DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 29, 2015

Laclede, Inc.
% Seth Mailhot
Attorney
Michael Best & Friedrich LLP
601 Pennsylvania Ave, NW, Suite 700
Washington, DC 20004

Re: K150841
Trade/Device Name: Luvena Enhanced Personal Moisturizer
Luvena Enhanced Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 30, 2015
Received: November 30, 2015

Dear Seth Mailhot,

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 yours,

Glenn B. Bell -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

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)*
K150841

Device Name
Luvena Enhanced Personal Moisturizer and
Luvena Enhanced Personal Lubricant

Indications for Use *(Describe)*
Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant is a personal lubricant, for penile and/or 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
K150841

Submitted by: Laclede, Inc.
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Date Submitted: November 10, 2015

Trade Name: Luvena Enhanced Personal Moisturizer and
Luvena Enhanced Personal Lubricant
Classification Name: Condom
Common Name: Personal Lubricant
Product Code /
Regulation: NUC (21 C.F.R. 884.5300)

Predicate Device: Aqua Lube Personal Lubricant: K110325, Mayer Laboratories, Inc.

Description: Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant are non-sterile, translucent, non-greasy, aqueous thick liquid intended for use as a personal lubricant. Luvena Enhanced Moisturizer and Luvena Enhanced Personal Lubricant are packed in a plastic bottle.

These devices are neither contraceptives nor spermicidals, nor do they contain any such component. They are compatible with latex and polyisoprene condoms and not compatible with polyurethane condoms as demonstrated in condom compatibility testing conducted according to the standards defined by ASTM D7661.

Product Specifications: The product specifications for the Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant include color/appearance, odor, pH, viscosity, osmolality, Total Aerobic Microbial Count (TAMC), Total Yeast and Mold Count (TYMC), absence of pathogenic organisms, and antimicrobial effectiveness.

Intended Use: Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant is a personal lubricant, for penile and/or 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 Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant have the same intended use as the predicate device. However, the subject lubricants and the predicate device have different technological characteristics – namely differences in formulation and specifications. The differences in technological characteristics do not raise different questions of safety and effectiveness.

Biocompatibility: Biocompatibility of the final formulation of Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant were established through testing generally following ISO 10993-1, and includes cytotoxicity, sensitization, irritation, and acute systemic toxicity testing. The results demonstrate that the subject lubricants are biocompatible.

Physical & Other Testing: The physical and other testing performed on Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal Lubricant included an Antimicrobial Preservative Effectiveness Validation testing under USP <51>, Lubricant-Condom Compatibility testing per ASTM D7661, and shelf life testing. Luvena Enhanced Personal Moisturizer and Luvena Enhanced Personal 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 real time testing support the proposed shelf life for the subject lubricants.

Conclusion: The subject lubricants are substantially equivalent to the proposed predicate device.