April 3, 2024

Resilia Inc.
% Roshana Ahmed
President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K233548
Trade/Device Name: Uresta®
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: February 26, 2024
Received: February 26, 2024

Dear Roshana Ahmed:

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,

Sharon M. Andrews -S

Sharon M. Andrews
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.

Submission Number *(if known)*

K233548

Device Name

Uresta®

Indications for Use *(Describe)*

The Uresta bladder support is indicated for use in adult women over 18 years of age who experience stress urinary incontinence (involuntary urine loss, such as a pee leak that occurs when you cough, laugh, sneeze or with some physical tasks).

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

I. Submitter

Resilia Inc.
644 Main Street
Suite S400, P.O. Box 1368
Moncton, NB E1C 1E2
Canada

Contact Person: Sam Imbeault, Chief Operating Officer
Phone: 506-874-8584
Date Prepared: February 23, 2024

II. Device

Device Proprietary Name:	Uresta®
Common or Usual Name:	Vaginal pessary
Classification Name:	Vaginal pessary
Regulation Number:	21 CFR 884.3575
Product Code:	HHW (pessary, vaginal)
Device Classification	2

III. Predicate Device

Uresta®, K081385, EastMed Inc. The predicate device has not been subject to a design-related recall.

IV. Device Description

Uresta® is a bell-shaped vaginal bladder support that is intended to support the urethra to help reduce leaks caused by stress urinary incontinence. It has a tapered tip for insertion into the vaginal introitus and a handle end to enable placement and removal. It may also be used with a water-based lubricant for easier insertion.

Uresta® is available in five (5) sizes, ranging from 34 mm (size 2) to 52 mm (size 6). It can be inserted in the morning and removed at bedtime every day or used just for specific activities such as exercise and removed after the activity.

Uresta® is molded from non-latex thermoplastic rubber and is provided non-sterile for single patient use.

V. Indications for Use

The Uresta bladder support is indicated for use in adult women over 18 years of age who experience stress urinary incontinence (involuntary urine loss, such as a pee leak that occurs when you cough, laugh, sneeze or with some physical tasks).

VI. Comparison of Technological Characteristics

Uresta® has the same intended use as the predicate device and is intended for use in the same user population; however, the subject device is intended for both Rx and OTC use, while the predicate device is indicated for Rx use only. With the exception of available product sizes, the subject device is identical to the predicate device with respect to material of construction and design. There have been no changes to the product since clearance under K081385.

A comparison of the subject and predicate devices is provided in the table below.

	Uresta® Subject Device	**Uresta® (K081385)**	**Analysis**
Intended Use/Indications for Use	The Uresta bladder support is indicated for use in adult women over 18 years of age who experience stress urinary incontinence (involuntary urine loss, such as a pee leak that occurs when you cough, laugh, sneeze or with some physical tasks).	This device is for the use in adult women, over 18 years of age who experience involuntary urine loss with physical activity (stress urinary incontinence).	Different; slight differences in wording do not alter the intended use of the subject device when compared to the predicate device.
User Population	Women, ages 18 and older	Women, ages 18 and older	Identical
Use	Rx and OTC	Rx	Different; performance testing demonstrates patients can self-select and use the device appropriately in an OTC setting.
Design	Bell-shaped pessary	Bell-shaped pessary	Identical
Number of models	Sizes 2 – 6	Sizes 1 – 7	Different, sizes 1 and 7 have been removed from the product offering.
Reuse	Yes	Yes	Identical
Sterile	No	No	Identical

VII. Performance Data

Non-clinical and clinical data submitted within K083185 is being leverage for the subject device.

In addition, a self-selection and labeling usability study was performed and demonstrates that the subject device can be appropriately self-selected and fit by the intended lay user population. Women who were naïve to the device reviewed the external product packaging and determined if they met the criteria to be an intended user. The self-selection decision was confirmed via clinical diagnosis. Intended users then participated in a labeling usability simulated study in which they reviewed the Instructions for Use and independently inserted and fit the device without guidance. Participant demographics were diverse with respect to race, ethnicity, age, educational level, and health literacy and representative of the US patient population. The results of the self-selection and usability study demonstrate that patients can self-select and use the device appropriately.

VIII. Conclusion

The information provided above supports that Uresta® is substantially equivalent to the predicate device.