July 19, 2019

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

Re: K191633
Trade/Device Name: Infyna Chic™
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: GBM
Dated: June 17, 2019
Received: June 21, 2019

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
Glenn B. Bell, Ph.D.
Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191633

Device Name
Infyna Chic

Indications for Use *(Describe)*
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.

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) 847-680-2122

Date Prepared: 17 June 2019

Trade Name: Infyna Chic™
Common Name: Catheter, Urethral
Product Code/Class: GBM / Class II
Classification Name: Urological catheter and accessories
CFR: 21 CFR 876.5130

Predicate Device:
Onli™ intermittent catheter K163179 by Hollister Incorporated

Indications 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.

Description of Subject Device:
The Infyna Chic is a hydrophilic coated, single use catheter to be used as a means of managing urinary incontinence by draining urine from the bladder. Infyna Chic has the following features:

- Hydrophilic-coated PVC catheter (phthalate free)
- Two smooth catheter eyelets
- Color-coded funnel

The packaging contains a sealed water compartment chamber from which the water migrates to the catheter compartment and hydrates (lubricates) the catheter. The primary packaging is designed to be easy to open, close and dispose of, with a discrete consumer design. The outer packaging also contains a 'first use label' that indicates to the end user if the product was previously opened.

Technological Characteristics:
The table below summarizes the technological characteristics of Infyna Chic as compared to the predicate device Onli.

	Predicate Device Onli Intermittent Catheter (K163179)	Subject Device Infyna Chic
Indication for Use	The Onli 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	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.
Condition of Use	Single Use	Single Use
Pre-lubricated	Yes-by water vapor hydration	Yes-by water vapor hydration
Ready to use	Yes	Yes
End Design	Funnel	Funnel
Sterile	Yes - Gamma Radiation	Yes - Gamma Radiation
Hydrophilic Coating	PVP Based (polyvinylpyrrolidone) Coating	PVP Based (polyvinylpyrrolidone) Coating
Catheter Material	PVC (phthalate free)	PVC (phthalate free)

Brief Description of Non-Clinical Testing:
The physical performance properties of Infyna Chic met all applicable requirements of EN 1616, 1618 and EN 13868.

Biocompatibility testing met the requirements of ISO 10993-1, 10993-5, 10993-10, 10993-11 and 10993-12.

Sterilization met all requirements of ISO 11137-1, 11137-2, 11737-1 and 11737-2.

Package integrity testing was performed to verify the maintenance of the sterile barrier through shelf life. The testing concluded that Infyna Chic packaging is capable of maintaining a sterile barrier for at least two years.

Catheter performance testing was performed following simulated distribution in order to verify that there is no impact to the safety or efficacy of the catheter performance due to the hazards associated with the transportation environment. The test produced successful results.

Conclusion:
It is concluded that the information supplied in this submission has demonstrated that Infyna Chic is substantially equivalent to the legally marketed device Onli intermittent Catheter.