December 13, 2019

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

Re: K193148
Trade/Device Name: VaPro Plus Pocket, VaPro Plus
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: November 11, 2019
Received: November 13, 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,

Angel A .Soler-Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193148

Device Name
VaPro 2 Pocket Line Extension

Indications for Use *(Describe)*
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.

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.

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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: 12 December 2019
Trade Name: VaPro 2™ Pocket Line Extension
Common Name: Catheter, Urethral
Product Code/Class: GBM/Class II
Classification Name: Urological catheter and accessories
CFR: 21 CFR 876.5130

Predicate Device:

VaPro 2 Plus & VaPro 2 Plus Pocket, K183253 by Hollister Incorporated.

Reference Device:

VaPro 2 Intermittent Catheter, K180824 by Hollister Incorporated

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.

Description of Applicant Device:

This submission is to add an additional size (Fr 08) to the currently cleared 16-inch Pocket and Plus Pocket configurations of VaPro 2.

The VaPro 2 Pocket Line Extension is a hydrophilic coated, single use catheter to be used as a means of managing urinary incontinence by draining urine from the bladder. VaPro 2 Pocket Line Extension has the following features:

- Hydrophilic-coated PVC catheter (phthalate free)

- Two smooth catheter eyelets
- Protective sleeve
- Protective introducer tip as a way to shield the sterile catheter from bacteria in the distal urethra during insertion
- Color-coded funnel.
- Urine Collection bag (for the Plus Pocket version)

The packaging contains a sealed water compartment chamber from which the water migrates to the catheter compartment and hydrates (lubricates) the catheter. The outer packaging is designed to facilitate access for those with limited dexterity. The Pocket version is designed to be discreet and easy to store. In the Plus Pocket configuration, the urinary catheter is connected to a collection bag for use when drainage into a suitable receptacle is not feasible or practical.

Technological Characteristics:

The table below summarizes the technological characteristics of VaPro 2 Line Extension as compared to the predicate and reference devices.

	Subject Device		**Predicate Device (K183253)**	**Reference Device (K180824)**
	Fr 08 Pocket	**Fr 08 Plus Pocket**		
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.			
Condition of Use	Single Use			
Pre-lubricated	Yes-by water vapor hydration			
Ready to use	Yes			
End Design	Funnel			
Sterile	Yes - Gamma Radiation			
No touch design	Yes - contains sleeve			
Hydrophilic Coating	PVP Based (polyvinylpyrollidone) Coating			
Protective Introducer Tip	Yes			
Protective Cap	Yes			
Catheter Material	PVC (phthalate free)			
Urine Collection Bag	No	Yes	Yes	No

Brief Description of Non-Clinical Testing:

The physical performance properties of VaPro 2 Pocket Line Extension met all applicable requirements of EN 1618, EN 1616 and EN 13868. Additionally the Plus Pocket version of the subject device met the physical performance properties of ISO 8669-2 and ASTM-D1003-13

Biocompatibility testing met the requirements of ISO 10993-1, 10993-5 and 10993-12. Additionally the Plus Pocket version met the requirements of ISO 10993-11.

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

Conclusion:

It is concluded that the information supplied in this submission has demonstrated that VaPro 2 Pocket Line Extension is substantially equivalent to the legally marketed predicate device.