January 15, 2021

URO-1, Inc.
Thomas Lawson, Ph.D.
Director, Regulatory Affairs
111 North Chestnut Street, Suite 106
Winston Salem, NC 27101

Re: K201650
Trade/Device Name: VMCore Biopsy Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: December 14, 2020
Received: December 15, 2020

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. 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,

Thelma Valdes, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201650

Device Name
VMCore Biopsy Needle

Indications for Use *(Describe)*

The VMCore biopsy needle is intended for use with the Bard Magnum reusable biopsy instrument for biopsies of soft tissues, such as the prostate, lung, kidney, or liver. The VMCore biopsy needle is not intended for use in bone

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5.

510(k) SUMMARY

General Information

Submitter	URO-1, Inc.
Address	URO-1, Inc. 111 North Chestnut Street Suite 106 Winston Salem, NC 27101
FDA Registration Number	No yet assigned
Correspondence Person	Thomas Lawson, PhD
Contact Information	Email: drthomlawson@gmail.com Phone: 510-206-1794
Date Prepared	15 January 2021

Proposed Device

Trade Name	VMCore Biopsy Needle
Common Name	VMCore Biopsy Needle
Regulation Number and Classification Name	21 CFR§876.1075, Gastroenterology-Urology Biopsy Instrument
Product Code	KNW
Regulatory Class	II

Predicate Device

Trade Name	RP Cutting Needle
Common Name	RP Cutting Needle
Premarket Notification	K092059
Regulation Number and Classification Name	21 CFR§876.1075, Gastroenterology-Urology Biopsy Instrument
Product Code	KNW
Regulatory Class	II
Note: This predicate device has not been subject to a design-related recall.	

Reference Device

Trade Name	Reprise Bladder Injection System
Common Name	Reprise Injector
Premarket Notification	K180214
Regulation Number and Classification Name	21 CFR§876.1500, Endoscope and Accessories
Product Code	FBK
Regulatory Class	II
Note: This reference device has not been subject to a design-related recall.	

Device Description

The VMCore Biopsy Needle Set is a set of two disposable needles used for collection of tissue samples. The set consists of an Outer Cannula and the Core Collector. The needles are made of stainless steel and have a plastic hub attached at their proximal ends.

Indications for Use

The indications for use for the VMCore Biopsy Needle is:

> The VMCore Biopsy Needle is intended for use with the Bard Magnum reusable biopsy instrument for biopsies of soft tissue, such as prostate, lung, kidney, or liver. The VMCore Biopsy Needle is not intended for use in bone.

Both the subject device and the predicate device have the same intended use of obtaining tissue samples during biopsy of soft tissue.

Comparison of Technological Characteristics with the Predicate Device

URO-1, Inc. has identified the RP Cutting Needle (K092059) as the predicate device. The VMCore Biopsy Needle is substantially equivalent to the predicate device based upon the following similarities:

1. The intended use of the predicate device and the subject device is for obtaining biopsies from soft tissue;
2. The two devices are introduced into the body under imaging control;

3. Both needles are advanced into tissue via a biopsy gun, specifically the Bard Magnum Biopsy Reusable Biopsy Instrument;
4. The subject device is similar to the predicate device in terms of dimensions of the needles; and
5. Both devices are made from biocompatible materials.

The Repris Bladder Injection System (K180214) is also manufactured for Uro-1, Inc. and is a reference device in this submission since the VMCore Biopsy Needle will use the material for its needles as did the Repris device, will be packaged in the exact same pouch as is the Repris device for a single unit, they both are sterilized by radiation.

Comparison of the VMCore Biopsy Needle to the predicate device, the RP Cutting Needle.

	Subject Device VMCore Biopsy Needle (URO-1, Inc.) (This Submission)	Predicate Device RP Cutting Needle (Riverpoint Medical) K092059
Device Class	II	II
FDA Product Code	KNW	KNW
Product Classification	876.1075	876.1075
Indication for Use	The VMCore Biopsy Needle is indicated for use with the Bard Magnum reusable biopsy instrument for biopsies of soft tissue, such as prostate, lung, kidney, or liver.	The RP Cutting Needle is indicated for use by medical professionals with the Bard Magnum reusable biopsy instrument for biopsies of soft tissue, such as liver, lung, kidney, or prostate.
Intended use	To obtain biopsies from soft tissue, such as	To obtain biopsies from soft tissue, such as liver,

	prostate, lung, kidney, or liver. It is not intended for use in bone.	lung, kidney, or prostate. It is not intended for use in bone.
Technical Characteristics		
Components of the Set	Outer Cannula Core Collector Needle	Outer Cannula Biopsy Needle
Outer Diameter (OD) of needle	16 & 18 gauge	14 to 20 gauge
Length of needle assembly	20 cm and 25 cm	10 and 25 cm
Needle material	Stainless Steel	Same
Needle hub material	Polycarbonate Acrylonitrile butadiene styrene (ABS)	Plastic not identified in labeling
Operational Characteristics		
Mechanism of action	Single puncture and sample	Same
Accessory Device	Bard Magnum Biopsy Instrument	Same
Method of advancement	Advanced under image guidance	Same
Location of Procedure	Hospitals, clinics, physician offices	Same
Duration of use	< 24 hours	< 24 hours
Single-use catheter	Yes	Yes
Provided Sterile	Yes	Yes

Performance Data

The performance testing conducted establishes that the VMCore Biopsy Needle does not raise new questions of the safety and effectiveness.

Biocompatibility testing

The VMCore Biopsy Needle is made from Stainless Steel 304 and passed cytotoxicity testing following sterilization. This material is the same as was used in the construction of another device marketed by Uro-1, Inc., the Reprise Bladder Injection System, and that

device was reviewed and cleared under K180214. The results of testing the Repris device for the following tests:

- Cytotoxicity;
- Sensitization; and
- Irritation.

are comparable to expected results with the VMCore Biopsy Needle so they were not necessary to repeat.

Mechanical Testing

The mechanical testing of the subject device included:

- Dimensions of the device at one-month real-time aging;
- Volume of tissue collection in an *in vitro* model
- Volume of tissue collected from 3 different depths of insertion in an *in vitro* model
- Measurement of the tissue weight collected in the first sample taken and the last sample taken by the device from an *in vitro* model;
- Measure of the strength of the attachment of the hub to the needle; and
- Bend strength of the needle cannula.

Animal Testing

No preclinical testing of the subject device was necessary.

Clinical Studies

No clinical testing of the subject device was necessary.

Conclusion

The information submitted in this premarket notification confirms that the VMCore Biopsy Needle raises no new questions of safety and effectiveness and that the VMCore Biopsy Needle is substantially equivalent to the predicate device.