March 6, 2024

Cosm Medical
Linda Wu
Head of Clinical, Regulatory and Quality
101 College Street
Toronto, ON M5G1L7
CANADA

Re: K231786
Trade/Device Name: Gynethotics™ Pessary
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: February 3, 2024
Received: February 5, 2024

Dear Linda Wu:

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)*
K231786

Device Name
Gynethotics™ Pessary

Indications for Use *(Describe)*
Gynethotics Ring Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse.

Gynethotics Ring with Support Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse.

Gynethotics Ring with Knob Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Ring with Support and Knob is indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Incontinence Ring Pessary is indicated for use in cases of stress urinary incontinence.

Gynethotics Marland Pessary is indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Marland with Support Pessary is indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Gellhorn Pessary is indicated for use in cases of mild (Stage I) to severe (Stage III or procidentia) pelvic organ prolapse.

Gynethotics Cube Pessary is indicated for use in cases of moderate (Stage II) to severe (Stage III or procidentia) pelvic organ prolapse.

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.

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510(k) Summary

16.2.1. Submitter Information

Company Name	Cosm Medical Corp.
Company Address	101 College Street, Toronto, ON M5G 1L7
Company Phone	1-888-589-2676
Contact Person	Linda Wu (Head of Clinical, Regulatory, Quality)
Date Prepared	March 5, 2024

16.2.2. Device Information

Device Trade Name	Gynethotics™ Pessary
Device Common Name	Vaginal Pessary
Product Code Name	Pessary, Vaginal
Product Code	HHW
Classification Panel	Obstetrical/Gynecological
Regulatory Class	2
Classification Number	21 CFR 884.3575
Classification Name	Vaginal pessary

16.2.3. Predicate Devices

Name	Manufacturer	510(k)
Bioteque Vaginal Pessary (primary)	Bioteque America, Inc.	K013289
Panpac vaginal pessary	Panpac Medical Corporation	K092981
Flexi-Shelf	Panpac Medical Corporation	K173351
PelvX Incontinence Ring	DesChutes Medical Products	K974116

The predicate devices have not been subject to a design-related recall.

16.2.4. Intended Use

Gynethotics pessaries are removable devices placed in the vaginal cavity to provide a non-surgical alternative for the treatment of pelvic organ prolapse and to relieve the symptoms of pelvic relaxation with or without urinary incontinence in adults.

16.2.5. Indications for use

Gynethotics Ring Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse.

Gynethotics Ring with Support Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse.

Gynethotics Ring with Knob Pessary is indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Ring with Support and Knob is indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Incontinence Ring Pessary is indicated for use in cases of stress urinary incontinence.

Gynethotics Marland Pessary is indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Marland with Support Pessary is indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.

Gynethotics Gellhorn Pessary is indicated for use in cases of mild (Stage I) to severe (Stage III or procidentia) pelvic organ prolapse.

Gynethotics Cube Pessary is indicated for use in cases of moderate (Stage II) to severe (Stage III or procidentia) pelvic organ prolapse.

16.2.6. Device Description

Gynethotics pessaries are vaginal pessaries made from silicone that are inserted into the vagina to function as a supportive structure of the vagina, uterus, bladder and/or rectum to manage and treat the symptoms of pelvic floor dysfunction, such as pelvic organ prolapse and incontinence. Gynethotics pessaries come in four general shapes, including: Ring, Gellhorn, Marland, and Cube. Each shape comes in a range of configurable features and dimensions.

16.2.7. Comparison to Predicate Devices

Gynethotics pessaries are vaginal pessaries used to provide support to prolapse organs and treat symptoms of pelvic floor dysfunction. Similar to predicates, Gynethotics pessaries are available in multiple shapes and sizes. The key difference between the subject and predicate devices is that Gynethotics pessaries allow for personalized configurations of certain shape features, as determined by the clinician. The differences do not raise different questions of safety or effectiveness, and can be evaluated through performance testing.

