July 1, 2025

Convatec
Cole Langham
Regulatory Affairs Specialist
First Avenue, Deeside Industrial Estate Deeside
Flintshire, CH5 2NU
UNITED KINGDOM

Re: K250699
Trade/Device Name: Cure Twist Female 8 Catheter (T8); Cure Twist Female 10 Catheter (T10); Cure Twist Female 12 Catheter (T12); Cure Twist Female 14 Catheter (T14); Cure Twist Female 16 Catheter (T16); Cure Twist Female 8 Catheter Kit with supplies (T8K); Cure Twist Female 10 Catheter Kit with supplies (T10K); Cure Twist Female 12 Catheter Kit with supplies (T12K); Cure Twist Female 14 Catheter Kit with supplies (T14K); Cure Twist Female 16 Catheter Kit with supplies (T16K)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: February 25, 2025
Received: March 7, 2025

Dear Cole Langham:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Angel A. Soler-garcia -S

for
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)*

K250699

Device Name

Cure Twist Female 8 Catheter (T8);
Cure Twist Female 10 Catheter (T10);
Cure Twist Female 12 Catheter (T12);
Cure Twist Female 14 Catheter (T14);
Cure Twist Female 16 Catheter (T16);
Cure Twist Female 8 Catheter Kit with supplies (T8K);
Cure Twist Female 10 Catheter Kit with supplies (T10K);
Cure Twist Female 12 Catheter Kit with supplies (T12K);
Cure Twist Female 14 Catheter Kit with supplies (T14K);
Cure Twist Female 16 Catheter Kit with supplies (T16K)

Indications for Use *(Describe)*

The Cure Twist® is a pre-lubricated intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for 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

Date Prepared	June 30, 2025
Submitter	ConvaTec, Ltd. First Avenue Deeside Industrial Park Deeside Flintshire, CH5 2NU UK
Contact person	Courtney Smith Courtney.smith@convatec.com Phone: 239-776-2947
Name of Device	Cure Twist® Female Catheter
Common Name	Intermittent Urinary Catheter
Product Code	EZD
Classification Name	Urological catheter and accessories
Classification	II
Predicate Device	Cure Ultra™ (K221593) The predicate device has not been subject to a design-related recall
Reference Devices	N/A
Device Description	The Cure Twist® Female Catheter is a ready-to-use intermittent catheter pre-lubricated with a water based gel and includes polished eyelets for smooth insertion and easy drainage. The catheters are manufactured in CH8 to CH16 sizes. They are single use devices made from polyvinyl chloride (PVC) and sterilized by ethylene oxide. The Cure Medical Catheter Insertion Kits components are used to aid catheter insertion. The Cure Twist® Female Catheter plus insertion kit include the Cure Twist® Female Catheter, ambidextrous gloves (PVC or nitrile), a benzalkonium chloride (BZK) wipe, an under pad and a urine collection bag with a universal connector. The Cure Twist catheters are expected to be used in professional healthcare facilities, homes, work, public bathrooms, as well as out and about.
Indications for Use	The Cure Twist® Female Catheter is a pre-lubricated intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for females. The urinary catheter comes in a variety of sizes and is packaged sterile for single-use.
Technological Comparison	The Cure Twist® Female Catheter device has the same indications for use and technological characteristics as the predicate device, Cure Ultra (K221593), for the female population. The difference between the predicate and subject devices is the primary packaging. Below is the Cure Twist® Female Catheter (subject device) and the Cure Ultra™ (predicate device) comparison of technological characteristics.

	Subject Device (K250669)	Predicate Device (K221593)	Comparison
	Cure Twist® Female Catheter	Cure Ultra	
	Straight Tip Catheter	Straight Tip Catheter	Equivalent
	Latex-Free PVC	Latex-Free PVC	Equivalent
	Smooth Tip	Smooth Tip	Equivalent
	Polished Eyelets	Polished Eyelets	Equivalent
	Multiple sizes for female use	Multiple sizes for both male and female use	Equivalent
	Sterile Packaged for single use in a plastic case with a twist cap	Sterile Packaged for single use	Primary pack is designed to be pocketed discreetly. This change does not affect the safety or performance of the subject device.
	Pre-lubricated	Pre-lubricated	Equivalent
	Open end system without collection bag	Open end system without collection bag	Equivalent
Performance Data	Performance testing for Cure Twist® Female Catheter was conducted on the subject devices or representative devices 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/AMD:2019 • Biocompatibility testing (cytotoxicity, irritation, sensitization, and chemical characterization) according to ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1" • Sterile packaging in accordance with ISO 11607-1:2019 and ISO 11607-2:2019 • Real time aged shelf-life testing according to ISO 11607-1:2006 with justification to version 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 Twist® female catheter device (subject device) is substantially equivalent to its predicate device Cure Ultra™ (K221593) and the proposed subject device is as safe and effective as the predicate device.		