

DEC 13 1999

**Mentor EvaCare™ Pessary
510(k) Notification
510(k) SUMMARY
Mentor EvaCare™ Vaginal Pessaries**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K993308

Contact Person: Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: (805) 879-6304
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Date Prepared: September 30, 1999

Device Name and Classification:

Proprietary Name: Mentor EvaCare™ Vaginal Pessaries
Common Name: Vaginal Pessary
Classification Name: Vaginal Pessary
Classification: Class II (21 CFR § 884.3575)
Product Code: 85 HHW

Manufacturer:

Mentor Urology
1615 West River Road North
Minneapolis, MN 55411

**Mentor EvaCare™ Pessary
510(k) Notification**

510(k) SUMMARY

Mentor EvaCare™ Vaginal Pessaries

Substantial Equivalence Claim:

Mentor EvaCare™ Vaginal Pessaries are substantially equivalent to pre-amendment devices and pessaries manufactured by:

- Milex Products, Inc.
K904026 Inflat-o-Ball

- DesChutes Medical Products, Inc.
K974117 Pelvx Donut, Pelvx Cube
K974116 Pelvx Incontinence Ring
K974115 Pelvx Ring, Pelvx Ring with Support

- Bioteque America, Inc.
K920747 Pessary Flexible Silicone Donut Ring
K920187 Flexible Silicone Gellhorn

Device Description:

Mentor EvaCare™ Vaginal Pessaries are manufactured from medical grade silicone elastomers and are available in the following styles:

- Cube Pessary
- Dish Pessary
- Gellhorn Pessary
- Ring Pessary
- Mar-Land Pessary
- Hodge Pessary
- Oval Pessary
- Gehrung Pessary
- Fitting Set
- Cube Pessary with Drainage
- Dish Pessary with Support
- Gellhorn Pessary with Drainage
- Ring Pessary with Support
- Mar-Land Pessary with Support
- Hodge Pessary with Support
- Shaatz Pessary
- Donut Pessary

Indications For Use:

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 are as follows:

Donut Pessary: Support of third degree prolapse, cystocele and rectocele.

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- 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 cystocele.
- 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 cervix, 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

Summary of Testing:

Mentor has previously performed biocompatibility testing on the pessary component materials.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Donna A. Crawford
Manager, Corporate Regulatory Affairs
MENTOR Corporation
201 Mentor Drive
Santa Barbara, CA 93111Re: K993308
Mentor EvaCare™ Vaginal Pessaries
Dated: October 25, 1999
Received: November 23, 1999
Regulatory Class: II
21 CFR 884.3575/Procode: 85 HHW

Dear Ms. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mentor EvaCare™ Pessary
510(k) Notification

510(k) Number (if known): K993308

Device Name: Mentor EvaCare™ Vaginal Pessary (various styles)

Indications For Use:

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.

Please refer to the attached page for a listing of indications for use for each pessary style.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993308/5cc

Prescription Use _____
(Per 21 CFR 801.109)

OR Over the Counter Use _____

(Optional Format 1-2-96)

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INDICATIONS FOR USE

- Donut Pessary:** Support of third degree prolapse, cystocele and rectocele.
- Ring Pessary:** Support of first or second degree prolapse. Ring with support can also be used on an accompanying cystocele.
- Dish Pessary:** Control of stress urinary incontinence and support of minor degrees of prolapse.
- Oval Pessary:** Support of first or second degree prolapse and accompanying cystocycle.
- Shaatz Pessary:** Support of first or second degree prolapse and accompanying cystocycle.
- Mar-Land Pessary:** Control of stress urinary incontinence and support of minor degrees of prolapse.
- Hodge Pessary:** Support of first to second degree prolapse, a cystocele, stress urinary incontinence and an incompetent cervix or uterine retroversion..
- Gehrung Pessary:** Support of cystocele and rectocele, as well as 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.