November 19, 2021

UroGen Pharma Ltd
% James G. Otinger, R.Ph.
Executive Vice President, Regulatory and Quality
UroGen Pharma Inc.
400 Alexander Park Drive
Princeton, NJ 08540

Re: K211032
Trade/Device Name: Urinary Catheter 12 Fr
Urinary Catheter 16 Fr
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: October 18, 2021
Received: October 20, 2021

Dear James G. Otinger:

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,

for Jessica K. Nguyen, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211032

Device Name
Urinary Catheter 12 Fr
Urinary Catheter 16 Fr

Indications for Use *(Describe)*
The Urinary Catheter is indicated for use to facilitate access to the urinary tract through a retrograde route for the delivery 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.

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UroGen Pharma

510(k) Summary
Urinary Catheter

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. SUBMITTER INFORMATION:

Applicant's Name: UroGen Pharma Ltd.
9 Ha`Ta`asiya Street
Ra'anana, Israel. 4365007
Tel: +972-9-770-7600
Fax: +972-77-4171410

Primary Contact Person: James G. Ottinger, R.Ph.
Executive Vice President,
Regulatory and Quality UroGen Pharma, Inc.
Telephone: +1-646-768-9780
Mobile: +1-610-745-1230
Fax: +1-646-918-1262

Date Prepared: November 17, 2021

2. DEVICE INFORMATION

Trade Name:	Urinary Catheter 12 Fr Urinary Catheter 16 Fr
Common Name:	Urinary Catheter
Classification Name:	Urological Catheter and Accessories
Regulation Number:	21 CFR 876.5130
Regulatory Class:	II
Product Code:	KOD
Review Panel:	Gastroenterology/Urology

UroGen Pharma

510(k) Summary
Urinary Catheter

3. PREDICATE AND REFERENCE DEVICES:

Predicate device: UroGen Ureteral Catheter, by UroGen Pharma Ltd., Product code KOD; cleared under K180354.

Reference devices: Rüsch®- Intermittent Urethral Catheters; by Teleflex Medical; Product code: EZC, EZD; cleared under K173596.

Both predicate and the reference devices have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The Urinary Catheter is a single use 12 Fr or 16 Fr urethral catheter with a fixed female Luer lock hub. The catheter has a Coudé (Tiemann) tip, is 40 cm long. The catheter tube is made of Polyvinylchloride (PVC) and the Luer lock hub is made of Polycarbonate. The catheter is uncoated.

The device is designed to assist in access to the urinary bladder using standard technique for drainage and delivery of gels or fluids. The catheter is indicated for use by healthcare professionals for facilitating access to the urinary tract through a retrograde route, for the delivery of gels or fluids into the urinary tract.

The catheter is supplied sterile in a Tyvek pouch. The catheter is inserted into the body for a typical duration of less than 1 hour.

5. INDICATIONS FOR USE

The Urinary Catheter is indicated for use to facilitate access to the urinary tract through a retrograde route for the delivery of gels or fluids into the urinary tract.

UroGen Pharma

510(k) Summary
Urinary Catheter

6. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE AND REFERENCE DEVICES:

Comparison Parameter	Urinary Catheter (Subject device)	UroGen Ureteral Catheter (Primary Predicate Device)	Rüsch® Intermittent Urethral Catheters (Reference Predicate Device)
Class	II	II	II
Regulation	876.5130	876.5130	876.5130
Product Code	KOD	KOD	KOD
Indication for Use	The Urinary Catheter is indicated for facilitating access to the urinary tract through a retrograde route for the delivery of gels or fluids into the urinary tract.	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.	The Intermittent Urethral Catheters are indicated for routine drainage of fluids from the bladder. These catheters are not intended or designed for indwelling use
Target population	Adult	Adult	Not stated
Catheter Type	Urethral catheter	Ureteral Catheter	Urethral Catheter
Where used	Health Care centers	Hospital	Not stated (routine practice) Home Use
Disposable	Yes	Yes	Yes
Duration of use	Limited	Limited	Limited
Supplied sterile	Yes (Single Use)	Yes (Single Use)	Yes (single Use)
Prescription/over- the-counter use	Rx only	Rx only	Rx only
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Materials	Tube: PVC Luer hub: Polycarbonate	Tube: Polyurethane Luer hub: Polycarbonate	Tube: PVC (phthalates free)
Hydrophilic Coating	Uncoated	Uncoated	Uncoated
Connector	Luer lock hub	Luer lock hub	Funnel
Length	40 cm	70 cm	40 cm
Size Range	12 Fr, 16 Fr	7 Fr	10-24 Fr
Catheter Tip Configuration	Tiemann tip	Open tip	Tiemann tip
2 Drainage eyelets	Yes	No	Yes
Shelf life	3 years	3 years	5 years

510(k) Summary
Urinary Catheter

The subject and predicate device have the same intended use. As evidenced by the above table, the subject and predicate device have different technological characteristics. The subject device is a urethral catheter whereas the predicate is a ureteral catheter and due to this difference, there are some design differences (Fr size, length, etc.) between the subject and the predicate device. However, a reference device of a urethral catheter, which has similar device design as that of the subject catheter, is included to support the catheter design. In addition, performance testing was conducted on the subject catheter, and it was established that the differences in technological characteristics between the subject and the predicate do not raise different questions of safety or effectiveness.

7. PERFORMANCE DATA

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

Biocompatibility:

Testing was performed in accordance with FDA guidance: Use of International Standard ISO 10993-1:2018, "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. Results showed that the Urinary Catheter materials meet the requirements.

Sterilization:

The Urinary Catheter is supplied sterile and is intended for single use only. Testing was performed according to ISO 11135:2014, “Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. The results showed that the Urinary Catheter meet the requirements.

Bench Testing:

The following Bench tests were performed using the Urinary Catheter which demonstrated that the device performs per its device specifications:

- Flow rate
- Kink test
- Peak Tensile Force
- Luer Hub performance
- High Viscosity Flow

8. CONCLUSION:

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate