November 7, 2023

ConvaTec, Inc.
% Dawn Norman
Partner
MRC Global, LLC
9085 East Mineral Circle, Suite 110
Centennial, CO 80112

Re: K230400
Trade/Device Name: Cure Dextra® and Cure Catheter® Closed System
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: October 11, 2023
Received: October 11, 2023

Dear Dawn Norman:

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. 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: 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,
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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.

510(k) Number *(if known)*
K230400

Device Name
Cure Dextra® and Cure Catheter® Closed System

Indications for Use *(Describe)*
The Cure Dextra® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.

The Cure Catheter® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.

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
Cure Dextra® and Cure Catheter® Closed System
November 7, 2023

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

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Director, Regulatory Affairs
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Trade Name: Cure Dextra® and Cure Catheter® Closed System

Common Name: Catheter, Urological

Classification: Class II

Regulation Number: 21 CFR 876.5130

Regulation Name: Urological Catheter and Accessories

Product Code: EZD

Primary Predicate: Cure Catheter® Closed System, K080881

Device Description:
The Cure Dextra® and Cure Catheter® Closed System catheters are intermittent urinary catheters intended to be used by males and females for the purpose of bladder drainage. They are manufactured with conventional medical grade, biocompatible materials that are not made with natural rubber latex. The tip has been designed to minimize trauma to the urethra and is provided in various sizes in easy-to-open, sterile, single-use packages.

The subject devices are pre-lubricated catheter systems that allow for patient convenience when catheterization is required. The Closed System catheter is attached to a collection bag and features polished eyelets on a straight or Coudé catheter tip. The Dextra catheter will advance from the bag with every forward stroke while the rearward strokes allow for the mechanism to get a new grip on the catheter. The urine collection bag of the Dextra catheter is reduced from 1500 ml in the predicate Closed System to 1000 ml to make it compact and portable.

The target population for the Closed System and Dextra is both males and females. The selection of the French size (Ch) of the catheter is based on the size of the patient and is prescribed by a health care professional. The effective shaft length of the catheter (i.e., Dextra 286 mm and Closed System 290 mm) meets the requirements of ISO 20696:2018 for the minimum effective shaft length (275mm) for males and minimum effective shaft length (60 mm) for females.

Indications for Use:

The Cure Dextra® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.

The Cure Catheter® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.

Comparison of Technological Characteristics:

The subject catheters are a modified version of the predicate Cure Catheter® Closed System (K080881). The subject device modifications do not raise different questions about safety and effectiveness. A detailed comparison between the subject devices and the predicate and reference devices is provided in the table below.

Comparison of Technological Characteristics Table:

Information	Subject Device	Primary Predicate Device	Reference Device	Substantial Equivalence
Device	**Cure Catheter® Closed System® and Cure Dextra® Closed System®**	**Cure Catheter® Closed System** **K080881**	**Cure Ultra®** **K221593**	**N/A**
Indications for Use	The Cure Catheter® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use. The Cure Dextra® Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.	The Cure Catheter™ Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.	The Cure Ultra® is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.	Identical to the primary predicate
Patient Population	For male and female adults	For male and female adults	For male and female adults	Identical to the primary predicate
Regulation	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130	Identical to the primary predicate
Product Code	EZD	KOD/FCM	EZD	Similar to the predicate, identical to reference device
Tube Size Range (Effective Length/OD French)	Closed System: 310mm (+/- 5) effective length 8-16 Fr Dextra: 310 mm (+/- 5) effective length 12-16 Fr	Male: 310 mm effective length 8-16Fr Female: 165mm (6.5 inch) length 8-16Fr	Male Ultra: 375 mm (14.76 inch) length, 8-18 Fr Female Ultra: 97 mm (3.82 inch) length, 8-16 Fr Female Ultra Plus: 175 mm (6.88) inch length, 8-18 Fr	The effective length of both the subject devices and the predicate devices is identical

