March 12, 2026

HR Healthcare
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K260502
Trade/Device Name: Liv Pre-lubricated Intermittent Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: January 26, 2026
Received: February 13, 2026

Dear Dave Yungvirt:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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
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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.	K260502

Please provide the device trade name(s).

Liv Pre-lubricated Intermittent Catheter

Please provide your Indications for Use below.

The Liv Pre-lubricated Intermittent Catheter is a device that is inserted through the urethra by female patients to drain urine from the bladder.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY (21 CFR §807.92)

Liv Pre-lubricated Intermittent Catheter

Submitter Name:	HR HealthCare
Submitter Address:	2600 Eastern Blvd., Suite 201 York, PA, 17402 USA
Contact Person:	Colby Wiesman
Email Address:	cwiesman@hrhealthcare.com
Phone Number:	717-252-1110
Date of Preparation:	March 11, 2026
Trade Name:	Liv Pre-lubricated Intermittent Catheter
Common Name:	Catheter, Straight
Classification Name:	Urological Catheter and Accessories
Classification Panel:	Gastroenterology/Urology
Regulation Number:	21 CFR 876.5130
Regulatory Class:	Class II
Product Code:	EZD
Primary Predicate	Cure Twist Female Catheter

Predicate Submission Number: K250699

Device Description

The Liv Pre-lubricated Intermittent Catheter is a ready to use, water based gel lubricated, PVC intermittent catheter with a straight tip. The subject device is ethylene oxide sterilized and packaged as a single use disposable catheter. The Liv Pre-lubricated Intermittent Catheter is used to drain urine from the bladder in adult women. The Liv Pre-lubricated Intermittent Catheter is 3.75 inches in effective length and in sizes from 8 Fr. to 14 Fr. The design is similar to the predicate device Cure Twist Female Catheter (K250699).

Indications for Use

The Liv Pre-lubricated Intermittent Catheter is a device that is inserted through the urethra by female patients to drain urine from the bladder.

Comparison of Technological Characteristics with the Predicate Device

The following table provides an overview of comparisons between the subject and the predicate devices. The predicate device has not been subject to any design-related recalls.

Characteristic	SUBJECT DEVICE Liv Pre-lubricated Intermittent Catheter	PREDICATE DEVICE Cure Twist Female Catheter K250699	Comparison
Manufacturer	HR Healthcare	Convatec	Different
Indications for Use	Prescription only	Prescription only	Same
	The Liv Pre-lubricated Intermittent Catheter is a device that is inserted through the urethra by female patients to drain urine from the bladder.	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.	Same
Population	Adult, Female	Adult, Female	Same
Contact Category per ISO 10993-1	Surface device contacting, mucosal membrane, and prolonged duration (>24 hours – 30 days)	Surface device contacting, mucosal membrane, and prolonged duration (>24 hours – 30 days)	Same
Effective Length	3.75 inches	3.25 inches	Different, the overall length is slightly longer than the predicate, but the testing confirmed it performs as intended.
Size Range	8-14 Fr	8-16 Fr	Same, within the range of the predicate.
Tip	Straight	Straight	Same
Shaft	Tubular	Tubular	Same
Shaft Material	PVC (Surface and mucosal membrane, prolonged contact >24 hours – 30 days)	PVC (Surface and mucosal membrane, prolonged contact >24 hours – 30 days)	Same
Lubricant	Gel Lubricant	Gel Lubricant	Same
Non-Pyrogenic	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life	3 years	Uknown	Different, HR Healthcare validated the shelf life for 3 years. There is no impact to the safety or effectiveness of the device.
Packaging Type	Individually packaged for single use	Individually packaged for single use	Same

Performance Testing

Nonclinical Testing

The Liv Pre-lubricated Intermittent Catheter was evaluated via non-clinical safety and performance testing to demonstrate that the subject device is substantially equivalent to the predicate device. Testing was conducted according to the following FDA recognized consensus standards listed below. The subject device met the applicable test specifications and acceptance criteria as described in the submission.

- Sterilization validation per AAMI/ISO 11135-1:2014/AMD 1:2018 and ISO 10993-7:2008/AMD:2019
- Sterile packaging in accordance with ISO 11607-1:2019 and ISO 11607-2:2019
- Seal Integrity: ASTM D3078-02 and ASTM F1886-16
- Seal Strength: F88/F88M-21
- Accelerated aging testing was performed to assure the shelf-life of 3 years in accordance with ASTM F1980-21.
- Flow Rate: ASTM F623-19
- Lubricity Visual Inspection
- Surface Finish: ISO 20696:2018
- Appearance Visual Inspection
- Peak Tensile Force: ISO 20696:2018
- Strength: ISO 20696:2018
- Catheter Outside Diameter: ASTM F623-19
- Effective Shaft Length: ISO 20696:2018
- Kink Stability: ISO 20696:2018
- Friction Force for Catheter Advancement Force: Internal Test Method
- Lock Ring Override Force: Internal Test Method
- Engagement Force: Internal Test Method

Biocompatibility

A biocompatibility evaluation was conducted in accordance with *ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*, and FDA guidance documents, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process"* (September 4, 2020*)*. Contact classification per ISO 10993-1 is as follows:

- Surface device contacting mucosal membrane for prolonged contact duration (>24 hours – 30 days)

The following tests were conducted based on this evaluation:

- Cytotoxicity per ISO 10993-5:2009 *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity* (2-245)
- Sensitization & Irritation per ISO 10993-10:2021 *Biological evaluation of medical device – Part 10: Tests for skin sensitization* (2-296)
- Irritation per ISO 10993-23:2021 (2-291)
- Acute Systemic Toxicity per ISO 10993-11:2017 *Biological evaluation of medical*

device – Part 11: Tests for systemic toxicity (2-255)

- Material Mediated Pyrogenicity per ISO 10993-11:2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity* (2-255)
- Subacute/Subchronic Systemic Toxicity per ISO 10993-11: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
- Intramuscular Implantation per ISO 10993-11:2017 *Biological evaluation of medical device – Part 11: Tests for systemic toxicity* (2-255).

Conclusion

The information in this submission, including non-clinical safety and performance testing, demonstrates that the LIV Pre-lubricated Intermittent Catheter is substantially equivalent to the predicate device. The subject and predicate devices share similar indications and intended use, and design verification and validation confirm that the subject device is as safe and effective as the predicate device.