January 29, 2026

HR Healthcare
% Dave Yungvirt, CMSgt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K251274
Trade/Device Name: EZ-Protect Hydrophilic Closed System Intermittent Catheter;
EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter And Accessories
Regulatory Class: II
Product Code: EZD
Dated: December 16, 2025
Received: December 16, 2025

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. However, you are responsible to determine that the medical devices you use as components in the kit 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: 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 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
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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)*

K251274

Device Name

EZ-Protect Hydrophilic Closed System Intermittent Catheter;
EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits

Indications for Use *(Describe)*

The EZ-Protect™ Hydrophilic Closed System Intermittent Catheter is intended to drain urine from the bladder.

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.

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510(k) SUMMARY (21 CFR §807.92)

EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits

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:	January 28, 2026
Trade Name:	EZ-Protect Hydrophilic Closed System Intermittent Catheters EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits
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	Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles)
Submission Number:	K183461
Reference Device:	MTG Instant Cath
Submission Number:	K080878

Device Description

The EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits are sterile, closed system, single use, disposable, hydrophilic coated PVC catheter with either a straight or coude tip, self-contained along with a water sachet pouch to activate the hydrophilic coating and a collection bag. The EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits are used to drain urine from the bladder. The EZ-Protect Hydrophilic Closed System Intermittent Catheters are 16 inches in length and in sizes from 8 Fr. to 18 Fr. The EZ-Protect Hydrophilic Closed System Intermittent Catheters are designed with the collection bag and introducer tip allowing the user to insert the catheter without having to touch the catheter. The available sizes configurations are provided below:

Subject Device Configurations

The EZ-Protect Hydrophilic Closed System Intermittent Catheter Kit consists of components used to drain urine from the bladder. The EZ-Protect Hydrophilic Closed System Intermittent Catheter Kit contains the sterile EZ-Protect Hydrophilic Closed System Intermittent Catheter (subject of this submission) along with the following Class I, exempt devices: gauze pad, Benzalkonium Chloride (BZK) swab/wipe, gloves, underpad and privacy disposal. The kit components are purchased, off the shelf by the kit packager Hangzhou Jimushi Medical CO., LTD. (Uricare). These components are similar to those provided in predicate device Rusch Hydrophilic Intermittent catheters (K183461) and reference device MTG Instant Cath (K080878).

Indications for Use

The EZ-Protect Hydrophilic Closed System Intermittent Catheter is intended to drain urine from the bladder.

Contraindication

None Known

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 EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits	PREDICATE DEVICE Rusch Flocath Hydrophilic Intermittent Catheter, Rusch MMG Hydrophilic Intermittent Catheter K183461	Comparison
Manufacturer	HR Healthcare	Teleflex Medical	Different

Indications for Use	Prescription only	Prescription only	Same
	The EZ-Protect™ Hydrophilic Closed System Intermittent Catheter is intended to drain urine from the bladder.	The Rusch Hydrophilic Intermittent catheters (Rusch FloCath Quick, Rusch FloCath Quick Kit, Rusch FloCath Intermittent Catheter, Rusch MMG H2O PVC Catheter Kit, Rusch MMG H2O Singles) are tubular devices that are inserted through the urethra to pass urine from the bladder.	Same
Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female	Same

Characteristic	**SUBJECT DEVICE** **EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits**	**PREDICATE DEVICE** **Rusch Flocath Hydrophilic Intermittent Catheter, Rusch MMG Hydrophilic Intermittent Catheter K183461**	**Comparison**
Contact Category per ISO 10993-1	Surface device contacting, mucosal membrane, and prolonged duration (>24 hours – 30 days)	Surface device contacting, breached or compromised surfaces, and limited duration (≤ 24 hours)	Different, additional testing completed and contact category has changed.
Overall Length	16 inches	16 inches	Same
Size Range	8-18Fr	6-20 Fr.	Same, within the range of the predicate.
Tip	Straight or Coude	Nelaton, Olive, or Tiemann	Same, the subject devices describe the tip at a high level, while the predicate devices specify the exact coude tip type.
Shaft	Tubular	Tubular	Same
Shaft Material	PVC (Surface and mucosal membrane , prolonged contact >24 hours – 30 days))	PVC (Mucosal and skin, limited contact <24hr)	Different, additional testing completed and contact category has changed.
Coating	Hydrophilic	Hydrophilic	Same
Liquid for Wetting	Sterile Water	0.9% Sterile saline	Different, the subject devices use sterile water to activate the hydrophilic coating, whereas the predicate device used saline. This difference is based on organizational preference; both liquids perform an equivalent function.
Non-Pyrogenic	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

Shelf Life	3 years	5 years	Different, HR Healthcare is validating the shelf life for 3 years but does not impact safety or effectiveness of the finished device.
Packaging Type	Individually packaged	Individually packaged	Same

The reference device**,** MTG Instant Cath (K080878), was used because it is identical to the subject devices design, geometry, materials, sterilization and packaging, the only difference is the inclusion of the water sachet.

Performance Testing

Nonclinical Testing

The EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits 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.

- Seal Strength: ASTM F88/F88M-21
- Seal Integrity: ASTM F1929-15 and ASTM F1886-16
- Flow Rate: ASTM F623-19
- Lubricity and Friction
- Surface Finish: ASTM F2096-11
- Appearance
- Peak Tensile Force: ISO 20696:2018
- Strength: ISO 20696:2018
- Diameter: ASTM F2096-11
- Effective Shaft Length: ISO 20696:2018
- Kink Stability: ISO 20696:2018
- Catheter Advancement Force
- Collection Bag Seal Integrity
- Shipping Container: ASTM D4169-23

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 or Intracutaneous Reactivity per ISO 10993-23:2021, FDA Recognition Number 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.

Conclusion

The information in this submission, including non-clinical safety and performance testing, demonstrates that the EZ-Protect Hydrophilic Closed System Intermittent Catheters and EZ-Protect Hydrophilic Closed System Intermittent Catheter Kits are substantially equivalent to the predicate and reference devices.