December 9, 2020

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

Re: K203321
Trade/Device Name: Cystoject Syringe Lever
Regulation Number: 21 CFR§ 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: QBL
Dated: November 11, 2020
Received: November 12, 2020

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/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,

Mark J. Antonino, M.S.
Acting 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

Enclosure

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)*
K203321

Device Name
Cystoject Syringe Lever

Indications for Use *(Describe)*
The Cystoject 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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9 Ha'Ta'asiya St. POB 2397
Ra'anana 4365405, Israel
Tel.: +972 - 9 - 770 – 7600
Fax:+972 - 77 - 417 – 1410
e-mail: info@urogen.com

510(K) SUMMARY [SPECIAL 510(K)]
Cystoject Syringe Lever

510(k) Number: K203321

I. SUBMITTER

Applicant's Name and address:

UroGen Pharma Ltd.
9 Ha`Ta`asiya Street
Ra'anana, Israel, 4365405
Tel: +972-9-770-7600
Fax: +972-77-417-1410

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
e-mail: jim.ottinger@urogen.com

Date Prepared: December 1, 2020

II. DEVICE

Trade Name: Cystoject Syringe Lever

Common or Usual Name: Syringe Lever
Classification Name:

Regulation:	Piston Syringe (21 CFR 880.5860)
Class:	II
Product Code:	QBL (Piston Syringe Lever)
Panel:	General Hospital

9 Ha'Ta'asiya St. POB 2397
Ra'anana 4365405, Israel
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Fax:+972 - 77 - 417 – 1410
e-mail: info@urogen.com

III. PREDICATE DEVICES

Predicate device Uroject12 Syringe Lever, by UroGen Pharma, Ltd., Product code QBL, cleared under: K190987.

This predicate has not been subject to a design-related recall.

510(k) Summary

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

IV. DEVICE DESCRIPTION

The Cystoject Syringe Lever is a reusable device that is intended for use in the delivery of sterile materials under aseptic conditions, in a clinical urology setting, by a clinician and in accordance with the best judgment of the physician. The Cystoject Syringe Lever body contains a housing for holding a standard syringe and a lever that pushes the syringe's plunger when the user rotates its knob. A clutch mechanism allows the user to quickly move the lever to the syringe plunger's position. The Cystoject Syringe Lever does not require an energy source, does not utilize electrical components, and does not utilize software or hardware. The Cystoject Syringe Lever does not come into direct or indirect contact with the patient nor with fluids intended for instillation.

The Cystoject Syringe Lever is provided non-sterile as a reusable, reprocessable device to be cleaned and sterilized or high-level disinfected before each use.

The Cystoject Syringe Lever indicated for use with a 30 mL syringe.

V. INDICATIONS FOR USE

The Cystoject 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 TO PREDICATE DEVICE

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

Intended Use
The intended use of the subject and predicate devices is identical.

UroGen Pharma

9 Ha'Ta'asiya St. POB 2397
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e-mail: info@urogen.com

Technology

Both the Cystoject Syringe Lever and the Uroject12 Syringe Lever have the same principle and mode of operation. The Cystoject Syringe Lever has the same general design as the Uroject12 Syringe Lever, except for modifications to enable a different compatible syringe size (i.e., 30 mL, vs. 20 mL with the Uroject12 Syringe Lever) and change in the exterior device color. These differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The summary of design control activities identified the following non-clinical performance tests to support the substantial equivalence determination.

Validation Testing

The only testing included in this submission that pertains to the validation activities for the additional device are the Residual Fluid Volume post dispensing and Load/Unload Testing.

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

Summary

The results of the validation testing demonstrate that the Cystoject Syringe Lever met all predetermined acceptance criteria.

VIII. CONCLUSION

The performance testing demonstrates that the Cystoject Syringe Lever is substantially equivalent to the predicate device.