May 18, 2026

Hollister Incorporated
Michelle Schiltz-Taing
Regulatory Affairs Manager
2000 Hollister Drive
Libertyville, Illinois 60048

Re: K253295
Trade/Device Name: Coude Sleeved IC; Coude Pocket Sleeved IC
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: April 15, 2026
Received: April 15, 2026

Dear Michelle Schiltz-Taing:

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
Office of Product Evaluation and Quality
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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. | K253295 |

Please provide the device trade name(s).

Coude Sleeved IC (Not Finalized)
Coude Plus Sleeved IC (Not Finalized) (To be determined)

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.

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)

# 510(k) Summary

Applicant: Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person: Michelle Schiltz-Taing
Hollister Incorporated
2000 Hollister Drive
Libertyville, Il 60048
(t) 224-864-0431

Date Prepared: May 15, 2026
Trade Name: Coudé Sleeved IC and Coudé Pocket Sleeved IC
Common Name: Catheter, Urethral
Product Code: EZD (catheter, straight)
Regulatory Class: 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.

**Indications for Use:**

| **Predicate**<br>**Sleeved IC 2 (K233524)**<br>**16" Product** | **Subject**<br>**Coudé Sleeved IC & Coudé Pocket Sleeved IC *** |
|---|---|
| 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. | |

**Description of Applicant Device:**

The Coudé Straight Sleeved IC and Coudé Pocket Sleeved IC are:

- E-beam sterilized.
- Hydrophilic-coated, single use catheter.
- Have two drainage eyelets that are used to manage urinary incontinence.
- Have a coudé (Tiemann/Curved) tip
- Inserted into the urethra to drain urine from the bladder.

- Available in 16-inch lengths.
- Available in Ch sizes ranging from Ch 12, Ch 14 and Ch16.
- Made from Thermo-plastic Elastomer (TPE), not made with phthalates/not made with PVC/not made with natural rubber latex.
- Packaged in a foil which was designed to be easy to open and to facilitate access to the catheter.
- Lubricated by direct contact with the hydration fluid.
- Available in straight and pocket packaging configurations

## Comparison of Technological Characteristics:

The table below summarizes the technological characteristics of the Coudé Sleeved IC and Coudé Pocket Sleeved IC as compared to the predicate device.

| | **Predicate K233524 Sleeved IC 2 16" Product** | **Subject Coudé Sleeved IC & Coudé Pocket Sleeved IC** | **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 |
| **Ready to use** | Yes | | No change |
| **Device Material** | Thermo-plastic Elastomer (TPE); tubing and funnel | | No change |
| | Not made with phthalates, not made with PVC | | |
| | TPE Introducer Tip | | No change |
| | Low density polyethylene cap | | No change |
| | Aliphatic Polyurethane Film Sleeve | | No change |
| **Hydration Method** | Direct hydration | | No change |
| **Hydrophilic Coating** | Hydration fluid<br>PVP Based (polyvinylpyrollidone) Coating | | No change |
| **Catheter length/ Fr. sizes** | Standard with tip<br>16 inches: Fr 12, 14, 16<br><br>Pocket<br>16 inches: Fr 12, 14, 16 | | No change |

| | **Predicate K233524 Sleeved IC 2 16" Product** | **Subject Coudé Sleeved IC & Coudé Pocket Sleeved IC** | **Same or Different/ Rationale for no impact to safety or efficacy** |
|---|---|---|---|
| **Tip of catheter design** | Rounded Tip (all sizes) | Coudé tip (all sizes) | Different tip profile/No impact to safety or efficacy. No new risks or changes to existing risks identified in risk assessment |
| **End Design** | Standard with Tip and Pocket: Color coded funnel | | No change |
| **Catheter Eyelets** | 2 smooth catheter eyelets | | No change |
| **Catheter Colour** | Clear | | No change |
| **Not Made with Natural Rubber Latex** | Yes | | No change |
| **Packaging Material** | Aluminum Foil Laminate | | No change |
| **Sterilization Method** | E-beam Irradiation Dose 25-65kGy SAL $10^{-6}$ | | No change |
| **Expiration Dating** | 2 years | | No change |
| **Storage Conditions** | 15-30° C / 59-86°F | | No change |
| **Environment of Use** | Hospital<br>Home<br>Setting<br>Public Places | | No change |

**Brief Description of Non-Clinical Testing:**

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

Testing was conducted to support size designation, show equivalence of lubricity and determination of the strength of the catheter, security of fit of the drainage funnel, flow rate through catheter, catheter kink stability and peak tensile force. Testing of the urine collection bag was conducted to verify that the liquid would flow into the collection bag within one minute and to confirm sufficient flowrate.

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 10993-10:2010, 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 10993-17:2023-09
- ISO 10993-18: Second edition 2023-09
- ISO 10993-23, Biological evaluation of medical devices – Part 23 Tests for irritation

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

Sterilization met all 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
- ANSI/AAMI/ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ANSI/AAMI/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

Both package integrity testing and bench performance testing were completed to support shelf life.

Packaging integrity testing was conducted to verify the maintenance of the sterile barrier through shelf life. Transportation testing was conducted in order to verify that there is no impact to the device safety or efficacy of the catheter performance due to the hazards associated with the transportation environment.

Packaging met all requirements of the following FDA recognized standards:

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly process
- ASTM F2096-11(2019) Standard test method for detecting gross leaks in packaging internal pressurization (bubble test)
- ASTM F88/F88M-23 Standard test method for seal strength of flexible barrier materials

**Conclusion:**

It is concluded that the information supplied in this submission has demonstrated that the safety and effectiveness of the Coudé Sleeved IC and Coudé Pocket Sleeved IC is substantially equivalent to the cleared predicate device.