

**Replens Vaginal Moisturizer (35g Tube) 510k:**

Idnr: 2.0 510k Summary  
Version: 2.2  
Date: August 13, 2010  
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**510(k) Summary**

AUG 17 2010

**Submitter:**

Lil' Drug Store Products, Inc.  
1201 Continental Place NE  
Cedar Rapids, IA 52402

**Contact Person:**

Tricia Miller  
Director of Regulatory  
Telephone: 319-294-3745  
Facsimile: 319-393-3494  
Email: [tmiller@lildrugstore.com](mailto:tmiller@lildrugstore.com)

**Date:**

August 13, 2010

**Proprietary Name:**

Replens Long-Lasting Vaginal Moisturizer (in 35g Tube with Reusable Applicator)

**Common name:**

Personal Lubricant

**Classification name:**

21 C.F.R. 884.5300 Lubricant, Patient, Vaginal, Latex Compatible  
Product Code: NUC  
Class: 2  
Review Panel: Obstetrics/Gynecology

**Predicate Devices:**

Device Name: CVS Personal Lubricant & Moisturizer  
510(k) Number: K062682  
Product Code: NUC, MMS

**Intended Use:**

Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible



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with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.

### Description of Device

Replens Vaginal Moisturizer is a non-sterile, water-based, white to off-white, non-irritating, non-greasy, non-staining vaginal gel delivered in a tube with a reusable applicator as a long-lasting moisturizer for vaginal dryness. The use of the reusable applicator provides less mess in application. Replens Vaginal Moisturizer is intended for ongoing use, not exclusively for use during intimate sexual activity.

Replens Vaginal Moisturizer contains ingredients commonly used in other products for vaginal use sold as medical devices and cosmetics. All ingredients are either NF, USP, or are considered "generally recognized as safe for their intended use". The quantitative formulation is considered confidential commercial information.

### Technological Characteristics of the Device

Replens Vaginal Moisturizer is substantially equivalent to the identified previously cleared vaginal lubricant predicate with respect to its design and materials, principle of operation, function, formulation, and intended use. It is also substantially equivalent to other water-based vaginal lubricants and personal lubricants being commercially marketed in the U.S.

### Summary of Performance Data

**Biocompatibility Testing:** The following biocompatibility testing has been performed on Replens Long-Lasting Vaginal Moisturizer:

- Cytotoxicity
- Acute Vaginal Irritation
- Subacute Vaginal Irritation
- Subacute Vaginal Irritation with Histological Examination
- Acute Systemic Toxicity
- Hypersensitivity
- Acute Oral Toxicity
- Acute Dermal Toxicity
- Dermal Irritation
- Eye Irritation.



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**Clinical Studies:** The following clinical studies have been performed on Replens Long-Lasting Vaginal Moisturizer:

- Bachmann GA, Notelovitz M, Gonzalez SJ, Thompson C, Morecraft BA. (1991) Vaginal Dryness in Menopausal Women: Clinical Characteristics and Nonhormonal Treatment. *Clinical Practice in Sexuality*, 7(9): 1-8.
- Bachmann GA, Notelovitz M, Kelly SJ, Owens A, Thompson C. (1992) Long Term Nonhormonal Treatment of Vaginal Dryness. *Clinical Practice in Sexuality*, 8(8/9): 3-8.
- Zinny MA, Lee S. (1991) Double-Blind Study of the Comparative Effects of Two Gels on Vaginal pH in Postmenopausal Women. *Today's Therapeutic Trends*, 8(4): 65-72.
- Young R, Goldzieher J, Kaufman R. (1991) A Study of the Effects of Col-1003 In Postmenopausal Women. Unpublished.
- Nakamura R. (1991) Evaluation of Col-1003 in the treatment of vaginal dryness in postmenopausal women. Unpublished.
- Whitehead M. (1991) A Randomised Double Blind Evaluation of Col-1003, a bioadhesive polymer system vaginal moisturizing gel and, KY Brand Lubricating Jelly in the treatment of vaginal dryness in postmenopausal women receiving concomitant oral hormone replacement therapy. Unpublished
- Nachtigall LE. (1994) Comparative study: Replens versus local estrogen in menopausal women. *Fertility and Sterility*, 61(1): 178-180.
- Gelfand MM, Wendman E. (1994) Treating Vaginal Dryness in Breast Cancer Patients: Results of Applying a Polycarbophil Moisturizing Gel. *J. Women's Health*, 3(6): 427-433.

