August 14, 2024

Utepreva LLC
% Melissa Paffenroth
Senior Regulatory Consultant
MEDIcept, LLC.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K240595
Trade/Device Name: Utepreva Endometrial Sampler (UP01)
Regulation Number: 21 CFR 884.1100
Regulation Name: Endometrial Brush
Regulatory Class: II
Product Code: HFE
Dated: March 4, 2024
Received: July 1, 2024

Dear Melissa Paffenroth:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240595

Device Name
Utepreva Endometrial Sampler (UP01)

Indications for Use *(Describe)*
The Utepreva Endometrial Sampler (UP01) is used to obtain endometrial cytological and histological samples.

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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510(k) Summary
Utepreva, LLC
Utepreva Endometrial Sampler (UP01)

I. SUBMITTER

510(k) Holder: Utepreva, LLC
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Suite 333
Jericho, NY 11753

Contact Person: Melissa Paffenroth, PhD, RAC-Devices
Senior Consultant, Regulatory
MEDIcept, Inc.
Tel: (617) 512-9943
Email: mpaffenroth@medicept.com

Date Prepared: March 4, 2024

II. DEVICE

Name of Device: Utepreva Endometrial Sampler (UP01)
Common Name: Endometrial brush
Classification Name: Brush, Endometrial
Regulation Number: 21 CFR 884.1100
Regulatory Class: Class II
Product Code: HFE

III. PREDICATE DEVICE

K170603, Tao Brush™ I.U.M.C Endometrial

The predicate device identified above has not been subject to design-related recalls.

IV. DEVICE DESCRIPTION

The Utepreva Endometrial Sampler (UP01) is a single-use, sterile device designed to obtain endometrial cytological and histological samples. The device is an Rx device that functions as follows: The Utepreva Endometrial Sampler is gently inserted though the cervix into the uterus. The skirt (guard) will reach the cervix indicating to the clinician to stop inserting the device. The brush is then extended by pushing the handle until resistance is felt when the tip meets the fundus of the uterus. The sponge on the tip is intended to minimize the risk of piercing of the fundus by the tip of the brush and enables additional tissue sampling by absorption of the fluid and the cells from the uterus. The Utepreva Endometrial Sampler is rotated in a clockwise or counterclockwise manner for four or five 360° rotations. Upon completion of the rotations, the handle is pulled back so that the brush and tip are withdrawn into the outer sheath. The suction

created by the plunger located inside of the sheath provides aspiration of the cells and prevents loss of the sample from the brush. The brush, sponge and any fluid that was aspirated can then be immersed into the preservative solution to be used by the pathology lab.

The device materials consist of polydimethylsiloxane, high density polyethylene, cyanoacrylate adhesive, Loctite, Permabond polyolefin primer, stainless steel, Nylon, polycarbonate, and polypropylene. The device is packaged in a Tyvek® pouch. One pouch is then packaged in a unit box. Fifteen unit boxes are packaged within a single master box to create the final shipped product.

V. INDICATIONS FOR USE

The Utepreva Endometrial Sampler (UP01) is used to obtain endometrial cytological and histological samples.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate and the subject devices is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences (Table 1). The technological characteristic differences rationale demonstrates that the subject device is safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Table 1. Comparison Table for Subject Device Utepreva Endometrial Sampler and Predicate Device Tao Brush™ I.U.M.C. Endometrial Sampler.

Characteristic	**Subject Device Utepreva Endometrial Sampler (UP01)** (K240595)	**Predicate Device Tao Brush™ I.U.M.C. Endometrial Sampler** (K170603)	**Comparison**
Regulatory Class	Class II	Class II	**Same**
Regulatory Number	884.1100	884.1100	**Same**
Regulation Name	Endometrial Brush	Endometrial Brush	**Same**
Product Code	HFE	HFE	**Same**
Manufacturer	Utepreva LLC	Cook Incorporated	**-**
Rx/OTC	Rx	Rx	**Same**
Sterile	Yes	Yes	**Same**
Sterilization	EtO	EtO	**Same**
Shelf-Life	3 months	3 years	**Different**
Insertion Depth Indicator	Skirt (Guard) on Sheath	Black Ink Mark on Sheath	**Different**
Dimensions			
Working Length	26.8 cm	26.9 cm	**Similar**
Ball Tip	10.2 Fr	9.5 Fr	**Similar**

Characteristic	Subject Device Utepreva Endometrial Sampler (UP01) (K240595)	Predicate Device Tao Brush™ I.U.M.C. Endometrial Sampler (K170603)	Comparison
Sheath OD	11.43 Fr	9.3 Fr	**Similar**
Outer Sheath Length	22.9 cm	21.5 cm	**Similar**
Brush Length	3.2 cm	3.5 cm	**Similar**
Brush Diameter	3 mm	6 mm	**Different**
Insertion Depth Indicator Distance from Distal Tip	6.58 cm	7 cm	**Similar**
Materials			
Insertion Depth Indicator	Skirt: Polycarbonate, acrylic adhesive	Black ink mark on sheath	**Different**
Wire Core	Stainless steel	Stainless steel	**Same**
Plunger	Polydimethylsiloxane	NA	**-**
Silicone Fluid	Polydimethylsiloxane	NA	**-**
Brush Bristles	Nylon	Nylon	**Same**
Backstop	Nylon 11	NA	**-**
Ball Tip	Polyurethane, Polypropylene	Acrylonitrile butadiene styrene (ABS)	**Different**

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted to verify the Utepreva Endometrial Sampler performance. The following performance data was provided in support of the substantial equivalence determination (Table 2).

Table 2. Non-Clinical Performance Testing

Test	Conclusion
Biocompatibility • Cytotoxicity Testing (ISO 10993-5:2009) • Sensitization (ISO 10993-10:2010) • Vaginal Irritation (ISO 10993-10:2010)	Pass
Visual & Dimensional Inspection	Pass
Tensile Strength	Pass
Torque	Pass
Bristle Retention	Pass
Fluid Retention	Pass
Fluid Transfer	Pass

VIII. CONCLUSIONS

The information provided and summarized in the substantial equivalence table and performance testing results demonstrate that the Utepreva Endometrial Sampler is as safe and effective as the predicate device and support a determination of substantial equivalence.