

510(k) Summary

As Required by 21 section 807.92 (c)

- 1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (770) 777- 4146
4-Fax: (678) 623- 3765
5-Contact Person: Jay Mansour
6-Date summary prepared: May 5th, 2003
7-Device Trade or Proprietary Name: MARINA MEDICAL SILICONE PESSARY
8-Device Common or usual name: PESSARY
9-Device Classification Name: VAGINAL PESSARY
10-Substantial Equivalency is claimed against the following device:
- Bioteque Vaginal pessary from BIOTEQUE AMERICA, INC., 510k # K013289

11-Description of the Device:

This device is made out of silicone, and it is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia. It is available with different sizes of the following models: CUBE (with and without drain), OVAL (with and without support), HODGE (with and without support), SHAATZ , GELLHORN (with and without drains), RING (with and without support), DONUT , GEHRUNG, DISH (with and without support), & MAR-LAND (with and without support).

All models with their dimensions are detailed within the labeling section of this submission.

12-Intended use of the device:

This device is made out of silicone, and it is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia.

CUBE: indicated for use for the support of a third-degree prolapse.

OVAL: indicated for use for the support of a first or mild second-degree prolapse.

HODGE: indicated for use for the support of a uterine retroversion.

SHAATZ: indicated for use for the support of a first or mild second-degree prolapse.

GELLHORN: indicated for use for the support of a third-degree prolapse or procidentia.

RING: indicated for use for the support of a first or mild second-degree prolapse.

DONUT: indicated for use for the support of a third-degree prolapse.

GEHRUNG: indicated for use for the support of cystocele or rectocele.

DISH: indicated for use for the control of stress urinary incontinence or a first or mild second-degree prolapse. It restores continence by applying gentle pressure to the urethra.

MAR-LAND: indicated for use for the control of stress urinary incontinence or a first or mild second-degree prolapse. It restores continence by applying gentle pressure to the urethra.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2003

Marina Medical Instruments, Inc.
% Mr. Jay Mansour
Managing Member
Mansour Consulting, LLC
1308 Morningside Park Dr.
ALPHARETTA GA 30022

Re: K031463
Trade/Device Name: Marina Medical Pessaries
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal pessary
Regulatory Class: II
Product Code: 85 HHW
Dated: September 29, 2003
Received: September 6, 2003

Dear Mr. Mansour:

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 (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. 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031463

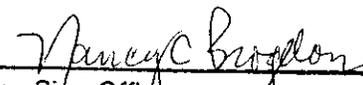
Device Name: MARINA MEDICAL PESSARIES

Indications for Use:

This device is made out of silicone, and it is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia. It is available with different sizes of the following models: **CUBE (with and without drain)**, **OVAL (with and without support)**, **HODGE (with and without support)**, **SHAATZ**, **GELLHORN (with and without drains)**, **RING (with and without support)**, **DONUT**, **GEHRUNG**, **DISH (with and without support)**, & **MAR-LAND (with and without support)**.

- CUBE: indicated for use for the support of a third-degree prolapse.
- OVAL: indicated for use for the support of a first or mild second-degree prolapse.
- HODGE: indicated for use for the support of a uterine retroversion.
- SHAATZ: indicated for use for the support of a first or mild second-degree prolapse.
- GELLHORN: indicated for use for the support of a third-degree prolapse or procidentia.
- RING: indicated for use for the support of a first or mild second-degree prolapse.
- DONUT: indicated for use for the support of a third-degree prolapse.
- GEHRUNG: indicated for use for the support of cystocele or rectocele.
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- MAR-LAND: indicated for use for the control of stress urinary incontinence or a first or mild second-degree prolapse. It restores continence by applying gentle pressure to the urethra.

Prescription Use _____ ✓



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K031463

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

Concurrence of CDRII, Office of Device Evaluation (ODE)