May 3, 2018

URO-1, Inc.
Thomas Lawson
Regulatory Consultant
391 Technology Way, Suite 168
Winston Salem, NC 27101

Re: K180214
Trade/Device Name: Repris Bladder Injection System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: March 28, 2018
Received: March 29, 2018

Dear Thomas Lawson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known): *To be assigned* K180214

Device Name: Repris Bladder Injection System

Indications for Use:

The Repris Bladder Injection System is indicated for injection of drugs to address abnormal physiology in the lower urinary tract of adults. It is intended to deliver a variety of legally marketed drugs into tissue structures during cystoscopic procedures. It is provided sterile for single use.

Prescription Use: **X** AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. SUBMITER:

URO-1, Inc.
391 Technology Way
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Phone: 336 930 5464

Contact Person: Thomas Lawson, PhD

Phone: 510 206 1794
eMail: drthomlawson@gmail.com

Submission Date: May 2, 2018

II. DEVICE

Device Name:	Repris Bladder Injection System
Common Name:	Bladder Injection Needle
Classification Panel:	Gastroenterology and Urology
Classification Number:	21 CFR 876.1500
Classification Name:	Endoscope and Accessories
Product Code:	FBK
Product Code Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Regulatory Class:	II

III. PREDICATE DEVICE

injeTAK Adjustable Tip Needle. K090830

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

IV. DEVICE DESCRIPTION

The Repris Bladder Injection System consists of an introducer that is positioned onto the shaft of a cystoscope lens, a needle that is contained within a lumen in the wall of the introducer, and a metered syringe. The fully assembled Repris device has an overall length of 32.4 cm (12.75 inches); the introducer's working length is 20.4 cm (8.06 inches). External to the introducer is a metered syringe that is attached to the luer connection at the proximal end of the needle. The metered syringe delivers a pre-determined dose for each of the multiple injection sites as the plunger is advanced. The syringe provides the user with a tactile and auditory feedback when the exact dose is delivered.

INDICATIONS FOR USE

The Repris bladder injection system is indicated for injection of drugs to address abnormal physiology in the lower urinary tract of adults. It is intended to deliver a variety of legally marketed drugs into tissue structures during cystoscopic procedures. It is provided sterile for single use.

V. SUBSTANTIAL EQUIVALENCE

The Repris Bladder Injection System is substantially equivalent to the injeTAK Adjustable Tip Needle manufactured by Laborie Medical Technologies, Corp. (K090830) in terms of indications for use, route the devices are introduced and advanced within the body, capability to injection medications or solutions into the wall of the bladder, and being made from biocompatible materials.

Table I. Comparison of the Repris Bladder Injection System to the predicate device, the InjeTAK Adjustable Tip Needle (K090830).

	Subject device Repris Bladder Injection System URO-1, Inc. (this submission)	Predicate device injeTAK Adjustable Needle Laborie Medical Technologies, Corp. (K090830)
Indication for use	Injection of drugs to address abnormal physiology in the lower urinary tract of adults.	Injection of drugs to address abnormal physiology in the lower urinary tract
Intended Use	To deliver a variety of legally marketed drugs into tissue structures during cystoscopic procedures. It is provided sterile for single use.	To deliver a variety of legally marketed drugs into tissue structures during cystoscopic procedures. It is provided sterile for single use.
Route of Advancement	Advanced to the bladder via the urethra in tandem with a cystoscope	Advanced to the bladder via the urethra through the working channel of a cystoscope
Target Populations	Female	Male & Female
Location of Injection	Bladder Wall	Bladder Wall

Site of Use	Hospitals, clinics, and physician offices	Hospitals, clinics, and physician offices
Device Features		
Components	Introducer Injection Needle Syringe	Injection Needle
Size of Needle	23 ga	25 ga
Size of Needle Assembly (Outer Diameter)	0.648 inch (1.6 mm)	4.8 Fr (1.6 mm)
Length of Needle Assembly	32.4 cm	35 and 70 cm
Introducer Size (Outer Diameter)	7 mm	N/A
Performance		
Duration of use	≤ 24 hours	≤ 24 hours
Sterilization	Provided sterile. Sterilized by gamma radiation (gamma).	Provided sterile. Sterilized by ethylene oxide (EtO).
Frequency of use	Single patient use.	Single patient use.
Tissue contact materials	Compliant with ISO 10993	Compliant with ISO 10993

Any differences between the Repris Bladder Injection System and the predicate device do not alter the intended use of the Repris Bladder Injection System.

VI. PERFORMANCE DATA

All necessary performance testing was conducted with bench testing and included:

- Design verification and validation studies;
- Packaging and shelf-life studies; and
- Biocompatibility testing.

Testing was conducted on the device to verify that it is compliant with biocompatibility requirements for a short duration indwelling device, as specified in ISO 10993 — Part 1.

No animal or clinical testing was necessary to support this submission.

VII. CONCLUSION

The Repris Bladder Injection System and the injeTAK Adjustable Tip Needle have the same intended use and indications for use and have equivalent technological characteristics. The minor differences between the Repris Bladder Injection System and the predicate device do not raise any new issues of safety or effectiveness. Therefore, the Repris Bladder Injection System is substantially equivalent to the identified predicate device.