August 5, 2026

Convatec
Kim Jones
Senior Regulatory Affairs Specialist
First Ave., Deeside Industrial Estate
Deeside
Flintshire, CH5 2NU
UNITED KINGDOM

Re: K260737
Trade/Device Name: Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Female (CH06 - CH16);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Straight (CH06 - CH18);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Coude (CH10 - CH18)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: July 3, 2026
Received: July 6, 2026

Dear Kim Jones:

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: 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,

ANDREW M. FALES -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260737

Please provide the device trade name(s).

Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Female (CH06 - CH16);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Straight (CH06 - CH18);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Coude (CH10 - CH18)

Please provide your Indications for Use below.

The Cure Aqua Ready to Use Hydrophilic Intermittent Catheter is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Date Prepared: 4-August-2026

Submitter:
Convatec,Ltd
Deeside Industrial Park
Deeside
Flintshire CH5 2NU

510K number:
K260737

Contact Person:
Kim Jones, +44 7590333564, kim.jones@convatec.com

Name of Device:
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Female (CH06 - CH16);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Straight (CH06 - CH18);
Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter Male Coude (CH10 - CH18)

Classification Name:
21 CFR 876.5130 Urological Catheter and Accessories

Product Code:
EZD

Classification:
Class II

Predicate Device:
Cure Hydrophilic Catheter (K132500)

The predicate device, K132500, has not been subject to a design-related recall.

Device Description:
Cure Aqua™ Ready-to-Use Hydrophilic Intermittent Catheter (Cure Aqua) is a sterile, single use, disposable, intermittent urethral catheter. A urethral catheter is a tubular device that is introduced through the urethra into the bladder, providing a pathway for drainage. The catheter is made from thermoplastic polyurethane (TPU) with a hydrophilic coating. The coated catheter is stored in a wetting solution of distilled water, Polyvinylpyrrolidone K30 (PVP) and NaCl within its primary pack, making it ready-to-use.
The device includes a low-density polyethylene (LDPE) sleeve and TPU molded funnel with different colorants according to the size designation. The catheter shaft is bonded to the funnel by an adhesive mixture of cyclohexanone and 2-Butanone.

Cure Aqua catheters come with either a straight or coudé tip option. Coudé tips are available for male catheters, and the bent tip allows the catheter to navigate the urethral structures and access the bladder. The coudé tip catheter has a blue stripe along the top portion of the entire length of the tubing for the purpose of providing visual confirmation of the coudé tip's orientation as the catheter is used.

The Cure Aqua catheter also has a color-coded funnel to indicate the French size (CH), a universal system for measuring the catheter's outer diameter. The color-coding helps users and healthcare professionals identify the correct size catheter.

Catheters are individually packed into a sealed, composite film, primary pouch along with a handling sleeve. The handling sleeve is provided to minimize touching the catheter shaft directly during insertion and retraction. The individual, packaged catheters are then placed in secondary and tertiary packaging and sterilized by E-beam irradiation.

The Cure Aqua is for both males and females. The selection of the French size (CH) size of the catheter is to be determined by healthcare professional and is based on the size of the patient. Cure Aqua is available by prescription use only.

The devices are surface devices with mucosal membrane contact with prolonged contact duration (> 24 hours to 30 days) due to cumulative use.

The devices are intended to be used in both professional healthcare facilities and the home environment.

***Table 1**: Catheter configurations by size and tip type*

Patient Sex	**Tip**	**Size** (CH)	**Effective Length** (mm)
Male	Straight	6 – 18	365
Male	Coudé	10 – 18	365
Female	Straight	6 – 16	155

Intended Use:
To provide an intermittent pathway for drainage of fluids from the bladder. The catheter is inserted through the urethra.

Indications for Use:

Subject Device Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter (K260737)	**Predicate Device** Cure Catheter Hydrophilic Coated, (K132500)
The Cure Aqua Ready to Use Hydrophilic Intermittent Catheter is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage.	The Cure Catheter™ Hydrophilic Coated is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage. The urinary catheter comes in a variety of sizes, packaged sterile for single-use.

Intended Users:
Males, Females, Pediatric (Infant, Child, Adolescent, Transitional Adolescent) and Adult who need assistance with bladder drainage due to conditions causing dysfunction of the urinary system. Additional users are healthcare professionals including nurses, and/or caregivers, and family members who help patients with catheterization. Target users will be those who are able to self-catheterise (intermittent self-catheterisation or ISC) and have no or minimal dexterity impairment. Cure Aqua is a prescribed medical device. During consultation with a Health Care Provider, the user will be assessed for a suitable and appropriate level of dexterity, cognitive understanding and anatomical size to perform ISC with Cure Aqua.
Technological Comparison:
The subject device, Cure Aqua, and the predicate device, Cure Hydrophilic Catheter (K132500), are hydrophilic intermittent urinary catheters and share the same intended technological principles. These devices provide a pathway for the intermittent drainage of urine from the bladder. The catheter is inserted through the urethra.

