DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2015

Hollister Incorporated
Jeanne Lee
Sr. Manager, Regulatory Affairs
2000 Hollister Drive
Libertyville, IL 60048

Re: K152268
Trade/Device Name: VaPro Plus Pocket Intermittent Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: August 7, 2015
Received: August 11, 2015

Dear Jeanne Lee:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152268

Device Name
VaPro Plus Pocket

Indications for Use *(Describe)*
VaPro Plus Pocket 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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Hollister

510(k) Summary

Submitted By: Jeanne Lee
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Date Summary Prepared: Aug 7, 2015

Device Name: Classification Name- Urological catheter and accessories

Common/Usual Name- Catheter, Urethral

Proprietary Name- VaPro Plus Pocket™ intermittent catheter

Device Class/Product Code: Urological catheter and accessories are Class II devices per 21 CFR 876.5130. Product code GBM.

Predicate Device: VaPro Plus intermittent catheter, K141642

Device Description: The VaPro Plus Pocket intermittent catheter is a single use catheter to be used as a means of managing urinary incontinence by draining urine from the bladder. The catheter has the following elements:

- 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

The packaging contains a sealed water compartment chamber of which the water migrates to the catheter compartment and lubricates the catheter. The outer packaging was designed to be discreet, easy to store, easy to open and facilitate access to the catheter. The catheter is connected to a collection bag for use when drainage into a suitable receptacle is not feasible or practical.

Intended 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.

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

	Modified Device: VaPro Plus Pocket intermittent catheter	**Predicate Device: VaPro Plus intermittent catheter (K141642)**
Intended 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.	
Condition of Use	Single Use	Single Use
Prelubricated	Yes-by water vapor hydration	Yes-by water vapor hydration
Ready to use	Yes	Yes
End Design	Funnel	Funnel
Sterile	Yes	Yes
No touch design	Yes-has protective sleeve	Yes-has protective sleeve
Catheter Material	PVC (phthalate free)	PVC (phthalate free)
Lubricant	PVP Based Coating (polyvinylpyrollidone)	PVP Based Coating (polyvinylpyrollidone)
Protective Tip	Yes	Yes
Collection Bag	Yes	Yes

Performance Testing:

There have been no changes to the device, only to the packaging. Therefore, no new biocompatibility testing was performed. For biocompatibility testing on the device in accordance with ISO 10993, please refer to 510(k) K141642. Biocompatibility was performed on the new packaging. This report is available upon request. All results were satisfactory.

Sterility testing was performed using Gamma Irradiation in accordance with Method I validation per ANSI/AAMI/ISO 11137-1:2006 & 2:2013. All results were satisfactory.

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

Transportation testing was performed in order to verify that there is no impact to the safety or efficacy of the catheter performance. The test produced successful results.

Conclusion: Based on the performance testing conducted it is concluded that the modified device, VaPro Plus Pocket, is as safe and effective and performs equivalent to the predicate device.