May 3, 2024

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

Re: K233524
Trade/Device Name: Sleeved IC 2 Family;
Sleeved IC 2 SWT (Name not Finalized);
Sleeved IC 2 Plus (Name not Finalized);
Sleeved IC 2 Pocket (Name not Finalized);
Sleeved IC 2 Plus Pocket (Name not Finalized)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Received: April 2, 2024

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: 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.

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,

Sharon M. Andrews -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

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)*

K233524/S001

Device Name

Sleeved IC 2 Family
Sleeved IC 2 SWT (Name not Finalized)
Sleeved IC 2 Plus (Name not Finalized)
Sleeved IC 2 Pocket (Name not Finalized)
Sleeved IC 2 Plus Pocket (Name not Finalized)

Indications for Use *(Describe)*

Sleeved IC 2 SWT (16" and 8"), Sleeved IC 2 Plus (16" and 8"), Sleeved IC 2 Pocket (16"), & Sleeved IC 2 Plus Pocket (16" and 8"):
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 2 Pocket (8"):
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.

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.

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: 22 April 2024
Trade Name: Sleeved IC 2 (Not finalized)
Common Name: Catheter, Urethral
Product Code/ Class: EZD (catheter, straight)/Class II
Classification Name: Urological catheter and accessories
CFR: 21 CFR 876.5130

Predicate Device:

Sleeved IC by Hollister Incorporated. (K220667)

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

Indications for Use:

Sleeved IC 2	Sleeved IC 2 Plus	Sleeved IC 2 Pocket	Sleeved IC 2 Plus Pocket
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.		16 Inch This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and paediatric (pediatric) patients who need to drain urine from the bladder. 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 male, female and pediatric patients who need to drain urine from the bladder.

Description of Applicant Device:

The Sleeved IC 2 (not finalized) catheters are:

- E-beam sterilized.
- Hydrophilic-coated, single use catheter.
- Have two drainage eyelets that is used to manage urinary incontinence.
- The Sleeved IC is inserted into the urethra to drain urine from the bladder.
- Available in 16 inch and 8 inch lengths.
- Available in various Fr sizes ranging from Fr 08 through Fr 16.
- Are made from Thermo-plastic Elastomer (TPE); not made with phthalates and not made with PVC.
- 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 with and without integrated urine collection bag.
- Available in pocket and straight packaging configurations.
- Environment of use: hospital, home setting, public places.

Comparison of Technological Characteristics:

The table below summarizes the technological characteristics of the Sleeved IC 2 as compared to the predicate device.

	Sleeved IC Predicate K220667	**Sleeved IC 2**	**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. 8-inch Sleeved IC 2 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.		No change The 8-inch Sleeved IC2 Pocket has the same indication for use but focuses on a subset of the population. There is no effect to the safety or efficacy or to the intended use.
Condition of Use	Single Use		No change
Ready to use	Yes		No change
Hydration Method	Direct hydration		No change
Hydration Fluid	Hydration Fluid		No change
Catheter hydrophilic coating	PVP Based (polyvinylpyrollidone) Coating		No change
Catheter Material	Thermoplastic Elastomer (TPE); not made with phthalates, not made with PVC		No change

	Sleeved IC Predicate K220667	**Sleeved IC 2**	**Same or Different/ Rationale for no impact to safety or efficacy**
Catheter length/ Fr. sizes	Diameter (Fr) 12 and 14 Length - 16 inches	Diameter (Fr) 08-16 Length – 16 inches and 8 Inches	Different The additional Fr sizes and catheter length meet the same requirements as the predicate device. (ISO 20696) There is no effect to safety or efficacy or to the intended use.
End of catheter design	Rounded tip		No change
End Design (Straight)	Color coded funnel		No change
End Design (Plus)	N/A	Urine collection bag	Different The urine collection bag was added for user convenience. The materials used in the collection bag have been assessed for biocompatibility and tested to verify sufficient flowrate of urine into the collection bag. There is no effect to safety or efficacy or to the intended use.
Catheter Eyelets	2 smooth catheter eyelets		No change
Catheter Color	Clear		No change
Not Made with Natural Rubber Latex	Yes		No change
Packaging Material	Aluminium Foil Laminate		No change
Sterilization Method	e-beam Irradiation Dose 25-65kGy SAL 10^{-6}		No change
Storage Conditions	15-30^{0}C / 59-86°F		No Change

	Sleeved IC Predicate K220667	**Sleeved IC 2**	**Same or Different/ Rationale for no impact to safety or efficacy**
Environment of Use	Hospital Home Setting Public Places		No Change

Brief Description of Non-Clinical Testing:

The physical performance properties of the Sleeved IC 2 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 1 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 10993-3:2014, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- 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 10993-23, Biological evaluation of medical devices – Part 23 Tests for irritation

The following biological endpoints were addressed: cytotoxicity, sensitization, 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-21 Standard test method for seal strength of flexible barrier materials
- 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 Sleeved IC 2 is substantially equivalent to the cleared predicate device.