Shape Description	Indications for Use (subject device)	Indications for Use (predicate devices)
Ring	Indicated for use in cases of mild (Stage I) pelvic organ prolapse.	**K013289:** Indicated for use in cases of first or mild second-degree prolapse.
Ring with Support	Indicated for use in cases of mild (Stage I) pelvic organ prolapse.	**K013289:** Indicated for use in cases of first or mild second-degree prolapse.
Ring with Knob	Indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.	**K092981:** Indicated for first or second-degree prolapse and stress urinary incontinence.

Shape Description	Indications for Use (subject device)	Indications for Use (predicate devices)
Ring with Support and Knob	Indicated for use in cases of mild (Stage I) pelvic organ prolapse, and stress urinary incontinence.	**K092981:** Indicated for first or second-degree prolapse and stress urinary incontinence.
Incontinence Ring	Indicated for use in cases of stress urinary incontinence.	**K974116:** for treatment of urinary incontinence.
Marland	Indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.	**K013289:** Indicated for use for the control of stress urinary incontinence and first or mild second-degree prolapse.
Marland with Support	Indicated for use in cases of mild (Stage I) and moderate (Stage II) pelvic organ prolapse, and stress urinary incontinence.	**K013289:** Indicated for use for the control of stress urinary incontinence and first or mild second-degree prolapse.
Gellhorn	Indicated for use in cases of mild (Stage I) to severe (Stage III or procidentia) pelvic organ prolapse.	**K173351:** Indicated for the support of a second to third degree prolapse or procidentia.
Cube	Indicated for use in cases of moderate (Stage II) to severe (Stage III or procidentia) pelvic organ prolapse.	**K013289:** Indicated for use in the support of a third degree prolapse, including procidentia, as well as cystocele and rectocele.

Any differences in wording of the Indications for use statements between subject and predicate devices, do not impact the intended use of the device. Indications for use language of the subject device is reflective of currently recognized medical terminology and reflects the same understanding of Indications for use in predicate devices.

Technological characteristic	Differences
Dimensions and sizing increments	The min and max feature sizes are within range of predicate pessaries. Subject device sizes increment with greater degrees of freedom within the cleared ranges, thereby offering greater sizing options.
Materials	Subject device is made of silicone and colorant. Predicate devices are also made of silicone and colorant, but formulation differs.

16.2.8. Performance Data

The following testing was conducted to evaluate that the device meets its specifications:

- **Mechanical testing** was performed to confirm that the device meets key performance specifications related to the functionality and safety of the device. Testing included: folding, 3-point bend, cord detachment, end of life, squeeze, knob displacement.

- **Biocompatibility** according to ISO 10993-1:2018 and applicable FDA guidance documents. Testing included:

Test name	Results	Standards
Cytotoxicity	Non-cytotoxic	ISO 10993-5:2009
Sensitization	Non-sensitizer	ISO 10993-10:2021
Irritation	Non-irritant	ISO 10993-23:2021
Acute systemic toxicity	No mortality or evidence of systemic toxicity	ISO 10993-11:2017
Implantation	Compared to negative control: Macroscopic – difference not significant; Microscopic – minimal or no reaction	ISO 10993-6:2016
Pyrogenicity	Non-pyrogenic	ISO 10993-11:2017
Chemical characterization and Materials and Toxicological Risk assessments	Acceptable risk of daily dose-exposure to compounds from device use	ISO 10993-17:2002 ISO 10993-17:2023 ISO 10993-18:2020

- **TSST-1 Risk** laboratory testing to evaluate the impact of the device on *Staphylococcus aureus* growth and TSST-1 production, following FDA guidance for Menstrual Tampons and Pads: Information for Premarket Notification Submissions, which demonstrated a low risk profile for the device.
- **Cleaning validation** conducted as per AAMI ST98:2022, AAMI TIR12 and FDA guidance on Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling, demonstrated that the cleaning removes soil and contamination effectively.
- **Packaging validation** conducted as per ASTM D4169-22 confirmed that the packaging materials are capable of withstanding the distribution environment during the rigors of shipping and handling.

16.2.9. Conclusions

Subject and predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the subject and predicate devices do not raise any new types of questions of safety and effectiveness. The results of performance testing demonstrate that the subject device is as safe and effective as the predicate devices to support a substantial equivalence determination.