December 2, 2019

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

Re: K190987
   Trade/Device Name: Uroject12 Syringe Lever
   Regulation Number: 21 CFR 880.5860
   Regulation Name: Piston Syringe
   Regulatory Class: II
   Product Code: QBL
   Dated: November 7, 2019
   Received: November 8, 2019

Dear James 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/comboination-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.


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,

Mark R. Kreitz -S

for Sharon M. Andrews
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

Enclosure
Indications for Use

510(k) Number (if known)
K190987

Device Name
Uroject12 Syringe Lever

Indications for Use (Describe)
The Uroject12 Syringe Lever Device is intended for use in the administration of sterile materials under aseptic conditions, in a clinical urology setting, by a clinician and in accordance with the best judgment of a physician.

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 K190987
Uroject12 Syringe Lever

Date Prepared: November 07, 2019

I. SUBMITTER

Applicant’s Name:
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e-mail: jim.ottinger@urogen.com

II. DEVICE

Device Name: Uroject12 Syringe Lever
Common/Usual Name: Piston Syringe Lever

Classification:

Device
Reg. Description
Target Area
Review Panel
Product Code
Reg. Number
Device Class
Piston Syringe Lever
Piston syringe
Urology
General Hospital
QBL
880.5860
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III. PREDICATE DEVICE

Predicate device Uroject12 Syringe Lever, by UroGen Pharma, Ltd., Product code QBL, cleared under K180345.
IV. DEVICE DESCRIPTION

The Uroject12 Syringe Lever body contains syringe housing for holding a standard 20 mL syringe and a dispensing mechanism that is manually operated by rotating a knob that presses the syringe piston. A clutch mechanism facilitates fast adaptation of the injection mechanism to the syringe piston position. The Uroject12 Syringe Lever is a reusable, reprocessed device to be sterilized before each use and cleaned after use.

The compatible syringes to be used with the Uroject12 are: 20 mL MEDALLION® syringe (Catalog Number MSS121, Merit Medical, Salt Lake City, UT, USA) and 20 mL MEDALLION® COP syringe (Catalog Number COP121PC, Merit Medical, Salt Lake City, UT, USA).

V. INDICATIONS FOR USE

The Uroject12 Syringe Lever Device is intended for use in the administration of sterile materials under aseptic conditions, in a clinical urology setting, by a clinician and in accordance with the best judgment of a physician.

VI. SUBSTANTIAL EQUIVALENCE

The Uroject12 Syringe Lever is substantially equivalent to the predicate device based on the following:

Intended Use
The intended use of the proposed device is identical to that of the cleared device.

Technology
No device modifications were made to the Uroject12 and therefore the technological characteristics of both devices are identical. The only modifications to the device are in the Instructions for Use; specifically, the inclusion of high-level disinfection and automated cleaning processes.

Discussion
A direct comparison of characteristics demonstrates that the Uroject12 Syringe Lever is substantially equivalent to its predicate device. The submitted validation testing supports our claim that the Uroject12 device is as safe and as effective as its predicate without raising any new safety and effectiveness concerns.

VII. PERFORMANCE DATA

Validation Testing
The only testing included in this submission pertains to the validation activities for the high-level disinfection and automated cleaning processes.

The results of the validation testing demonstrated that the Uroject12 Syringe Lever is considered safe and effective for its intended use.

VIII. CONCLUSION

UroGen has demonstrated that the Uroject12 Syringe Lever is substantially equivalent to the predicate device. Differences between the proposed Uroject12 Syringe Lever and the predicate device do not raise new questions of safety or efficacy.