November 29, 2023

Uro-1 Medical, Inc.
Thomas Lawson, Ph.D.
Regulatory Consultant
3701-A Alliance Drive
Greensboro, NC 27407

Re: K230646
Trade/Device Name: SUREcore Prime Biopsy Instrument
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: November 1, 2023
Received: November 2, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Kreitz -S

for Mark J. Antonino, M.S.
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)*
K230646

Device Name
SUREcore Prime Biopsy Instrument

Indications for Use *(Describe)*
The UR0-1 SUREcore Prime Device is a reusable system for histological core biopsies. It is used to obtain tissue from transrectal or transperineal biopsy of the prostate. It has a throw (advancement) of 25 mm and is used in conjunction with a single use SUREcore biopsy needle.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

General Information

Submitter	Uro-1, Inc.
Address	3703-A Alliance Drive Greensboro, NC 27404
Correspondence Person	Thomas Lawson, PhD Regulatory Affairs Uro-1, Inc.
Contact Information	Email: drthomlawson@gmail.com Phone: 510-206-1794
Date Prepared	15 November 2023

Proposed Device

Trade Name	SUREcore Prime Biopsy Instrument
Common Name	SUREcore Prime
Regulation Number and Classification Name	21 CFR§876.1075 Gastroenterology-urology biopsy instrument
Product Code	KNW
Regulatory Class	II
Note: This is the first 510(k) submission for this device.	

Predicate Device

Trade Name	Cook BX Biopsy Device
Common Name	BX Biopsy Device
Premarket Notification	K980226
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.	

Device Description

The SUREcore Prime Biopsy Instrument facilitates collection of tissue for analysis by pathology in order to assist with a diagnosis of a disease condition in a patient. The SUREcore Prime device consists of two elements: (1) a handle and (2) a needle set. The handle contains springs that energize the biopsy needles and when used will cause rapid advance of the needles into target tissue. This action causes tissue to be held within a component of the needle (the core collector) intact from the body. The tissue samples are removed from the needle set and prepared for transfer to a pathologist or lab. The user can re-energize the springs by pulling back on the cocking slide so that multiple tissue samples can be collected from different locations within the target tissue.

Indications for Use

The indication for use for the SUREcore Plus biopsy instrument is:

> The URO-1 SUREcore Prime Device is a reusable system for histological core biopsies. It is used to obtain tissue from transrectal or transperineal biopsy of the prostate. It has a throw (advancement) of 25 mm and is used in conjunction with a single use SUREcore biopsy needle.

Comparison to the Predicate Device

Uro-1, Inc. has identified the Cook BX Biopsy Device (Cook Medical) as the predicate device. The SUREcore Prime Biopsy Instrument is substantially equivalent to the predicate device based upon the following similarities:

1. The intended use of both the predicate device and the SUREcore Prime device is exactly the same for both devices, which is to obtain biopsies from the prostate.
2. Both devices introduce a biopsy needle into the body under imaging control (*e.g.*, ultrasound, X-Ray, CT, *etc.*)
3. Both devices are designed to collect multiple samples.
4. Both devices are made from biocompatible materials.

Table 1 shows the comparison of the SUREcore Prime Biopsy Device (the subject of this submission) to the predicate device, Cook BX Biopsy Device. The similarities between the two devices satisfy the criteria for a 510(k) notice.

Table 1. Comparison of the SUREcore Prime Biopsy Device to the predicate device, the Cook BX Biopsy Device.

	Predicate device Cook BX Biopsy Device Cook Medical (K980226)	Subject device SUREcore Prime Biopsy Instrument URO-1, Inc. (this submission)
Indication for use	For obtaining histological core biopsies of tissue	Same
Intended Use	Used to obtain tissue core biopsies from transrectal or transperineal biopsy of the prostate	Same
Route of advancement	Transrectal or transperineal	Same
Target populations	Male	Same
Location of biopsy	Prostate	Same
Site of use	Hospitals, clinics, and physician offices	Same
Device Features		
Components	(1) Handle/Gun (2) Needle set consisting of a core collector and outer cannula	Same

Dimensions of the handle	6.3 inches long x 1.3 inches tall x 1.4 inches wide (2.3 inches wide at cocking grip)	6.3 inches long x 1.9 inches tall x 1 inch wide (2 inches wide at cocking grips)
Mechanics of Energizing the needle	2-stroke cocking action (using lever on handle)	2-stroke cocking action (using cocking grips on handle)
Mechanics of Releasing the needle to puncture tissue	Pressing an activator button on the handle	Same
Size of needle	14-20 ga	Same
Length of needle Tissue collection trough (sample notch)	18-19 mm	19 mm
Length of needle assembly	10-20 cm	Same

Performance

Depth of penetration possible (needle)	25 mm	Same
Sterilization	Not provided sterile	Same
Frequency of use	Reusable	Same
Tissue contact materials	Instrument does not contact tissue	Same

Comparison of Technological Characteristics of the Subject Device with the Predicate Device

The technological characteristics of the subject device are substantially equivalent to those of the predicate device in terms of the following:

- The exact same intended use
- The exact same indications for use
- Similar penetration depth
- Similar sample notch
- Same mechanics of action
- Same mode of action
- Same energy used/delivered

- Similar patient-contacting materials (needles)
- Same fundamental scientific technology
- Same patient population

Performance Data

The performance testing conducted establishes that SUREcore Prime Biopsy Device does not raise new questions of the safety and effectiveness for a biopsy system.

Biocompatibility testing

The handle of the SUREcore Plus Biopsy Instrument does not come into contact with the patient, but it has been assessed for cytotoxicity and found to pass such testing. The needle set does contact patient tissue and passed all tests (as noted in K220611):

- Cytotoxicity,
- Sensitization,
- Irritation, and
- Systemic toxicity.

Electrical safety and electromagnetic compatibility (EMC)

The subject and predicate devices do not have electronic components, so such testing was not required.

Software Verification and Validation Testing

Neither the subject nor predicate devices contain software.

Mechanical Testing

The mechanical testing of the subject device included:

- Capacity to collect tissue in a prostate model; and
- Force necessary to deform the needle set (16 and 18 gauge).

Preclinical (Animal) Studies

Bench testing was sufficient to demonstrate performance of the device. No preclinical testing of the subject device was necessary.

Clinical Studies

Bench testing was sufficient to demonstrate performance of the device. No clinical testing of the subject device was necessary.

Conclusion

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