October 3, 2025

Hollister Incorporated
Sandra Mullen
Regulatory Affairs Manager
2000 Hollister Drive
Libertyville, IL 60048

Re: K251468
Trade/Device Name: Sleeved IC 3 Family,
Sleeved IC 3 SWT (name not finalized),
Sleeved IC 3 Pocket (name not finalized),
Sleeved IC 3 Plus (name not finalized),
Sleeved IC 3 Plus Pocket (name not finalized) (N/A)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: September 3, 2025
Received: September 3, 2025

Dear Sandra Mullen:

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: 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,

Negeen Haghighi -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.	K251468

Please provide the device trade name(s).

Sleeved IC 3 Family
Sleeved IC 3 SWT (name not finalized)
Sleeved IC 3 Pocket (name not finalized)
Sleeved IC 3 Plus (name not finalized)
Sleeved IC 3 Plus Pocket (name not finalized) (N/A)

Please provide your Indications for Use below.

This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.

Note: 8 inch Sleeved IC 3 Pocket consists of a subset of the original population:

8 inch Sleeved IC 3 Pocket
This intermittent catheter is a flexible tubular device that is inserted through the urethra by female and female paediatric (pediatric) patients who need to drain urine from the bladder.

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

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

510K Summary

Applicant: Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person: Sandra Mullen
Hollister Incorporated
2000 Hollister Drive
Libertyville, Il 60048
(t) +353 86 3011706

Date Prepared: 1 October 2025
Trade Name: Sleeved IC 3 Family
Sleeved IC 3 SWT (name not finalized)
Sleeved IC 3 Pocket (name not finalized)
Sleeved IC 3 Plus (name not finalized)
Sleeved IC 3 Plus Pocket (name not finalized) (N/A)
Common Name: Catheter, Urethral
Product Code/Class: EZD/Class II
Classification Name: Urological catheter and accessories
CFR: 21 CFR 876.5130

Predicate Device:

Sleeved IC 2 by Hollister Incorporated. (K233524)

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

Description of Applicant Device:

Sleeved IC 3 (not finalized) catheters are E-beam sterilized hydrophilic-coated, single-use catheters. The subject device has two drainage eyelets that are used to manage urinary incontinence.

The device is inserted into the urethra to drain urine from the bladder.

The device is available in 16 inch and 8-inch lengths. The device is available in various Fr sizes ranging from Fr 08 through Fr 16. The catheter is made from Thermo-plastic Elastomer (TPE), (not made with phthalates, not made with PVC). The catheter sleeve is manufactured from Low Density Polyethylene (LDPE). The catheter sleeve allows for the user to grip the catheter anywhere along the length during insertion.

The device is packaged in a foil which was designed to be easy to open and to facilitate access to the catheter. The device is contained in a primary package that consists of both the catheter assembly and the hydration fluid. This means that the coated catheter surface is lubricated by direct contact with the hydration fluid. The device is available with and without the integrated urine collection bag. The device is available in straight and pocket packaging configurations.

The subject device covers several configurations:

- Sleeved IC 3 straight (SWT) is an intermediate catheter in a straight configuration
- Sleeved IC 3 Plus is the same catheter with an attached urine bag
- Sleeved IC 3 Pocket has the catheter coiled up for a smaller footprint
- Sleeved IC 3 Plus Pocket is the same coiled catheter with an attached urine bag

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.

Indications for Use:

Model	Subject Device (K251468)	Predicate Device (K233524)
Sleeved IC Straight, **Sleeved IC Plus,** **Sleeved IC Plus Pocket** **Sleeved IC Pocket (16 inch)**	This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.	This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.
Sleeved IC Pocket (8 inch)	This intermittent catheter is a flexible tubular device that is inserted through the urethra by female and female paediatric (pediatric) patients who need to drain urine from the bladder.	This intermittent catheter is a flexible tubular device that is inserted through the urethra by female and female paediatric (pediatric) patients who need to drain urine from the bladder.

Comparison of Technological Characteristics:

The table below summarizes the technological characteristics of the new device as compared to the predicate device.

