November 17, 2022

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

Re: K221593
Trade/Device Name: Cure Ultra® Female, Cure Ultra® Male, Cure Ultra® Plus
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: October 6, 2022
Received: October 18, 2022

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. 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221593

Device Name
Cure Ultra® Female, Cure Ultra® Male, Cure Ultra® Plus

Indications for Use *(Describe)*
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.

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 Ultra®
November 17, 2022

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

Company: ConvaTec, Inc.
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Trade Name: Cure Ultra® Female, Cure Ultra® Male, Cure Ultra® Plus

Common Name: Catheter, Urological

Regulation Name: Urological Catheter and Accessories

Classification: Class II

Regulation Number: 21 CFR 876.5130

Panel: Gastroenterology/Urology

Product Code: EZD

Predicate Device Cure Catheter® Closed System, K080881

Description:

The Cure Ultra® catheters, which include the Cure Ultra® Male, Cure Ultra® Female and Cure Ultra® Plus products 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 eliminate trauma to the urethra and is provided in various sizes in easy-to-open, sterile, single-use packages.

Indications for 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.

The Intended Use Population
Adults who need assistance with bladder drainage due to conditions causing dysfunction of the urinary system.

The target population for Cure Ultra® is male and female adults. The selection of the CH size of the catheter is based on the size of the patient and is prescribed by a health care professional. The length of the catheter meets the requirements of ISO 20696:2018 for the minimum effective shaft length (275 mm) for males and minimum effective shaft length (60 mm) for females.

Additional users are healthcare professionals including nurses, and/or caregivers, and family members who help patients with catheterization.

Cure Ultra® target users will be those who are able self-catheterize and have no or minimal dexterity impairment. However, users with dexterity impairments are not excluded from the intended users should they wish to use the device with assistance from others.

Basis of Substantial Equivalence:
The subject Cure Ultra® is substantially equivalent to the predicate Cure Catheter® Closed System (K080881).

The subject catheter is a modified version of the predicate Cure Catheter® Closed System (K080881). The subject device is a pre-lubricated, open catheter system that allows for patient convenience when catheterization is required while away from home. It does not include a collection bag and instead should be used to allow urine to flow directly into a toilet or other collection system (similar to the previously cleared Cure Catheter® (K072539)). Modifications to French size and length have been validated, the addition of male coude tip type, addition of the male gripper sleeve improved handling, and the lack of the collection bag does not present new safety or effectiveness questions or new risk to patients. The catheter tube and funnel are manufactured from Polyvinyl chloride (PVC) and pre-lubricated with Lubrajel MG, identical to the predicate device.

Thus, it can be concluded that the subject device modifications do not raise new questions about safety and effectiveness.

Performance Testing:
Performance testing for the Cure Ultra® device system was 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 10993-7:1995
- Biocompatibility testing (cytotoxicity, irritation, sensitization, and chemical characterization) 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 11607-2:2006
- Real time aged shelf-life testing according to ISO 11607-1:2006
- 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 Ultra® device system (subject device) is substantially equivalent to its predicate device (K080881) and the proposed modification does not significantly affect the safety or effectiveness of the device.