September 17, 2021

Uramix, Inc.
% Michael Mooreville, MD
Medical Director
Uramix, Inc
272 N. Lansdowne Ave.
Lansdowne, Pennsylvania 19050

Re: K203141
Trade/Device Name: URAMIX CuraWay Automatic Core Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 21, 2021
Received: July 21, 2021

Dear Dr. Mooreville :

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,

Long Chen, Ph.D.
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)*
K203141

Device Name
Uramix Curaway Automatic Core Biopsy Instrument

Indications for Use *(Describe)*
The Uramix Curaway Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as liver, kidneys, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone, or breast.

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.

K203141
510(k) Summary

SUBMITTER

Uramix, Inc
272 N. Lansdowne Ave.
Lansdowne, PA 19050

Contact Person: Michael Mooreville, MD
Medical Director
Telephone: (610) 304-9070
Email: uramix@comcast.net

DEVICE

Name of the Device: URAMIX CuraWay Automatic Core Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Instrument, Biopsy/Regulatory Class II
Regulatory Specialty: Gastroenterology/Urology
Product code: KNW

Manufacturer: Zhejiang CuraWay Medical Technology Co., Ltd
Company Address: Room 106, Building 1, No.600, 21st Street, Qiantang New Area, Hangzhou, Zhejiang, China

PREDICATE DEVICE

Primary: K133948, BARD® MAX-CORE® Disposable Core Biopsy

DEVICE DESCRIPTION

The URAMIX CuraWay Automatic Core Biopsy Instrument is a *single use* only core biopsy device and is individually packaged and sterilized. The packaging is compatible with the product's EO sterilization method. The sterilization validation confirms the packaging is qualified to maintain the sterilization condition of the device. It is available in several needle gauge sizes and lengths. The side and rear actuator buttons are color coded according to the various gauge sizes. The 18 gauge is the one used for current intended marketing, for prostate and kidney biopsies.

K203141
510(k) Summary

According to gauge and length, the following variants are available:

ABN 1208, ABN 1208A	ABN 1408, ABN 1408A	ABN 1608, ABN 1608A	ABN 1808, ABN 1808A	ABN 2008, ABN 2008A
ABN 1210, ABN 1210A	ABN 1410, ABN 1410A	ABN 1610, ABN 1610A	ABN 1810, ABN 1810A	ABN 2010, ABN 2010A
ABN 1213, ABN 1213A	ABN 1413, ABN 1413A	ABN 1613, ABN 1613A	ABN 1813, ABN 1813A	ABN 2013, ABN 2013A
ABN 1216, ABN 1216A	ABN 1416, ABN 1416A	BN 1616, ABN 1616A	ABN 1816, ABN 1816A	ABN 2016, ABN 2016A
ABN 1220, ABN 1220A	ABN 1420, ABN 1420A	ABN 1620, ABN 1620A	ABN 1820, ABN 1820A	ABN 2020, ABN 2020A
ABN 1225, ABN 1225A	ABN 1425, ABN 1425A	ABN 1625, ABN 1625A	ABN 1825, ABN 1825A	ABN 2025, ABN 2025A
12G (2.7mm) Blue	14G (2.1mm) Green	16G （1.7mm） Violet	18G （1.2mm） Pink	20G （0.9mm） Yellow

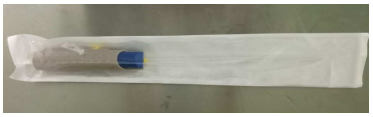
The operating handle is color coded and the Type A is a variant in the position of the needle markings, which provide reference for depth of placement.

INDUCATIONS FOR USE

The URAMIX CuraWay Automatic Core Biopsy Instrument is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue tumors. It is not intended for use in bone, or breast.

