December 2, 2022

Uro-1, Inc.
Thomas Lawson
Regulatory Consultant
3701-A Alliance Drive
Greensboro, North Carolina 27407

Re: K220611
Trade/Device Name: SUREcore Plus Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 28, 2022
Received: March 3, 2022

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,

Jessica Carr -S

for Long Chen
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K220611

Device Name
SUREcore Plus Biopsy Instrument

Indications for Use *(Describe)*

The SUREcore Plus Biopsy Instrument is intended for use in obtaining biopsies from soft tissue such as liver, kidney, and prostate. It 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.

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SECTION 5.

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	1 December 2022

Proposed Device

Trade Name	SUREcore Plus Biopsy Instrument
Common Name	SUREcore Plus
Regulation Number and Classification Name	21 CFR§876.1075 Gastroenterology-urology biopsy instrument
Product Code	KNW
Regulatory Class	II

Predicate Device

Trade Name	Max-Core Biopsy Instrument
Common Name	Max-Core
Premarket Notification	K133948
Regulation Number and Classification Name	21 CFR§876.1075 Gastroenterology-urology biopsy instrument
Product Code	KNW
Regulatory Class	II
Note: This predicate device has been subject to a design-related recall.	

Device Description

The SUREcore Plus 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 Plus 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. When the user has determined that sufficient amount of tissue has been obtained, the SUREcore Plus device is disposed in accordance with local and facility policies and procedures. The device is single-use only and is not to be resterilized by the user.

Indications for Use

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

> The SUREcore Plus biopsy instrument is intended for use in obtaining biopsies from soft tissue such as liver, kidney, and prostate. It is not intended for use in bone.

Comparison to the Predicate Device

Uro-1, Inc. has identified the Max-Core Biopsy Instrument (Bard Medical) as the predicate device. The SUREcore Plus 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 Plus device are equivalent for the two devices, which is to obtain biopsies from soft tissues such as liver, kidney, and prostate. Neither are not intended for use in bone.
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 Plus Biopsy Instrument (the subject of this submission) to the predicate device, Max-Core Biopsy Instrument (K133948). The similarities between the two devices satisfy the criteria for a 510(k) notice.

Table 1. Comparison of the SUREcore Plus Biopsy Instrument to the predicate device, the Bard Max-Core Biopsy Instrument.

	Subject device SUREcore Plus Biopsy Instrument URO-1, Inc. (this submission)	Predicate device Max-Core Biopsy Instrument Bard Medical (K133948)
Indication for use	For use in obtaining biopsies from soft tissues	Same
Intended use	The introduction of the needle into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.). It is provided sterile for single use.	Same
Route of advancement	Percutaneous	Same
Target populations	Male & Female	Same
Location of biopsy	Liver, kidney, and prostate.	Liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors.
Site of use	Hospitals, clinics, and physician offices	Same
Device Features		
Components	(1) Handle (2) Needle set consisting of a core collector and an outer cannula	Same

Dimension of the handle	5.5 in X 1.5 in X 1 in	6 in X 1.4 in (cylinder diameter)
Mechanics of energizing the needle	2-stroke cocking action (using a lever on the handle)	Same
Mechanics of releasing the needle to puncture tissue	Pressing on an activator button on the handle	Same
Size of needle	18 gauge	14 to 20 ga
Length of needle tissue collection trough (sample notch)	19 mm	Same
Length of needle assembly	10-25 cm	Same
Performance		
Depth of penetration	22 mm	Same
Sterilization	Gamma Radiation	ETO
Frequency of use	Single patient use	Same
Tissue contact materials	Compliant with ISO 10993	Same

Comparison of Technological Characteristics 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:

- Equivalent intended use;
- Equivalen 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;
- Same fundamental scientific technology;
- Same patient population;
- Single-use device;

- Supplied sterile; and
- Similar packaging.

Performance Data

The performance testing conducted establishes that SUREcore Plus Biopsy Instrument 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 VMCore needle set does contact patient tissue and passed all tests, as noted in K201650:

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

In this respect, the VMCore needle set is a reference device for the biocompatibility information for this submission related to the needle set.

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 ex vivo models of liver, kidney & prostate tissue, and
- Force necessary to deform the needle set.

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 Plus Biopsy Instrument raises no new questions of safety and effectiveness and that the SUREcore Plus Biopsy Instrument is substantially equivalent to the predicate device.