Description	Subject Device	Primary Predicate Device	Comparison
Name	Cure Aqua™ Ready to Use Hydrophilic Intermittent Catheter	Cure Catheter Hydrophilic Coated, K132500	N/A
Manufacturer	Convatec	Convatec	Same
Product Code	EZD (catheter, straight)	EZD (catheter, straight)	Same
Classification Regulation	876.5130 – Urological catheter and accessories	876.5130 – Urological catheter and accessories	Same
Classification	II	II	Same
Use Environment	Home and healthcare (hospital/clinical) settings	Home and healthcare (hospital/clinical) settings	Same
Device Uses	Single patient, single use	Single patient, single use	Same
Size Range Effective length and outer diameter (OD)	Female straight tip Effective Length: 155 mm OD (CH): 6, 8, 10, 12, 14, 16 Male straight tip Effective Length 365 mm OD (CH): 6, 8, 10, 12, 14, 16, 18 Male coudé tip Effective Length 365 mm OD (CH): 10, 12, 14, 16, 18	Female straight tip Length (nominal): 6 in (152.5 mm) OD (CH): 6, 8, 10, 12, 14, 16, 18 Male straight & coude tip: Length (nominal): 16 in (390 mm) OD (CH): 8, 10, 12, 14, 16, 18 Pediatric straight tip: Length (nominal): 10 in (250 mm) OD (CH): 6, 8, 10, 12, 14.	Change in catheter size. The predicate device includes a larger outer diameter size for the female straight tip configuration (18Fr). The subject device includes a smaller outer diameter for the male straight tip (6Fr).
Tube Material	TPU and hydrophilic coating. Coudé tipped tubing contains a blue stripe comprised of TPU and <1% of colorant.	Polyvinyl chloride (PVC) and hydrophilic coating. Coudé tipped tubing contains a blue stripe comprised of PVC and <1% of colorant.	Change in tube material.
Catheter Coating and Wetting solution	Catheter coating: Hydrophilic polymer made of PU and polyacrylamide. Lubricating wetting solution: sterile water, PVP, and NaCI.	Catheter coating: Hydrophilic polymer made of PVP. Lubricating wetting solution: sterile water.	Change in catheter coating and wetting solution.
Catheter Funnel Material	TPU and colorants CH06: Light Green CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red	PVC and colorants CH06: Light Green CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red	Change in catheter funnel material.
Bonding adhesive	Cyclohexanol and butanone.	Cyclohexanol	Change in bonding adhesive

Description	Subject Device	Primary Predicate Device	Comparison
Catheter Tube Outer Diameter (mm)	CH6: 2.0 mm CH8: 2.7 mm CH10: 3.3 mm CH12: 4.0 mm CH14: 4.7 mm CH16: 5.3 mm CH18: 6.0 mm.	CH6: 2.3 mm CH8: 3.0 mm CH10: 3.6 mm CH12: 4.3 mm CH14: 5.0 mm CH16: 5.6 mm CH18: 6.0 mm.	Change in catheter size. The predicate device includes a larger outer diameter size for the female straight tip configuration (18Fr). The subject device includes a smaller outer diameter for the male straight tip (6Fr).
Catheter Tensile Strength	Minimum tensile strength: CH06: ≥10N CH08: ≥10N CH10: ≥10N CH12: ≥10N CH14: ≥20N CH16: ≥20N CH18: ≥20N	Minimum tensile strength: CH06 – CH08: ≥1.0kg (9.8N) CH10 – CH14: ≥1.5kg (14.7N) CH16 – CH18: ≥2.0kg (19.6N)	Change in catheter tensile strength.
No Touch Functionality	Handling sleeve composed of LDPE.	Handling sleeve composed of LDPE.	Same
Primary Packaging	Bottom and top films: Composite film made of polyamide, aluminum, and PE.	Bottom film: Polypropylene and PE. Top film: Dialysis medical grade paper.	Change in primary catheter packaging. The subject device has different packaging to enable the device to be sterilized by e-beam rather than Ethylene Oxide.
Sterilization	E-beam SAL: 10^{-6}	Ethylene Oxide (EO) SAL: 10^{-6}	Change in sterilization method
Shelf Life	3 years	3 years	Same
Biocompatibility	Contact classification according to ISO 10993-1:2018: • Surface medical device, with mucosal membrane contact • Prolonged duration (>24 hours - ≤30 days) due to potential repeated cumulative contact.	Contact classification according to ISO 10993-1:2018: • Surface medical device, with mucosal membrane contact • Prolonged duration (>24 hours - ≤30 days) due to potential repeated cumulative contact.	Same

The differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data:
Non-clinical performance testing for Cure Aqua was conducted per applicable sections of voluntary and FDA consensus standards.

Qualification of biological safety assessment according to ISO 10993-1:2018, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process and FDA Guidance "Use of International Standard ISO 10993-1". The following biological endpoints were addressed:

- Cytotoxicity was conducted according to ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for *In Vitro* cytotoxicity.
- Sensitization was conducted according to ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- Irritation was conducted according to ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation.
- Acute systemic toxicity was conducted according to ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- Subacute/subchronic toxicity was conducted according to ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Sterilization and packaging validation met the requirements of the following FDA recognized standards:

- Sterilization validation was performed by conducting dose setting per ISO 11137-1:2015 A1: 2023.
- Sterile packaging in accordance with ISO-11607-1: 2020+A1:2023 and 11607-2: 2020+A1:2023.
- Accelerated Real Time aged shelf-life testing according to ASTM F1980-21.
- Performance testing of Shipper Containers and Systems according to ASTM D4169-22.
- Package integrity testing according to ASTM F88/F88M.

The physical performance properties of the Cure Aqua Catheter met the following standards:

- Dimensional analysis was conducted in accordance with ISO 20696:2018.
- Tensile testing performed in accordance with ISO 20696:2018.
- Flow Rate testing performed in accordance with ISO 20696:2018.
- Kink Stability testing performed in accordance with ISO 20696:2018.
- Coefficient of friction according to ASTM D1894:24.

All tests met the predetermined acceptance criteria. The results of the testing show substantial equivalence in performance of the subject device when compared to the predicate device (K132500).

Conclusion:
The data and information provided in this submission support the conclusion that the Cure Aqua device (subject device) is substantially equivalent to its predicate device, Cure Hydrophilic Catheter (K132500) and the proposed subject device is as safe and effective as the predicate device.