January 27, 2022

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

Re: K211436
Trade/Device Name: Intermittent Catheter (not finalized)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: December 29, 2021
Received: December 30, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211436

Device Name

Intermittent Catheter (not finalized)

Indications for Use *(Describe)*

The 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Applicant: Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person: Michelle Schiltz-Taing
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60018
(t) 224-864-0431

Date Prepared: January 25, 2022
Trade Name: Intermittent Catheter (not finalized)
Common Name: Catheter, Urethral
Product Code/Class: GBM/Class II
Classification Name: Urological catheter and accessories
Classification Number: 21 CFR 876.5130

Predicate Device:

Onli Intermittent Catheter by Hollister Incorporated (K163179)

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

Indications 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.

Device Description:

The Intermittent Catheter (final name to be determined) is a hydrophilic-coated, single use catheter with drainage eyelets that is used to manage urinary incontinence. The Intermittent Catheter is inserted into the urethra to drain urine from the bladder. The Intermittent Catheter is available in 7 in. and 16 in. lengths. The 7 in. catheter is available in sizes 8, 10, 12, 14 Fr and the 16 in. catheter is available in sizes 8, 10, 12, 14, 16 Fr. The Intermittent Catheter is provided sterile, using e-beam Irradiation sterilization. The device is made from Thermo-plastic Elastomer (TPE), and is phthalate free, PVC free. This directly hydrated catheter is packaged in a peel-able 4 sided pouch which was designed to be easy to open and to facilitate access to the catheter. The primary pack contains both the catheter assembly and the hydration fluid in one compartment. This means that the coated catheter surface is lubricated by direct contact with the hydration fluid There is a gripper on the 16 inch catheter to aid with the insertion process, if desired.

510(k) Summary
Intermittent Catheter

Comparison of Technological Characteristics:

The table below summarizes the technological characteristics of the Intermittent Catheter as compared to the predicate and reference devices.

	Predicate Onli K163179	Intermittent Catheter	Same or Different/Rational for no impact to efficacy or safety
Indications for Use	The 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
Device Material	Polyvinyl Chloride (PVC); phthalate free funnel and catheter Thermo-plastic Elastomer (TPE); phthalate free, PVC free gripper	Thermo-plastic Elastomer (TPE); phthalate free, PVC free funnel, catheter, and gripper	Testing shows differences do not affect safety and effectiveness compared to the predicate device.
Length/Fr Sizes	7 inches: Fr 8, 10, 12, 14 16 inches: Fr 8, 10, 12, 14, 16		No change
Gripper on 16 in. Catheter	Yes		No change
Attachment of Funnel to Catheter Tube	Solvent Bonded	Insert molded funnel (created by a thermal bond)	Although the attachment of the funnel to the catheter tube is different, the differences do not affect safety and effectiveness compared to the predicate device.
End of Catheter Design	Rounded tip		No change
End Design	Color-coded funnel		No change
Number of Eyelets	2		No change
Catheter Color	Opaque	Clear	The appearance of the catheter does not impact functionality.
Coating	PVP Based Coating (polyvinylpyrollidone)		The Hydrophilic coating on the predicate and the Intermittent Catheter is PVP based. Testing shows differences do not affect safety and effectiveness compared to the predicate device.
Fluid	DI water	Hydration fluid	Although the hydration fluid is different between the predicate and the Intermittent Catheter, testing shows differences do not affect safety and effectiveness compared to the predicate device.

Hydration Method	Vapor Hydration	Direct Hydration	Although a different method of hydration is utilized between the predicate device and the Intermittent Catheter, substantial equivalency of catheter lubricity is demonstrated via testing.
Packaging Material	Oriented Polyamide/Aluminum/Polyethylene (OPA/ALU/PE) foil (foil laminate)	Polyethlyene Terephthalate/Aluminum/ Polyethylene (PET/ALU/PE) foil (foil laminate)	Testing shows differences do not affect safety and effectiveness compared to the predicate device.
Sterilization Method	Gamma Irradiation Dose 25-40kGy SAL 10^{-6}	e-beam Irradiation Dose 25-65kGy SAL 10^{-6}	The difference in sterilization method does not affect the safety and effectiveness compared to the predicate device.
Expiration Dating	2 years		No change
Storage Conditions	15-30^{0}C / 59-86°F		No change

Brief Description of Non-Clinical Testing:

The physical performance properties of the Intermittent Catheter 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, the security of fit of the drainage funnel, flow rate through catheter, kink stability and peak tensile force of urethral catheter.

Biocompatibility testing met the requirements of the following standards:

- 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 10993-17:2002, 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

The following biological endpoints were addressed: cytotoxicity, intracutaneous irritation, vaginal irritation, 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

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.

Conclusion:

It is concluded that the information supplied in this submission has demonstrated that the Intermittent Catheter is substantially equivalent to the legally marketed predicate device.