The format of the studies listed above is summarized in the table below:

Citation	No. Patients Enrolled (Replens)	Study Design*	Dosage Regimen	Duration
Bachmann et al	89	D-B, X-over	2.5 g per day	5 days
Bachmann et al	54	Open	2.5 g, 3 x weekly	12 months
Zinny and Lee	26	D-B, parallel	2.5 g alternate nights	4 weeks
Young et al	30	Open	2.5 g, 3 x weekly, plus option of additional application prior to intercourse.	12 months
Nakamura	10	Open, X-over between treatment durations	2.5 g daily	1-5 days



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Citation	No. Patients Enrolled (Replens)	Study Design*	Dosage Regimen	Duration
Whitehead	32	D-B, X-over	2.5 g, 3 x weekly plus option of additional application prior to intercourse.	8 weeks
Nachtigall	15	Open, parallel	2.5 g, 3 x weekly	3 months
Gelfand and Wendman	25	Open	2.5 g, 3 x weekly, plus option of additional application prior to intercourse.	3 months

\* D-B = double-blind; X-over = cross-over design

The parameters employed in the studies included the influence of Replens on vaginal pH and the vaginal mucosa, the relief of the patient's symptoms, the vaginal dryness index, determination of vaginal pH at varying time intervals after single or multiple applications of the gel, PAP smears and the completion of diary cards by the patient. All of the studies concluded that Replens was safe and well-tolerated.

**Stability Data:** Real-time stability data confirms a shelf life of three (3) years for Replens Long-Lasting Vaginal Moisturizer.

**Preservative Effectiveness:** Replens Long-Lasting Vaginal Moisturizer has successfully passed the requirements of the USP <51> Antimicrobial Effectiveness Test.

**Condom Compatibility Testing:** Condom compatibility testing confirms that Replens Long-Lasting Vaginal Moisturizer does not materially affect the strength or integrity of natural rubber latex or synthetic condoms (polyurethane and polyisoprene).

### Conclusion

Based on the information presented in the 510(k) notice, it is concluded that Replens Long-Lasting Vaginal Moisturizer (in 35g Tube with Reusable Applicator) for OTC use is safe and effective for its proposed indications and is substantially equivalent in intended use, formulation, safety, and technological characteristics to the identified predicate device and other similar water-based personal lubricants.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Lil Drug Store Products, Inc.  
c/o Mr. Mark A. Job  
Responsible Third Party  
Regulatory Technology Services, Inc.  
1394 25<sup>th</sup> Street, NW  
BUFFALO MN 55313

AUG 17 2010

Re: K101098  
Trade/Device Name: Replens Long-Lasting Vaginal Moisturizer  
(in 35 Tube with Reusable Applicator)  
Regulation Number: 21 CFR §884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: July 30, 2010  
Received: August 2, 2010

Dear Mr. Job:

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. 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.

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

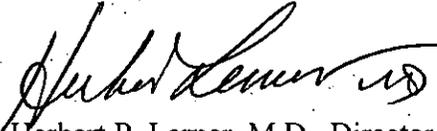
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Replens Vaginal Moisturizer (35g Tube) 510k**

K101098

Idnr: 1.0 Indications Statement  
Version: 2.1  
Date: May 12, 2010  
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**STATEMENT OF INDICATIONS FOR USE**

**510(k) Number:** K101098

**Device Name:** Replens Long-Lasting Vaginal Moisturizer (in 35g Tube with Reusable Applicator)

**Indications for Use:** Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use  X   
(Optional Format 1-2-96)

(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,  
and Radiological Devices

510(k) Number K101098