Information	Subject Device	Primary Predicate Device	Reference Device	Substantial Equivalence
Device	**Cure Catheter® Closed System® and Cure Dextra® Closed System®**	**Cure Catheter® Closed System** **K080881**	**Cure Ultra®** **K221593**	**N/A**
Technological Features	Straight or Coude Tip Catheter PVC Smooth Tip Polished Eyelets Multiple sizes for both male and female use Sterile Packaged for single Pre-lubricated: Water Based Hydrophilic Coating Drainage Bag for collecting urine Gripper for ease of indexing tube Modified the interface tube to increase surface area of the bag weld	Straight Tip Catheter PVC Smooth Tip Polished Eyelets Multiple sizes for both male and female use Sterile Packaged for single use Pre-lubricated: Water Based Hydrophilic Coating Drainage Bag for collecting urine	Straight or Coude Tip Catheter PVC Smooth Tip Polished Eyelets Multiple sizes for both male and female use Sterile Packaged for single use Handling gripper for male catheters Pre-lubricated: Water Based Hydrophilic Coating Open end for convenient use without collection bag	The Closed System modified the interface tube to increase surface area of the bag weld and the Dextra has a gripper for ease of indexing the tubing. These additions do not create different questions of safety or effectiveness.
Sterilization	Ethylene Oxide SAL: 10^{-6}	Ethylene Oxide SAL: 10^{-6}	Ethylene Oxide SAL: 10^{-6}	Identical to primary predicate
Biocompatibility	Evaluation and testing as applicable within the risk management process, the FDA Biocompatibility Guidance Document (September 2023) and ISO 10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The test articles were considered biocompatible under the conditions tested.	All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part- 10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The test articles were considered biocompatible under the conditions tested.	All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The test articles were considered biocompatible under the conditions tested.	Biological equivalency between the subject device and the predicate was established by biological testing or justification.
Catheter Tube Material	PVC Coudé tipped tubing contains a blue stripe comprised of <1% of colorant Phthalocyanine Blue (CAS No. 147-14-8)	PVC	PVC Coudé tipped tubing contains a blue stripe comprised of <1% of colorant Phthalocyanine Blue (CAS No. 147-14-8)	Identical to primary predicate for regular tip devices and identical to reference device for Coudé tip devices

Information	Subject Device	Primary Predicate Device	Reference Device	Substantial Equivalence
Device	**Cure Catheter® Closed System® and Cure Dextra® Closed System®**	**Cure Catheter® Closed System** **K080881**	**Cure Ultra®** **K221593**	**N/A**
Catheter Collection Bag Material	LDPE	LDPE	N/A	Identical to primary predicate
Collection Bag Size	Closed System: 1500mL Dextra: 1000 mL	1500 mL	N/A	Dextra has a smaller collection bag than the predicate device for portability. This does not create different questions of safety or effectiveness.
Catheter Lubrication	Lubrajel MG	Lubrajel MG	Lubrajel MG	Identical to primary predicate

Summary of Non-Clinical Performance Testing:

Performance testing for the Cure Dextra® and Cure Closed System® were conducted per applicable sections of voluntary and FDA consensus standards:

- Sterilization validation was adopted into an existing terminal cycle validation per AAMI/ISO 11135-1:2014/AMD 1:2018 and ISO 10993-7:2008
- Biocompatibility testing (cytotoxicity, irritation, sensitization, and subacute systemic toxicity) according to ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1" (2020)
- Sterile packaging in accordance with ISO 11607-1:2006 and ISO 11607-2:2019
- Real Time aged shelf-life testing according to ISO 11607-1:2019
- Packaging integrity testing according to ASTM F2096-11 (2019)
- Diameter and Effective Shaft Length testing performed according to ISO 20696:2018
- Flow rate, Tensile, Strength, and Kink Stability testing performed in accordance with ISO 20696:2018

Conclusion:

The data and information provided in this submission support the conclusion that the Cure Dextra® and Cure Closed System (subject devices) are substantially equivalent to the predicate device (K080881).