

# CDRH Consumer Information



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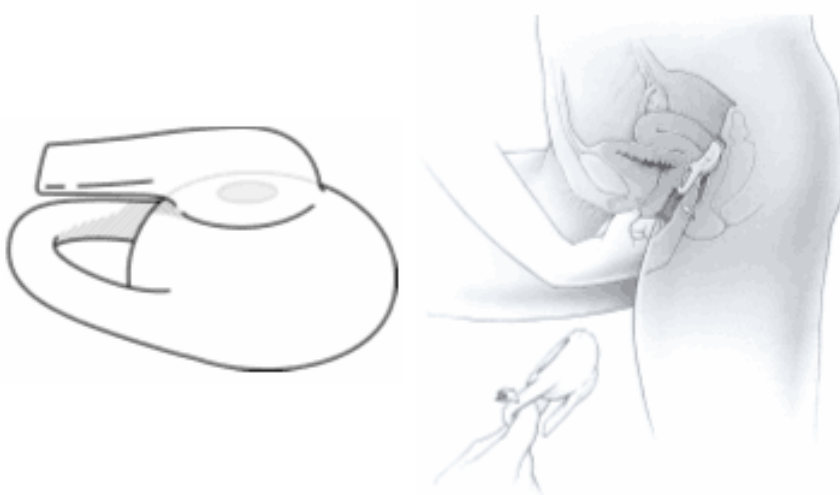
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## New Device Approval

### Lea's Shield® - P010043



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** Lea's Shield®, Vaginal Barrier Contraceptive Device

**Manufacturer:** Yama Inc.

**Address:** 67-61 E. Willow Street, Millburn, NJ 07041

**Approval Date:** March 14, 2002

**Approval Letter:** <http://www.fda.gov/cdrh/pdf/P010043a.pdf>

**What is it and when is it used?** The Lea's Shield® is a device for women of childbearing age who wish to prevent or postpone pregnancy. It is made of medical grade silicone and comes in only one size. The device is for one woman's personal use. It can be reused, but it must be washed between uses. It should remain in place at least 8 hours

after intercourse, but no longer than 48 hours total.

**How does it work?** The Lea's Shield® has a cup-shaped design intended to cover the cervix without actually being held by the cervix. It has a valve to place it in the vagina and a loop to remove it between uses. The thick lip of the device is designed to fill the area surrounding the cervix. By covering the cervix, the device prevents sperm from entering.

**What will it accomplish?** Based on a clinical effectiveness study of 90 women who used the device for six months, the estimated one-year failure rate (pregnancy) is approximately 15%. There are no serious side effects associated with use of this device for the user or her partner. The device is used with a spermicidal lubricant, however, that can cause vaginal irritation.

**When should it not be used?** This device should not be used if there is an infection in the vagina, cervix, or pelvic areas or if there are lacerations (tears) in the vagina or cervix.

**Additional information:** Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/P010043.html>

**Other:**

- Information on pregnancy prevention: <http://www.nlm.nih.gov/medlineplus/birthcontrolcontraception.html>
- Type "contraception" for a variety of related articles: <http://www.health.gov/healthypeople/healthfinder/>

Link updated 4/15/03

Updated 06/07/2002