or 16 inches (406 mm)
Sterilization Method	Ethylene Oxide	Ethylene Oxide