May 29, 2026

C.R. Bard, Inc.
Marc Persad
Senior Regulatory Affairs Specialist
8195 Industrial Blvd.
Covington, Georgia 30014

Re: K254076
Trade/Device Name: BD Touchless™ Plus Unisex Pre-Lubricated Urethral Catheter Kit
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: FCM
Dated: April 29, 2026
Received: April 29, 2026

Dear Marc Persad:

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. 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/tray. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K254076

Device Name

BD Touchless™ Plus Unisex Pre-Lubricated Urethral Catheter Kit

Indications for Use *(Describe)*

The BD Touchless™ Plus Unisex Urethral Catheter Kit is indicated for intermittent catheterization of the urethra to drain urine from the bladder by adult 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, Georgia 30014 USA

bd.com

510(k) Summary
K254076

In accordance with 21 CFR 807.92, the following information is provided for the BD Unisex Pre-Lubricated Urethral Catheter Kit 510(k) Premarket Notification. This submission was prepared in accordance with 21 CF 807 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: 770-826-3867
Contact Person: Marc Persad, Senior Regulatory Affairs Specialist
Date of Submission: May 29, 2026

Subject Device

Trade Name:	BD Touchless™ Plus Unisex Pre-Lubricated Urethral Catheter Kit
Common Name(s):	Unisex Pre-Lubricated Urethral Catheter Kit, Rubber Urethral Catheter
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	FCM
Device Classification Name:	Tray, catheterization, sterile urethral, with or without catheter (kit)
Review Panel:	Gastroenterology/Urology
Basis for Submission:	Modified Device

Predicate Device

Trade Name:	Bard Touchless II Intermittent Catheter tray
Predicate 510(k) Number:	K910653
Common Name(s):	Rubber Utility Catheter, Urological Catheter, All-Purpose Urological Catheter, Latex Intermittent Catheter
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	FCM

C. R. Bard, Inc.

8195 Industrial Boulevard

Covington, Georgia 30014 USA

bd.com

Device Classification Name:	Tray, catheterization, sterile urethral, with or without catheter (kit)
Review Panel:	Gastroenterology/Urology

The predicate device has not been subjected to any design-related recalls.

Additionally, a reference device was selected within the 510(k) to support updated performance standards.

Reference Device

Trade Name:	Self-Cath Closed System
Reference 510(k) Number:	K223821
Common Name(s):	Intermittent Catheter, Urethral
Recommended Classification Regulation:	21 CFR 876.5130
Classification:	II
Product Code:	FCM
Device Classification Name:	Tray, catheterization, sterile urethral, with or without catheter (kit)
Review Panel:	Gastroenterology/Urology

Device Description

The BD Touchless Plus Unisex Pre-Lubricated Urethral Catheter Kit contains a pre-lubricated Red Rubber intermittent urethral catheter that is housed within a urine collection bag. The kit also contains gloves, under pad and Povidone-Iodine swabs. The kit is provided sterile and is intended for single use.

Indications for Use

The BD Touchless Plus Unisex Pre-Lubricated Urethral Catheter Kit is indicated for intermittent catheterization of the urethra to drain urine from the bladder by adult patients who are not capable of voluntary urination.

C. R. Bard, Inc.

8195 Industrial Boulevard

Covington, Georgia 30014 USA

bd.com

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 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 (2025) – *Standard Performance Specification for Foley Catheter*
- ASTM D8389-2021 – *Standard performance specification for urinary intermittent catheters*

Non-clinical functional performance testing of the urine collection bag used with the subject device was performed in accordance with applicable sections of
- ISO 8669-2:1996 – *Urine collection bags Part 2: Requirements and test methods*

Non-clinical performance testing of the subject device's primary packaging was performed in accordance with applicable sections of
- ASTM F2096 -11(2019) – *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 -2021 – *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
- ASTM F88/F88M-2023 – *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F2096 -11(2019) – *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*

C. R. Bard, Inc.

8195 Industrial Boulevard

Covington, Georgia 30014 USA

bd.com

- ISO 11607-1 2019-02 – *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ASTM D4169-2023 – *Standard Practice for Performance Testing of Shipping Containers and Systems*

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

Technological Characteristic Comparison

The subject **BD Touchless Plus Unisex Pre-Lubricated Urethral Catheter Kit** has similar technological characteristics compared to the predicate device, Bard Touchless II Intermittent Catheter tray, cleared via K910653. The subject and predicate devices share the following elements:

- Same intended use
- Same principle of operation
- Same design features and technological characteristics
- Provided sterile for single-use

Table 1 below provides a comparison of the technological characteristics between the subject and predicate devices. The subject device is substantially equivalent to the predicate device since they share the same technological characteristics as noted above. The subject device when compared to the predicate device differs in the indications for use statement and the supplier of the latex material. The minor difference in technological characteristics does not raise different questions of safety and effectiveness..

Conclusion

The subject BD Touchless™ Plus Unisex Pre-Lubricated Urethral Catheter Kit 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.

C. R. Bard, Inc.

8195 Industrial Boulevard

Covington, Georgia 30014 USA

bd.com

Table 1. Technological Characteristic Comparison

Design/ Technological Characteristic	Subject Device K254076 BD Touchless® Plus Unisex Pre-Lubricated Urethral Catheter Kit	Predicate Device K910653 Bard Touchless II Intermittent Catheter Tray
Regulation Number	21 CFR 876.5130	21 CFR 876.5130
Regulation Description	Urological Catheter and Accessories	Urological Catheter and Accessories
Product Code	FCM	FCM
Classification	II	II
Intended Use	Intermittent catheterization of the urethra to drain urine from the bladder	Intermittent catheterization of the urethra to drain urine from the bladder
Indications for Use	The BD Touchless™ Plus Unisex Uretheral Catheter Kit is indicated for intermittent catheterization of the urethra to drain urine from the bladder by adult patients who are not capable of voluntary urination.	For Urological Use Only.
Target Population	Adult patients, Unisex	Adult patients, Unisex
Sterile State	Provided sterile	Provided sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide
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.
Catheter Design	Single lumen catheter with lateral opposing drainage eyelets (proximal end, inserted into body orifice) to funnel (distal end)	Single lumen catheter with lateral opposing drainage eyelets (proximal end, inserted into body orifice) to funnel (distal end)
Where Used	Hospital, nursing home, rehabilitation facilities, or home use environment	Hospital, nursing home, rehabilitation facilities, or home use environment
Catheter Material	Natural Rubber Latex	Natural Rubber Latex
Catheter Coating	Pre-Lubricated, Water-soluble lube	Pre-Lubricated, Water-soluble lube
Tip Configuration	Straight tip	Straight tip
Diameter/French Sizes	12 Fr & 14 Fr	12 Fr & 14 Fr
Effective Length	401 mm	401 mm
Urine collection bag, size	Self-contained, 1100cc	Self-contained, 1100cc
Kit Accessories	Povidione Iodine Swabs 2 Ambidextrous gloves Waterproof underpad	Povidione Iodine Swabs 2 Ambidextrous gloves Waterproof underpad