DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 24, 2017

Laclede, Inc.
Michael Pellico
President
2103 E. University Dr.
Rancho Dominguez, CA 90220

Re: K162235
Trade/Device Name: Luvena Vaginal Moisturizer and Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: February 21, 2017
Received: February 24, 2017

Dear Michael Pellico:

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 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K162235

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162235

Device Name
Luvena Vaginal Moisturizer and Lubricant

Indications for Use *(Describe)*
Luvena Vaginal Moisturizer and Lubricant 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 and polyisoprene condoms, but is not compatible with polyurethane condoms.

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.

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510 (k) Summary

Submission By: Laclede, Inc.
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Telephone: 310-605-4280
Facsimile: 310-605-4288

Contact Name: Michael A. Pellico, President
Email: mpellico@laclede.com

Date 510(k) Summary Prepared: March 23, 2017

Trade Name: Luvena Vaginal Moisturizer & Lubricant
Common Name: Personal Lubricant
Classification Name: Condom (21 C.F.R. 884.5300)
Classification: Class II
Product Code: NUC (lubricant, personal)

Primary Predicate Device:
Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant: K150841, Laclede, Inc. This predicate device has not been subject to any design related recall.

Device Description:
Luvena Vaginal Moisturizer & Lubricant is non-sterile, translucent, non-staining, non-greasy, aqueous-based, cranberry-flavored gel and is packed in EVA/PE copolymer plastic applicator tube. Each application tube is single-use. It is for personal vaginal use as need for moisturizing and lubrication during intimate sexual activity.

This device is not a contraceptive or spermicide, nor does it contain any such component. It is compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms as demonstrated in condom compatibility testing conducted according to ASTM D7661-10.

Device Specifications:
The device specifications for the Luvena Vaginal Moisturizer and Lubricant include appearance, odor, pH, viscosity, osmolality, Total Aerobic Microbial Count ((TAMC) (USP<61> and <1111>)), Total Yeast and Mold Count ((TYMC) (USP<61> and <1111>)), and absence of pathogenic organisms ((*Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans* (USP<62>)). These specifications were evaluated during the length of the proposed shelf life.

Intended Use:
Luvena Vaginal Moisturizer and Lubricant 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 and polyisoprene condoms, but is not compatible with polyurethane condoms.

Substantial Equivalence:
Luvena Vaginal Moisturizer & Lubricant have the same intended use as the predicate device. However, the subject moisturizer & lubricants and the predicate device have different technological characteristics – namely differences in viscosity, formulation and package type. These differences do not raise different questions of safety & effectiveness.

Features	**Luvena Vaginal Moisturizer & Lubricant**	**Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant K150841**	**Differences**
Water Based	Yes	Yes	Same, The subject and predicate device are water based
Water Soluble	Yes	Yes	Same, The subject and predicate device are soluble in water
Non Sterile	Yes	Yes	Same, The subject and predicate device are non-sterile.
Flavoring	Cranberry	Cranberry	Same, The subject and predicate device have same flavoring.
Container Type	Single use Applicator	Bottle with pump	The subject and predicate device are different size and shape for OTC packaging, but these differences have no impact on the safety or efficacy of the personal lubricant.
Condom compatibility	Yes ASTM D7661-10 Compatible with natural rubber latex and polyisoprene condoms, and not compatible with polyurethane condoms.	Yes ASTM D7661-10 Compatible with natural rubber latex and polyisoprene condoms, and not compatible with polyurethane condoms.	Same, The subject and predicate device have been tested for condom compatibility in accordance with ASTM D7661-10.
pH	Yes 3.8 – 4.8	Yes 3.8 – 4.8	Same, The subject and predicate device have same pH range.
Microbiological Examination of Non-sterile Products Testing	USP <61>/<62>	USP <61>/<62>	Same, The subject and predicate device have been tested for Microbial Limit test in accordance with USP <61> and <62> and have same specifications as recommended in USP<1111> for vaginal use

			products.
Body Location Target area	Vaginal application	Penile and/or Vaginal application	Same, Subject and predicate device are for Vaginal application.
Intended Use	Moisturize & Lubricate during sexual activity	Moisturize & Lubricate during sexual activity	Same, Subject and predicate device have same intended use.

Biocompatibility:
Biocompatibility of the final formulation of Luvena Vaginal Moisturizer & Lubricant was established through testing generally following ISO 10993, and includes cytotoxicity, sensitization, irritation, and acute systemic toxicity testing. The results demonstrate that the subject lubricant is biocompatible.

- Acute Systemic Toxicity: ISO 10993-11:2006
- Cytotoxicity: ISO 10993-5:2009
- Vaginal Irritation Testing: ISO 10993-10:2010
- Sensitization Testing - Guinea Pig Maximization Test (GPMT): ISO 10993-10:2010.

Physical & Other Testing:
The physical and other testing performed on Luvena Vaginal Moisturizer & Lubricant included an Antimicrobial Preservative Effectiveness Validation testing under USP <51> Category 2, Lubricant- Condom Compatibility testing per *ASTM D7661 - 10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms* and Shelf life testing. Luvena Vaginal Moisturizer and Lubricant passed the Antimicrobial Effectiveness test and were found to be compatible with natural rubber latex and polyisoprene condoms, but not compatible with polyurethane condoms. The results of accelerated time testing and real time testing according to ICH-Q1A (Stability testing of new drug substances and products) and ICH-Q1E (Evaluation of stability data) support the proposed shelf life for the subject lubricant.

Conclusion:
The subject and predicate device have the same intended use and the different technological characteristics do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.