October 30, 2018

UroGen Pharma Ltd.
% James G. Ottinger, R.Ph.
VP Regulatory Affairs, UroGen Pharma
UroGen Pharma
499 Park Avenue, 12th Floor, Suite 1200
New York, NY 10022

Re: K180354
Trade/Device Name: UroGen Ureteral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: September 26, 2018
Received: September 28, 2018

Dear James G. Ottinger:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Timothy Martin -S
2018.10.30 09:14:32 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180354

Device Name
UroGen Ureteral Catheter

Indications for Use *(Describe)*
The UroGen Ureteral Catheter is indicated for use by physicians for facilitating access to the urinary tract through a retrograde route and may be used in conjunction with a guidewire or for the injection of gels or fluids into the urinary tract.

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

[as required by section 807.92(c)]

UroGen Ureteral Catheter

510(k) Number K180354

1. SUBMITTER

Applicant's Name:
UroGen Pharma Ltd.
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Contact Person:
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USA
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Date Prepared:
October 30, 2018

2. DEVICE

Trade Name:
UroGen Ureteral Catheter

Common or Usual Name:
Ureteral Catheter

Classification:

Classification Name:	Urological catheter and accessories
Regulatory Class:	Class II per 21 CFR 876.5130
Product Code:	KOD
Classification Panel:	Gastroenterology-Urology

3. PREDICATE DEVICES

Primary predicate:

- Backstop Catheter, by Pluromed, Inc., product code KOD; cleared under K110491

Reference devices:

- Ureteral Catheter, by Boston Scientific, product code: GBM; cleared under K830840

4. DEVICE DESCRIPTION

The device is a single use ureteral catheter, designed to assist in access to the upper urinary tract using standard endoscopic technique for drainage and delivery of gels or fluids. The catheter is indicated for use by physicians for facilitating access to the urinary tract through a retrograde route and may be used in conjunction with a guidewire or for the injection of gels or fluids into the urinary tract.

The catheter is supplied sterile in a Tyvek pouch with a sterilization indicator. The catheter is inserted into the body for a typical duration of less than 1 hour. The catheter is placed over a guidewire of up to 0.038 inches in diameter that is pre-positioned through the urological tract.

5. INDICATIONS FOR USE

The UroGen Ureteral Catheter is indicated for use by physicians for facilitating access to the urinary tract through a retrograde route and may be used in conjunction with a guidewire or for the injection of gels or fluids into the urinary tract.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The UroGen Ureteral Catheter has similar technological characteristics as its predicate devices. The main difference between the UroGen Ureteral Catheter and other FDA cleared ureteral catheters is that in the UroGen Catheter, the Luer lock is glued to the catheter body. This allows the UroGen Ureteral Catheter to withstand higher pressures associated with the delivery of fluids with varying viscosities. This minor technological difference was tested to ensure the device functions as intended and does not raise new safety or effectiveness concerns.

7. PERFORMANCE DATA

Below is a list of the tests that have been performed and successfully completed for the UroGen Ureteral Catheter.

Biocompatibility:
Testing was conducted in accordance with FDA guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The Catheter underwent the following GLP biocompatibility testing per ISO 10993: Cytotoxicity, Sensitization and Irritation.

Bench: Test (Standard)

- Flow rate (ISO 10555, ASTM F623-99)
- Kinking (EN 13868)
- Peak Tensile Force (ISO 10555-1, EN1618)
- Connector security (EN 1616)
- Luer Hub Performance (ISO 594)
- Hub Liquid Leakage (ISO 594)

- Sterilization, Shelf Life and Packaging (ANSI/AAMI/ ISO 11135, AAMI/ISO 11138, ISO 10993 and EN 1422)
- Instillation force test (Internal Standard)

Conclusion:

The UroGen Ureteral Catheter has similar indications for use as the Backstop predicate device and is substantially equivalent in technological and performance characteristics to the predicate device.

Consequently, it is concluded that the UroGen Ureteral Catheter is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns. Any differences have been addressed by bench testing and validation and therefore negate any safety or effectiveness concerns.