DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 20, 2016

Robling Medical, Inc.
Diane Peper
Director of Quality and Regulatory Affairs
90 Weathers Street
Youngsville, NC 27596

Re: K160877
Trade/Device Name: United Urologics Closed System Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: KOD
Dated: May 4, 2016
Received: May 5, 2016

Dear Diane Peper,

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,

Herbert P. Lerner -S

for 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)*

K160877

Device Name
United Urologics Closed System Catheter

Indications for Use *(Describe)*
United Urologics Closed System Intermittent Catheterization kit is intended to be used to drain urine from the patient's bladder into a collection bag.

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
K160877 United Urologics Closed System Catheter

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

1.0 SUBMITTER:

Robling Medical, Inc.
90 Weathers Street
Youngsville NC 27596
Telephone: 919-570-9605
Fax: 919-570-9611
Contact: Diane N. Peper, Director RA/QA
Date Prepared: March 31, 2016

2.0 DEVICE NAME:

Trade Name: United Urologics Closed System Catheter

Common Name: Urological Catheter

Classification: Class II, 21 CFR Part 876.5130, Product Code KOD

3.0 PREDICATE DEVICE: Hollister Inc.
Apogee Closed System Intermittent Catheterization Kit (K032710)
Classification: Class II, 21 CFR Part 876.5130, Product Code KOD

4.0 DEVICE DESCRIPTION

The United Urologics Closed System Catheter is a pre-lubricated sterile, single use, disposable, urinary incontinence device designed to drain urine from the patient's bladder into a urine collection bag. The device is manufactured of a flexible tube with a smooth radius, atraumatic tip to facilitate introduction into the urethra. The catheter is manufactured with drainage holes in the side of the tubing closest to the tipped end of the catheter in order to allow drainage of urine from the bladder through the central lumen of the catheter tube. The catheter is provided with a funnel bonded to the end of the catheter tube opposite the tipped end. The catheter is pre-lubricated with a water soluble lubricant and sealed in a urine collection bag. It is designed with a molded silicone tip at the top of the bag which acts as an introducer sheath for the tip of the catheter. This introducer and holding mechanism on the inside of the bag, provide a mechanism for inserting and advancing the catheter to the bladder without direct hand contact to the catheter.

The device may be used by the patient or caregiver in a healthcare facility, hospital, and home or public restroom facility to facilitate drainage of urine from the bladder.

5.0 INDICATIONS FOR USE

The United Urologics Closed System Intermittent Catheterization Kit is intended to be used to drain urine from the patient's bladder into a collection bag.

6.0 TECHNOLOGICAL CHARACTERISTICS

Both the subject device and the predicate device are pre-lubricated, sterile, single use, disposable catheterization systems and have been designed and tested in accordance with BS

EN 1616:1997 (plus A1:1999)- *Sterile urethral catheters for single use* and BS EN 1618:1997 – *Catheters other than intravascular catheters – test methods for common properties.*

Both the subject device and the predicate device use the same materials and processes to manufacture, package and sterilize the product.

Both the subject device and the predicate device have the same technological characteristics.

- Both latex free catheters use Polyvinylchloride tubing for the catheter shaft.
- For the Non-PVC catheters, both use natural rubber latex
- Both catheters have smooth, atraumatic closed tips
- Both have drainage holes in the side to allow for urine drainage
- The PVC catheters have polyvinylchloride funnels/connectors bonded on the end of the catheter
- The Non-PVC catheters have a flared end
- Both devices contain a silicone introducer tip that acts as a sheath over the tip of the catheter as it is introduced into the urethra.
- Both devices are pre-lubricated with a water-soluble lubricant
- Both devices are sealed in a sterile urine collection bag
- Both devices have a holding mechanism built inside the bag which facilitates advancement of the catheter during insertion.
- Both are provided sterile

7.0 PERFORMANCE CHARACTERISTICS

Functionality

There are no FDA recognized performance standards for urethral catheters under product code KOD that are not Foley catheters.

The following International standards were utilized in designing and testing the United Urologics Intermittent Catheters:

BS EN 1616:1997 (plus A1:1999)- *Sterile urethral catheters for single use*

BS EN 1618:1997 – *Catheters other than intravascular catheters – test methods for common properties.*

Biocompatibility

The United Urologics Closed System Catheter is characterized as a mucosal membrane contacting for a period of less than 24 hours. Therefore, the fully assembled, sterile device was tested required by Annex A of ISO 10993-1:2003, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.* Testing for cytotoxicity, sensitization and irritation was completed.

Sterilization

The United Urologics Closed System Catheter is an Ethylene oxide sterilized device. Sterilization validation complies with ANSI/AAMI/ISO 11135-1: 2007 – Sterilization of heath care products -- Ethylene oxide -- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.