June 6, 2025

ConvaTec Limited
Alexandra Hyde
Regulatory Affairs Manager
First Avenue
Deeside Industrial Park
Deeside, CH5 2NU
UNITED KINGDOM

Re: K250891
Trade/Device Name: Cure Catheter Insertion Kit (K1); Cure Catheter Insertion Kit (K2); Cure Catheter Insertion Kit (K2-90); Cure Catheter Insertion Kit (K3); Cure Hydrophilic Catheter Kit (HM12UK); Cure Hydrophilic Catheter Kit (HM14UK); Cure Hydrophilic Catheter Kit (HM16UK); Cure Pocket Catheter Kit (M14UK); Cure Catheter Closed System Kit (CS8); Cure Catheter Closed System Kit (CS10); Cure Catheter Closed System Kit (CS12); Cure Catheter Closed System Kit (CS14); Cure Catheter Closed System Kit (CS14C); Cure Catheter Closed System Kit (CS16)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: FCM
Received: May 7, 2025

Dear Alexandra Hyde:

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 kits 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.

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,

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)*

K250891

Device Name

The Cure Catheter insertion Kits (K1, K2, K2-90, K3, Cure Hydrophilic Catheter Kit (HMxxUK), Cure Pocket Catheter Kit (MxxUK), Cure Catheter Closed System Kit (CSxx)

Indications for Use *(Describe)*

The Cure Catheter insertion Kit is an intermittent urinary catheter kit indicated for the purpose of bladder drainage for males and females. The urinary catheter kit comes in a variety of configurations and sizes packaged sterile for single-use.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [X] 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	05th June 2025
Submitter	ConvaTec, Ltd. First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU
Contact person	Alexandra Hyde Alexandra.hyde@convatec.com
Name of Device	Cure Catheter Insertion Kit
Common Name	Tray, catheterization, sterile urethral, with or without catheter (kit)
Regulation Name	Urological catheter and accessories
Regulation Number	21 CFR 876.5130
Product Code	FCM
Classification	II
Primary Predicate Device	Cure Catheter Closed System (K230400)
Purpose of Submission	Device modification
Device Description	The Cure Catheter Insertion Kits (K1, K2, K2-90, K3), Cure Hydrophilic Catheter Kit (HMxxUK), Cure Pocket Catheter Kit (MxxUK), Cure Catheter Closed System Kit (CSxx)) contain sterile products used during intermittent urinary catheterization. Two types of kit are provided, one where a urinary catheter is included and one without a catheter. The components allow users to select one or more of the products to help prevent contamination of the environment and the user and to maintain a no-touch technique during the insertion of the catheter. Catheters are inserted through the urethra and indicated for the purpose of bladder drainage.
Intended Use	The Cure Catheter Insertion Kit is an intermittent urinary catheter kit indicated for the purpose of bladder drainage for males and females.
Indications for Use	The Cure Catheter Insertion Kit is an intermittent urinary catheter kit indicated for the purpose of bladder drainage for males and females. The urinary catheter kit comes in a variety of configurations and sizes packaged sterile for single-use.
Performance Data	Performance testing for Cure Catheter Insertion Kit was conducted on the subject devices or representative devices per applicable sections of voluntary and FDA consensus standards: • Sterilization validation per AAMI/ISO 11135-1:2014/AMD 1:2018 and ISO 10993-7:2008/AMD:2019 • Biocompatibility testing 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) • Urinary catheter testing according to ISO 20696:2018
Technological Comparison:	

		Subject Device	Predicate Device	Substantial Equivalence
	Device	**Cure Catheter Insertion Kit**	**Cure Catheter Closed System**	**N/A**
	Intended Use	The Cure Catheter Insertion Kit is an intermittent urinary catheter kit indicated for the purpose of bladder drainage for males and females.	The Cure Catheter Closed System is an intermittent urinary catheter indicated for the purpose of bladder drainage for males and females.	Equivalent to predicate.
	Classification Regulation	876.5130 – Urological catheter and accessories	876.5130 – Urological catheter and accessories	Equivalent to predicate.
	Product Code	FCM	KOD	N/A
	Technological Features	Convenience kit to aid insertion, components include: Underpads, BZK wipes, gloves, urine collection bags, PVP swabsticks, lubricating gel, sterile wipes and a urinary catheter.	Convenience kit to aid insertion, components include: Underpads, BZK wipes, gloves, urine collection bags, PVP swabsticks, lubricating gel, sterile wipes and a urinary catheter.	Equivalent to predicate.
	Kit Configurations	Cure Catheter Insertion Kits – contain: underpads, BZK wipes, gloves, collection bags, lubricating gel (K3 does not contain any lubricating gel). Kits provided over-the-counter (OTC), Cure Hydrophilic Catheter Kit – contains: underpads, BZK wipes, gloves, urine collection bags, and a Cure Hydrophilic Catheter. Kits provided prescription only, Cure Pocket Catheter Kit – contains: underpads, BZK wipes, gloves, urine collection bags, and a Cure Pocket Catheter. Kits provided prescription only,	Cure Catheter Closed System Kit – contains: underpads, BZK wipes, gloves, urine collection bags, PVP swabsticks, lubricating gel, sterile wipes and Cure Closed System Catheter.	Substantially equivalent.

		Cure Catheter Closed System Kit – contains: underpads, BZK wipes, gloves, urine collection bags, PVP swabsticks, lubricating gel, sterile wipes and Cure Closed System Catheter. Kits provided prescription only.		
	Biocompatibility	All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part- 10993-1 of the International Standard Organisation (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 Organisation (ISO) Standard (Biological Evaluation of Medical Devices). The test articles were considered biocompatible under the conditions tested.	Equivalent to predicate.
	Sterilization	EO, SAL^{-6}	EO, SAL^{-6}	Equivalent to predicate.
	Shelf Life	3 years	3 years	Equivalent to predicate.
Conclusion	The intended use, indications, technological characteristics and performance data between the subject device, Cure Catheter Insertion Kits and the predicate Cure Catheter Closed System (K230400) has been established as being substantially equivalent.			