September 13, 2022

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

Re: K213575
Trade/Device Name: Female IC (not Finalized)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: August 9, 2022
Received: August 9, 2022

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,

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)*
K213575

Device Name
Female IC (not finalized)

Indications for Use *(Describe)*

This intermittent catheter is a flexible tubular device that is inserted through the urethra by female and female 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 60018
(t) 224-864-0431

Date Prepared: 13 September 2022
Trade Name: Female IC (Not Finalized)
Common Name: Catheter, Urethral
Product Code/Class: EZD/Class II
Classification Name: Catheter, Straight
Regulation Number: 21 CFR 876.5130

Predicate Device:

Infyna Chic K191633 by Hollister Incorporated. The predicate 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 female and female pediatric patients who need to drain urine from the bladder.

Description of Applicant Device:

The Female IC (not finalized) is a sterile, hydrophilic-coated, single use catheter with drainage eyelets that is used to manage urinary incontinence. The Female IC is inserted into the urethra to drain urine from the bladder. This directly hydrated catheter is packaged in a polypropylene/polyethylene case which was designed to be easy to open, close and dispose of, with a discrete consumer design. A "first use label" on the case indicates to the end user if the product was previously opened.

Technological Characteristics:

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

	Predicate Device Infyna Chic (K191633)	**Female IC**	**Same or Different/Rationale for No impact to Efficacy or Safety**
Indication for Use	This intermittent catheter is a flexible tubular device that is inserted through the urethra by female 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 pediatric patients who need to drain urine from the bladder	No change-additional verbiage was used to clarify that "female" includes female pediatric patients. No impact to the existing Female IC risk file was identified and no additional safety concerns were added due to the clarification of the patient population.
Condition of Use	Single Use		No Change
Pre-lubricated	Water vapor hydration	Direct Hydration	Although a different method of hydration is utilized between the predicate and subject device; equivalency of catheter lubricity is demonstrated within this submission
Ready to use	Yes		No change
End Design	Color coded Funnel		No Change
Sterile	Gamma Radiation	E-Beam Radiation	Gamma and E-Beam sterilization methods are both forms of radiation sterilization. The required Sterility Assurance Level (SAL) has been validated for both methods.
Hydrophilic Coating	PVP Based (polyvinylpyrrolidone) Coating		No Change
Catheter Eyelets	2 smooth catheter eyelets		No Change
Not Made with Natural Rubber Latex	Yes		No Change
Catheter Material	Polyvinyl Chloride (PVC); phthalate free	Thermo-plastic Elastomer (TPE); phthalate free, PVC free)	Catheter material changes has no impact as both the predicate and subject device conform to BS EN 20696-

			"Sterile urethral catheters for single use". Biocompatibility has been assessed and all requirements have been met
Catheter Length	5 inches	5.5 inches	The subject device has a length of 0.5 inches more than the predicate. No impact as both the predicate and subject device conform to BS EN 20696- "Sterile urethral catheters for single use" effective shaft length.
Fr Size	Fr 8, 10, 12, 14		No Change
Environment of Use	Hospital Home Setting Public Places		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.

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.
- 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.
- 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances.
- 10993-18:2020, Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process.

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 Female IC is substantially equivalent to the legally marketed predicate device.