October 17, 2018

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

Re: K180345
Trade/Device Name: Uroject12 Syringe Lever
Regulation Number: 21 CFR§ 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: QBL
Dated: September 14, 2018
Received: September 18, 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,

Mark R. Kreitz -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180345

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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UroGen Pharma

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

Uroject12 Syringe Lever

510(k) Number K180345 **Date Prepared:** September 17, 2018

I. SUBMITTER

Applicant's Name:
UroGen Pharma Ltd.
9 Ha`Ta`asiya Street
Ra'anana, Israel, 4365405
Tel: +972-9-770-7600
Fax: +972-77-4171410

Primary Contact:
James G. Ottinger, R.Ph.
Vice President, Regulatory Affairs
UroGen Pharma Ltd.
Telephone: 610-745-1230
Fax: (646) 918-1262
e-mail: jim.ottinger@urogen.com

II. DEVICE

Trade Name: Uroject12 Syringe Lever
Common or Usual Name: Syringe Lever
Classification:
Product Code: QBL (Piston Syringe Lever)
Regulation: 21 CFR 880.5860 (Piston Syringe)
Class: II
Panel: General Hospital

III. PREDICATE DEVICES

Predicate device: iSecure Syringe Cartridge Holder, by Hospira, Product code FMF 21 CFR 880.5860; K063180

Reference device: Medi-SIS Syringe Infusion System; by: I-Flow Corp.; Product code: MEB, 21 CFR 880.5725 (K953028, K954059, K972173); FRN, LZH, 21 CFR 880.5725 (K111381)

IV. DEVICE DESCRIPTION

UroGen Pharma

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

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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The principle of operation of the Uroject12 Syringe Lever device is similar to the predicate device, the iSecure Syringe Cartridge Holder, in that:

a. Both devices encase a syringe to actuate an injection
b. Both devices are used with a container closure system containing a drug solution with no direct contact to the drug.

The design and operating principles of the Uroject12 Syringe Lever Device are similar to those of the Medi-SIS Syringe Infusion System reference device. Both devices:

a. Consist of an outer syringe holder and an inner syringe driver;
b. Are used for injection of substances from a standard syringe;
c. Are operated by the user rotating a rotary driver mechanism in order to apply pressure on the housed syringe plunger, thereby pushing out the fluid in the syringe in a controlled and accurate manner; and
d. Are designed to provide visual markings on the syringe and allows visualization of the drug volume during administration

E. SUBSTANTIAL EQUIVALENCE

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

Intended Use

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The intended use of the proposed Uroject12 Syringe Lever is similar to the predicate device, the iSecure Syringe Cartridge Holder, in which both devices are intended to administer sterile materials under aseptic conditions in accordance with the best judgement of the physician. While not identical to the predicate device, the intended use of the Uroject12 is limited to administration of fluids compared to the predicate device, which includes both administration and withdrawal. Performance of the Uroject12 in a urological setting has been demonstrated through bench testing and supports that these differences do not raise new questions of safety and effectiveness of the Uroject12 device.

Technology
The proposed Uroject12 Syringe Lever is similar in technology to the predicate device, the iSecure Syringe Cartridge Holder, on the basis that the devices are used in conjunction with a pre-loaded syringe to perform administration of fluids operated by the user. The technological characteristics of the Uroject12 Syringe Lever is supported by the reference device, the Medi-Sis Syringe Infusion System, which uses the same principle of operation (rotary mechanism). The technological characteristics of the Uroject12 device have also been demonstrated through performance testing.

Discussion
A direct comparison of characteristics demonstrates that the Uroject12 Syringe Lever is substantially equivalent to the iSecure Syringe Cartridge Holder by intended use and the principle of operation. The reference device, the Medi-SIS Syringe Infusion System, further supports the technological characteristics of the Uroject12 device. Performance characteristics demonstrate that the proposed Uroject12 Syringe Lever is as safe and effective as the predicate device for use in a urological setting.

F. PERFORMANCE DATA

Bench Testing
Performance of the Uroject12 Syringe Lever has been demonstrated through the following:

- Instillation Pressure and Force Testing
- Extreme Dispensing Resistance Testing
- Residual Volume Testing
- Clutch Mechanism Functionality Testing
- Lifetime Functionality Testing

Cleaning and Sterilization
The Uroject12 Syringe Lever is provided non-sterile and is a reusable, reprocessed device. The Uroject12 device is intended to be cleaned and sterilized before each

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use. The cleaning instructions were validated in accordance with AAMI TIR30:2011. The sterilization instructions were validated to demonstrate a sterility assurance level (SAL) of $\leq 10^{-6}$.

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

G. CONCLUSION

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