	Sleeved IC 2 (Predicate K233524) **Sleeved IC 2 Straight** **Sleeved IC 2 Plus** **Sleeved IC 2 Plus Pocket Sleeved IC 3 Pocket**	**Sleeved IC 3** **Sleeved IC 3 Straight** **Sleeved IC 3 Plus** **Sleeved IC 3 Plus Pocket** **Sleeved IC 3 Pocket**	**Same or Different/ Rationale for no impact to safety or efficacy**
Indication for Use	This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric patients who need to drain urine from the bladder.		No change
Condition of Use	Single Use		No change
Duration of use	Prolonged (>24 hours to 30 days)		No change
Ready to use	Yes		No change
Hydration Method	Direct hydration		No change
Hydration Fluid	Hydration Fluid		No change
Catheter Sleeve Material	Aliphatic Thermoplastic polyurethane	Low Density Polyethylene	Catheter sleeve material change Sleeved IC 3 and the predicate device use different sleeve materials.

	Sleeved IC 2 **(Predicate K233524)** **Sleeved IC 2 Straight** **Sleeved IC 2 Plus** **Sleeved IC 2 Plus Pocket** **Sleeved IC 3 Pocket**	**Sleeved IC 3** **Sleeved IC 3 Straight** **Sleeved IC 3 Plus** **Sleeved IC 3 Plus Pocket** **Sleeved IC 3 Pocket**	**Same or Different/ Rationale for no impact to safety or efficacy**
			The sleeve material does not affect how the catheter is used or how the user interacts with the catheter. The sleeve material remains transparent in appearance. The sleeve allows the catheter to be gripped anywhere along its length. The sleeve provides a barrier that helps keep microbes from the catheter surface During risk analysis activities, no new risks were identified. No changes to existing risks were made.

	Sleeved IC 2 (Predicate K233524) **Sleeved IC 2 Straight** **Sleeved IC 2 Plus** **Sleeved IC 2 Plus Pocket** **Sleeved IC 3 Pocket**	**Sleeved IC 3** **Sleeved IC 3 Straight** **Sleeved IC 3 Plus** **Sleeved IC 3 Plus Pocket** **Sleeved IC 3 Pocket**	**Same or Different/ Rationale for no impact to safety or efficacy**
Catheter hydrophilic coating	PVP Based (polyvinylpyrollidone) Coating		No Change
Catheter Material	Thermoplastic Elastomer (TPE); Not made with Phthalates, not made with PVC		No Change
Catheter length/ Fr. sizes	Diameter (Fr) 08-16 Length – 16 inches and 8 Inches		No Change
End Design (Straight)	Color-coded funnel		No Change
End Design (Plus)	Urinary Collection Bag		No Change
Catheter Eyelets	2 smooth catheter eyelets		No Change
Not Made with Natural Rubber Latex	Yes		No Change
Packaging Material	Aluminum Foil Laminate		No Change

	Sleeved IC 2 (Predicate K233524) **Sleeved IC 2 Straight** **Sleeved IC 2 Plus** **Sleeved IC 2 Plus Pocket** **Sleeved IC 3 Pocket**	**Sleeved IC 3** **Sleeved IC 3 Straight** **Sleeved IC 3 Plus** **Sleeved IC 3 Plus Pocket** **Sleeved IC 3 Pocket**	**Same or Different/ Rationale for no impact to safety or efficacy**
Sterilization Method	e-beam Irradiation Dose 25-65kGy SAL 10^{-6}		No Change
Storage Conditions	15-30 °C / 59-86°F		No Change
Environment of Use	Hospital Home Setting Public Places		No Change

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

Brief Description of Non-Clinical Testing:

The physical performance properties of the Sleeved IC 3 met all applicable requirements of BS EN ISO 20696:2018: Sterile urethral catheters for single use.

Biocompatibility testing met the following requirements:

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2021, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-17:2002, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-23 Biological Evaluation of Medical Devices Part 23: Tests for Irritation

The following biological endpoints were addressed: cytotoxicity, intracutaneous irritation, vaginal irritation, sensitization, acute systemic toxicity and subacute systemic toxicity.

Sterilization met all the requirements of the following FDA recognized standards:

- ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2019, Sterilization of Medical Devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

- Packaging integrity test data verifies the maintenance of the sterile barrier through shelf life. Transportation test data verifies that there is no impact to the device safety or efficacy of the catheter performance due to the hazards associated with the transportation environment.

Conclusion:

The data and information provided in this submission support the conclusion that the Sleeved IC 3 device (subject device) is substantially equivalent to its predicate device, Sleeved IC 2 (K233524) and the proposed subject device is as safe and effective as the predicate device.