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

August 22, 2014

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

Re: K141642
Trade/Device Name: VaPro™ intermittent catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: June 16, 2014
Received: June 19, 2014

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Device Name

VaPro™ intermittent catheter
VaPro Plus™ intermittent catheter

Indications for Use

The VaPro™ 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.

The VaPro Plus™ 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

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH)

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510(k) Summary

Submitted By: Jeanne Lee
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Date Summary Prepared: June 16, 2014

Device Name: Classification Name- Urological catheter and accessories

Common/Usual Name- Catheter, Urethral

Proprietary Name- VaPro™ intermittent catheter
VaPro Plus™ intermittent catheter

Predicate Device: The VaPro intermittent catheter (with modification) is substantially equivalent to its original design, VaPro intermittent catheter, K090960.

The VaPro Plus intermittent catheter (with modification) is substantially equivalent to its original design, VaPro Plus intermittent catheter, K110862.

Device Description: The VaPro intermittent catheter is a hydrophilic coated, single use catheter to be used as a means of managing urinary incontinence by draining urine from the bladder. The catheter comes in a protective sleeve and is offered with a protective introducer tip as a way to shield the sterile catheter from bacteria in the distal urethra during insertion. The packaging contains a vapor strip that hydrates the catheter coating which then lubricates the catheter. The outer packaging was designed to facilitate access for those with limited dexterity.
The VaPro Plus has the addition of a collection bag that is connected to the catheter for use when drainage into a suitable receptacle is not feasible or practical.

Intended Use: The VaPro 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.

The VaPro Plus 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 devices.

	Modified Device: VaPro intermittent catheter	**Predicate Device: VaPro intermittent catheter (K090960)**	**Modified Device: VaPro Plus intermittent catheter**	**Predicate Device: VaPro Plus intermittent catheter (K110862)**
Intended Use	The VaPro/VaPro Plus 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	Single Use	Single Use
Prelubricated	Yes-by water vapor hydration	Yes-by water vapor hydration	Yes-by water vapor hydration	Yes-by water vapor hydration
Ready to use	Yes	Yes	Yes	Yes
End Design	Funnel	Funnel	Catheter funnel attached to collection bag	Catheter funnel attached to collection bag
Sterile	Yes	Yes	Yes	Yes
No touch design	Yes-contains sleeve	Yes-contains sleeve	Yes-contains sleeve	Yes-contains sleeve
Lubricant	PVP Based (polyvinylpyrollidone) Coating	PVP Based (polyvinylpyrollidone) Coating	PVP Based (polyvinylpyrollidone) Coating	PVP Based (polyvinylpyrollidone) Coating
Protective Tip	Yes	Yes	Yes	Yes
Collection Bag	No	No	Yes	Yes

Performance Testing Conclusions: Biocompatibility testing was performed based on the United States Food and Drug Administration Office of Device Evaluation General program Memorandum #G95-1 and ISO 10993 biocompatibility testing standards. Results indicate compliance to the standard.

Product evaluation also supports device functionality.