December 8, 2022

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

Re: K220667
Trade/Device Name: Sleeved IC
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter And Accessories
Regulatory Class: II
Product Code: EZD
Dated: November 17, 2022
Received: November 17, 2022

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 (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,

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

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)*

K220667

Device Name
Sleeved IC (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: Sandra Mullen
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60018

(t) +00 353 86 301 1706

Date Prepared:	7 December 2022
Trade Name:	Sleeved IC (not finalized)
Common Name:	Catheter, Straight
Classification Number	21 CFR 876.5130
Classification Name	Urological catheter and accessories
Product Code	EZD
Product Code Name	Gastroenterology-Urology
Regulatory Class	Class II

Predicate Device:

VaPro2 Intermittent Catheter by Hollister Incorporated. (K180824)

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

Indications for Use:

This Sleeved IC 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 (final name to be determined) is a sterile, hydrophilic-coated, single use catheter with drainage eyelets that is used to manage urinary incontinence. The Sleeved IC is inserted into the urethra to drain urine from the bladder. The catheter is available in 16in length. The catheter is available in 12 and 14 Fr sizes. The catheter is provided in a sterile manner, utilizing e-beam sterilization method. The device is made from Thermo-plastic Elastomer (TPE) and is phthalate free and PVC free. This directly hydrated catheter is packaged in a foil 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. This means that the coated catheter surface is lubricated by direct contact with the hydration fluid.

Comparison of Technological Characteristics

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

	Predicate VaPro 2 Intermittent Catheter (K180824)	**Sleeved IC**	**Rationale for no impact to safety and 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.		There is no change to Indications for Use including intended patient population. Testing provided in relation to product differences demonstrate no impact to device safety, effectiveness or functionality per the intended use when compared to predicate device.
Condition of Use	Single Use		No change
Ready to use	Yes		No change
Hydration Method	Water vapor hydration	Direct Hydration	Testing provided shows differences do not affect the safety and effectiveness compared to predicate and reference devices. Although a different method of hydration is utilized between the predicate device and the Sleeved IC, substantial equivalency of catheter lubricity is demonstrated via testing.
Hydration Fluid	DI Water	Hydration Fluid	Testing provided shows differences do not affect safety and effectiveness compared to the predicate device.
Catheter Hydrophilic Coating	PVP Based (polyvinylpyrollidone) Coating		The hydrophilic coating on the predicate and Sleeved IC is PVP based. Testing provided shows differences do not affect the safety and effectiveness compared to predicate and reference devices.
Catheter Material	Polyvinyl Chloride (PVC); (Not manufactured with Phthalates)	Thermoplastic Elastomer (TPE); (Not manufactured with Phthalates or with PVC)	Testing shows differences in materials do not affect safety and effectiveness compared to the predicate device. Both Sleeved IC and representative device conform to BS EN 20696

	Predicate VaPro 2 Intermittent Catheter (K180824)	Sleeved IC	Rationale for no impact to safety and efficacy
			'Sterile Urethral Catheters for Single Use'. Biocompatibility has been assessed and all requirements met.
Catheter length/ Fr. sizes	Diameter (Fr) - 8, 10, 12, 14 and 16 Length - 16 inches	Diameter (Fr) 12 and 14 Length - 16 inches	The sleeved IC diameter sizes are within the range of the predicate product family No change in catheter length
End of catheter design	Rounded tip		No change
End Design	Color coded funnel		No change
Catheter Eyelets	2 smooth catheter eyelets		No change
Catheter Color	Opaque	Clear	The appearance of the catheter tubing does not impact functionality
Not Made with Natural Rubber Latex	Yes		No change
Packaging Material	OPA/ALU/PE Foil laminate	PET/ALU/PE 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	The difference in Sterilization method does not affect the safety and effectiveness compared to the predicate device. Gamma and E-beam sterilization methods are both forms of radiation sterilization. The required Sterility Assurance Level (SAL) has been validated for both methods.
Storage Conditions	15-30^{0}C / 59-86°F		No change
Environment of Use	Hospital Home Setting Public Places		No Change

Brief Description of Non-Clinical Testing:

The physical performance properties of the 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.

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 10993-17:2002, 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 Sleeved IC is substantially equivalent to the legally marketed predicate device.