January 20, 2026

Cooper Surgical
Timothy Good
Regulatory Affairs Supervisor
95 Corporate Dr.
Trumbull, Connecticut 06611

Re: K253698
Trade/Device Name: Milex™ Incontinence Dish Pessaries; Milex™ Incontinence Dish Pessaries with Support; Milex™ Cube Pessaries; Milex™ Cube Pessaries with Drainage Holes
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: HHW
Dated: November 20, 2025
Received: November 24, 2025

Dear Timothy Good:

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, the Food and Drug Administration (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,

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)*
K253698

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™ Incontinence Dish Pessaries and Incontinence Dish Pessaries with Support:

Incontinence dish 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.

Milex™ Cube Pessaries and Cube Pessaries with Drainage Holes:

Cube pessary is indicated for nonsurgical management of pelvic organ prolapse in Stage III prolapse including rectocele and/or cystocele.

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

CooperSurgical Milex™ Pessaries

I. Submitter Information

Company Name:	CooperSurgical Inc.
Company Address:	95 Corporate Drive Trumbull, CT 06611 Telephone: 203-601-5200
Contact Person:	Timothy Good Regulatory Affairs Supervisor
Date Prepared:	January 16, 2026

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)
EIS Vaginal Pessaries	EIS Corporation	K132313
Mentor Evacare Vaginal Pessaries	Mentor Corporation	K993308

Reference Device:

Name	Manufacturer	510(k)
CooperSurgical Milex™ Pessaries	CooperSurgical Inc.	K250438

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

IV. Device Description:

Milex™ Incontinence Dish Pessaries, Incontinence Dish Pessaries with Support, Cube Pessaries, and Cube Pessaries with Drainage Holes are intended for support to pelvic organs when inserted into the vagina. Milex™ Pessaries are made of silicone and distributed in a non-sterile condition. The Milex™ Pessaries are available in a variety of styles, each having a range of sizes. 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: Incontinence Dish Pessary (Dish without Support, Dish with Support) and Milex™ Cube Pessary (Cube without Drainage Holes, Cube with Drainage Holes).

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™ Incontinence Dish Pessaries and Incontinence Dish Pessaries with Support:
Incontinence dish 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.

Milex™ Cube Pessaries and Cube Pessaries with Drainage Holes:
Cube pessary is indicated for nonsurgical management of pelvic organ prolapse in Stage III prolapse including rectocele and/or cystocele.

VI. Comparison of 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 devices.

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 devices, 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™ Incontinence Dish Pessaries**: Incontinence dish 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 (K132313) EIS Vaginal Pessaries	EIS Vaginal Pessaries are indicated for the use as removable structures placed in the vagina to treat uterine prolapse, including cystocele and rectocele, as well as stress urinary incontinence in women.
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™ Cube Pessaries**: Cube pessary is indicated for nonsurgical management of pelvic organ prolapse in Stage III prolapse including rectocele and/or cystocele.
Predicate Device (K993308) Mentor EvaCare™ Vaginal Pessaries	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: • Cube Pessary: Support of third degree prolapse, procidentia, cystocele, and rectocele.

Reference Device (K250438)	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** o 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** o Gellhorn pessary is indicated for temporary, nonsurgical management of pelvic organ prolapse in Stage III prolapse or procidentia. **Milex® Ring Folding Pessaries** o 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.

As shown in the table above, the subject Milex™ pessaries and the predicate devices, EIS Vaginal Pessaries and Mentor EvaCare™ Vaginal Pessaries, cleared under K132313 and 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.

The reference device submission (K250438) describes pessary materials identical to those in this 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 Differences

Technological characteristic	Differences Compared to Predicates
Dimensions and sizing	
Milex™ Dish Pessaries	**Milex™** - 2.125 in. (55mm) – 3.375 in. (85mm)

	The size range for the Milex™ Dish Pessaries is within the dimensional envelope of the identified predicate device. The CooperSurgical sizes do not raise different questions of safety or effectiveness.
Milex™ Cube Pessaries	**Milex™** - 1.00 in. (25mm) – 2.25 in. (57mm) The size range for the Milex™ Cube Pessaries is within the dimensional envelope of 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 devices are 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/Use Life of Device
  - Accelerated aging testing was performed to support a 5-year use life for the subject device per ASTM F1980.
- Cleaning
  - The subject device is provided non-sterile and is intended as a single patient multiple use device. The patient labeling includes instructions for cleaning, which specify that the pessary should be washed using mild soap and warm water. These cleaning instructions are consistent with those cleared for the identified predicate devices and are identical to the instructions previously reviewed and cleared in K250438 for other Milex pessary devices.

- Biocompatibility
  - Biocompatibility for the Milex™ Pessary Devices was performed in accordance with 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 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

Test Description	Results	ISO Standard
Irritation or Intracutaneous Reactivity	Non-Irritant	10993-23:2023
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 devices 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 devices 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 devices.