April 11, 2025

CooperSurgical, Inc
Drake Schaffer
Senior Regulatory Affairs Specialist
95 Corporate Drive
Trumbull, Connecticut 06611

Re: K250438
Trade/Device Name: CooperSurgical Milex® Pessaries
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: February 14, 2025
Received: February 14, 2025

Dear Drake Schaffer:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Reginald K. Avery -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250438

Device Name
CooperSurgical Milex® Pessaries

Indications for Use *(Describe)*
The CooperSurgical Milex pessaries are intended to provide support to pelvic organs when inserted in the vagina.

The following Indications for Use are associated with each of the following pessary styles:

Milex® Shaatz Folding Pessaries:
Shaatz pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage I and Stage II prolapse, complicated by a mild cystocele.

Milex® Gellhorn Pessaries:
Gellhorn pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage III prolapse or procidentia.

Milex® Ring Folding Pessaries:
Milex Ring Pessary is indicated for use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women.

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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CooperSurgical®

510(k) Summary

CooperSurgical MILEX Pessaries

I. Submitter Information

Company Name:	CooperSurgical Inc.
Company Address:	95 Corporate Drive Trumbull, CT 06611 Telephone: 203-400-1385
Contact Person:	Drake Schaffer Sr. Regulatory Affairs Specialist
Date Prepared:	April 11, 2025

II. Device Information:

Trade Name:	CooperSurgical Milex® Pessaries
Common Name:	Vaginal pessary
Classification Name:	Vaginal pessary
Regulatory Class:	Class II
Regulation Medical Specialty:	Obstetrics/Gynecology
Regulation Number:	884.3575
Product Code:	HHW (pessary, vaginal)

III. Predicate Devices:

Name	Manufacturer	510(k)
Mentor Evacare Vaginal Pessaries (Primary)	Mentor Corp.	K993308

Reference Devices:

Gynethotics Gellhorn Pessary	Cosm Medical	K231786
EIS Vaginal Pessaries	EIS Corporation	K132313

The predicate device has not been subject to a design related recall.

IV. Device Description:

Milex® Pessaries are intended for adult women as Obstetrical and Gynecological medical devices. Milex® Pessaries are distributed in a non-sterile condition made from silicone. The Milex Pessaries are available in a variety of styles, each having a range of sizes that is inserted

into the vagina to function as a supportive structure of the uterus, bladder and rectum. All pessaries are produced in a like fashion, utilizing injection molding of liquid silicone rubber. The Milex Pessaries are manufactured in pink for single patient use.

This submission includes the following designs of Milex Pessaries: Shaatz Pessary, Gellhorn Pessary (Short and Long Stem), and Ring Folding Pessaries (Ring without support, Ring with support, Ring with knob without support, Ring with knob with support).

V. Indications for Use:
The CooperSurgical Milex pessaries are intended to provide support to pelvic organs when inserted in the vagina.

The following Indications for Use are associated with each of the following pessary styles:

Milex® Shaatz Folding Pessaries
- Shaatz pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage I and Stage II prolapse, complicated by a mild cystocele.

Milex® Gellhorn Pessaries
- Gellhorn pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage III prolapse or procidentia.

Milex® Ring Folding Pessaries
- Milex Ring Pessary is indicated for use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women.

VI. Comparison of Indications for Use and Technological Characteristics with the Predicate Device

The subject Milex Pessary Devices have identical intended use, principles of operation, similar fundamental scientific technology and equivalent or identical Indications for Use with the legally marketed predicate device.

CooperSurgical Milex Pessaries are vaginal pessaries used to function as a supportive structure of the uterus, bladder and/or rectum. Similar to the identified predicate device, CooperSurgical Milex Pessaries are available in multiple shapes and sizes and are manufactured from liquid silicone.

Table 1. Indications for Use Comparison

Device	Indications for Use
Milex Pessaries	The CooperSurgical Milex pessaries are intended to provide support to pelvic organs when inserted in the vagina. The following Indications for Use are associated with each of the following pessary styles: • **Milex® Shaatz Folding Pessaries**: Shaatz pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage I and Stage II prolapse, complicated by a mild cystocele. • **Milex® Gellhorn Pessaries**:

	Gellhorn pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage III prolapse or procidentia. • **Milex® Ring Folding Pessaries**: Milex Ring Pessary is indicated for use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women.
Predicate Device (K993308)	A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse. The specific indications for use by pessary style is as follows: • Donut Pessary: Support of third degree prolapse, cystocele and rectocele. • Ring Pessary: Support of first or mild degree prolapse. Ring Pessary with support can also be used on an accompanying cystocele. • Dish Pessary: Control of stress urinary incontinence and minor degrees of prolapse. • Oval Pessary: Support of first or second degree prolapse and cystocyle. • Shaatz Pessary: Support of first or mild second degree prolapse and cystocele. • Mar-Land Pessary: Control of stress urinary incontinence and minor degrees of prolapse. • Hodge Pessary: Support of first to second degree prolapse, uterine retroversion or incompetent cervic, stress urinary incontinence. • Gehrung Pessary: Support of cystocele and rectocele, support of second to third degree prolapse. • Gellhorn Pessary: Support of second to third degree prolapse or procidentia. • Cube Pessary: Support of third degree prolapse, procidentia, cystocele, and rectocele. Fitting Set: Used to determine the proper size of pessary for each patient.

As shown in the table above, the subject Milex pessaries and the predicate device, Mentor EvaCare™ Vaginal Pessaries, cleared under K993308 share the same intended use: both are removable structures placed in the vagina to provide nonsurgical support to pelvic organs. This intended use is consistent across all pessary styles included in the subject device and aligns with the general use of vaginal pessaries included in the subject device, to manage conditions such as uterine prolapse, cystocele, rectocele, and stress urinary incontinence.

We identify reference device submissions (K231786, K132313) that describe additional pessary shapes and clinical indications similar to those in our submission, but not included in the predicate submission. These reference devices support that the inclusion of other shapes and the broader range of indications included in this CooperSurgical Milex® Pessaries submission do not represent a new intended use and that the bundled shapes and indications included in this submission are consistent with 510k cleared pessaries of the same type.

Therefore, there are no intended use concerns.

Table 2: Technological Characteristics Differences

Technological characteristic	Differences Compared to Predicates
Dimensions and sizing (Outer Diameters)	
Milex Shaatz Pessaries	1.50 in. (38 mm) – 3.75 in. (95 mm) The size range for the Milex Shaatz Pessaries is slightly larger than the identified predicate device. The CooperSurgical sizes do not raise different questions of safety or effectiveness.
Milex Gellhorn Pessaries	1.50 in. (38 mm) – 3.75 in. (95 mm) The size range for the Milex Gellhorn Pessaries is slightly larger than the identified predicate device. The CooperSurgical sizes do not raise different questions of safety or effectiveness.
Milex Ring Pessaries	1.75 in. (44 mm) – 4.25 in. (108 mm) The size range for the Milex Ring Pessaries is slightly larger than the identified predicate device. The CooperSurgical sizes do not raise different questions of safety or effectiveness.
Materials	The subject device is made of liquid silicone and colorant. The predicate device is also made of silicone and colorant, but silicone and additive formulations may differ. The differences do not raise different questions of safety and effectiveness.

VII. Performance Data

Evidence was submitted to support the following verification activities for the Milex Pessary Devices:

- Shelf Life of Device
- Cleaning and Use Life
- Engineering Rationale for additional sizes of Milex Pessaries
- Biocompatibility

Biocompatibility for the Milex Pessary Devices was performed in accordance with the 2023 FDA biocompatibility guidance Use of International Standard ISO 10993-1, "Biological evaluation of

medical devices - Part 1: Evaluation and testing within a risk management process" and the and testing performed by CooperSurgical is provided in Table 3.

Table 3: Summary of biological testing

Test Description	Results	ISO Standard
Cytotoxicity	Non-cytotoxic	10993-5:2009
Sensitization	Non-sensitizer	10993-10:2021
Irritation or Intracutaneous Reactivity	Non-Irritant	10993-23:2021

Test Description	Results	ISO Standard
Subacute/Subchronic Toxicity	Non-Subacute/Subchronic Toxic	10993-11:2017, and 10993-6:2016
Material Mediated Pyrogenicity	Non-Material Mediated Pyrogenic	10993-11:2017
Acute System Toxicity	Non-Acute Systemic Toxic	10993-11:2017
Genotoxicity	Non-Mutagenic/Non-Genotoxic	10993-3:2014, 10993-33:2015, 10993-11:2017
Implantation	Device induced no local response	10993-6:2016
Chronic Toxicity	Device induced no systemic toxicity	10993-6:2016, and 10993-11:2017

VIII. Conclusion

The subject and predicate device share the same intended use, fundamental scientific technology, principles of operation, and identical or similar Indications for Use. Differences in design sizes or materials between the subject and predicate device do not raise any new questions of safety and effectiveness. Based on the verification evidence activities provided in this pre-market notification application, the subject Milex Pessaries are substantially equivalent to the legally marketed predicate device.