COMPARISON TO PREDICATE

Item	Predicate Device	Subject Device	Outcome
	BARD® MAX-CORE® Disposable Core Biopsy Instrument, K133948	URAMIX CuraWay Automatic Core Biopsy Instrument, K203141	
Intended Use	Obtaining biopsies from soft tissues such as liver, kidney, thyroid, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	The URAMIX Curaway Automatic Core Biopsy Instrument is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone, or breast.	It was used for the same clinical condition, and same intended purpose, and at the same site.
Material	Stainless steel + ABS	The shaft of cutting cannula and inner stylet is made of medical grade stainless steel (SUS304/06Cr19Ni10). The operating handle and actuator button are made of acrylonitrile butadiene styrene (ABS).	Same material used
Types/ Sizes	14G, 16G, 18G, 20G	12G, 14G, 16G, 18G, 20G	12G is also available from Zhejiang CuraWay, this has no significant influence on clinical use.
Design Attributes	Each needle has numerically ordered centimeter markings on the outer cannula to provide reference for depth placement Needles feature an adjustable needle stop which allows the user to restrict forward movement, localizing the needle tip to the biopsy site Color coded stylet hubs indicate gauge size of needles available in a variety of gauge sizes and centimeter lengths Available with an echogenic tip on the outer cannula to promote accurate placement under ultrasound guidance	Automatic Core Biopsy Instrument is a puncture needle consisting of an inner stylet and a cutting cannula with etched tip (s. Figure 1). The cutting cannula has numerically ordered centimeter markings on it to provide reference for depth placement. In the distal area of the cutting cannula, an ultrasound enhancement is available to promote accurate placement under ultrasound or X-ray guidance. An adjustable depth stopper allows the user to restrict forward movement, localizing the needle tip to the biopsy site. The Type A is a variant in position of the depth stopper. The operating handle is color-coded, which indicates gauge size of the needle. The needle is protected in a needle sheath. Automatic Core Biopsy Instrument is available in several needle gauge sizes and lengths.	Very similar design

Length (mm)	100mm, 160mm, 200mm, 250mm	80mm, 100mm, 130mm, 1600mm, 200mm, 250mm	This has no significant influence on clinical use.
Slot size	18mm	18mm	Same
Structure a. Photo (examples)			Very similar structure and design concept
Packaging	Tyvek 1073B + PE	Tyvek 1073B + PET/PE	Critical component Tyvek is the same. Both packaging systems are common packaging.
Biocompatibility	ISO 10093-1, ISO 10993-5 and ISO 10993-10	ISO 10093-1, ISO 10993-5 and ISO 10993-10	Same.
Sterilization method	EO sterilization	EO sterilization	Same.
Conclusion	After comparison of the device in question with the predicate device, K133948 regarding clinical, technical and biological characteristics, it can be concluded that both devices have similar design, perform the same function under the same clinical conditions. They use the same materials and have the same durability. Tissue penetration and sample size are the same and the device is in contact with the same human tissues and body fluids. They can be considered as equivalent devices.		

SUMMARY OF NON_CLINICAL TESTING

The following testing was conducted to demonstrate the safe and effective use of the URAMIX Curaway Automatic Core Biopsy Instrument:

- Biocompatibility Testing per ISO 10993-5, including in vitro cytotoxicity
- ISO 10993-10 – tests for irritation and skin sensitization
- ISO 10883-11 – test for systemic toxicity
- Sterilization Testing per ISO 11138-2, and ISO 11737-2 – sterility test
- Residuals per EN ISO 10993-7 – EO residuals = 1.13 mg/device
- Packaging and Shelf-life per ISTA2A and ASTM F1980-16 – 3-year shelf life

- Puncture Force Value: Predicate - 5.3N; Subject - 2.7N
- Resistance during operation: Predicate - none; Subject - none
- Abnormal noise during operation: Predicate - none; Subject - none
- Connection firmness (needle tube + plastic parts): P - 181 to 230N; S - 190 to 212N
- Samples of various tissues: similar length, weight between Predicate and Subject
- The ex-vivo tissue studies (porcine muscle, liver) demonstrate equivalent tissue samples in terms of length and weight.

CONCLUSION

Based upon the performance data provided in this submission and comparing indicated use, design, materials, principle of operation and overall technological characterisitics, the URAMIX Curaway Automatic Core Biopsy Instrument has been determined to be substantially equivalent to the predicate device, BARD Max-Core, K133948