



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2017

Love Alchemy LLC
Eric Weiss
CEO
421 Kingsley Ave, #200
Orange Park, FL 32073

Re: K151857
Trade/Device Name: Love Alchemy's Love Lotion
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: December 20, 2016
Received: December 22, 2016

Dear Eric Weiss,

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,


Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K151857

Device Name

Love Alchemy's Love Lotion

Indications for Use (Describe)

Love Alchemy's Love Lotion 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 not for use with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) Summary

510(k) NUMBER: K151857

1. Owner Information

PRODUCT NAME: Love Alchemy's Love Lotion

OWNER: Love Alchemy, LLC ADDRESS:
421 Kingsley Ave. Suite 200
Orange Park, FL 32073

CONTACT NAME: Eric A. Weiss

TELEPHONE NUMBER: 904-612-3434

DATE PREPARED: January 9, 2017

2. Device Information

TRADE NAME: Love Alchemy's Love Lotion

COMMON NAME: Personal Lubricant

CLASSIFICATION NAME: Condom, 21 CFR 884.5300

PRODUCT CODE NUC (Lubricant, Personal)

DEVICE CLASS Class II

3. Predicate Device Information

PREDICATE NAME: Elegant Woman's Lubricant (K070587)

The predicate device has not been subject to a design related recall.

4. Description of Device

Love Alchemy's Love Lotion 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.

Love Lotion ingredients are Shea Butter, Coconut Oil, Grapeseed Oil, Lavender Oil, Orange Peel Oil, Jasmine Oil, Sandalwood Oil, Patchouli Oil and Ylang-Ylang Oil.

Device specifications are color, odor, appearance, viscosity, total aerobic microbial count, total yeast and mold count, absence of pathogenic microorganisms (*P. aeruginosa*, *S. aureus* and *C. albicans*) and antimicrobial effectiveness.

5. Indication for Use

Love Alchemy's Love Lotion 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 not for use with condoms.

The intended use of the subject device is similar to the predicate device.

6. Technological Characteristics of Device Compared to Predicate Devices

The subject and predicate device have different technological characteristics, including their formulation and specifications. These differences do not raise different questions of safety and effectiveness because these differences are routinely encountered during 510(k) reviews of personal lubricants.

7. Summary of Nonclinical Performance Testing

Below is the summary of the performance testing used to support substantial equivalence:

- *Condom Compatibility Testing* – The lubricant is not compatible with condoms.
- *Microbiological Testing* - Tested was performed in accordance with the following standards and passed.
 - USP <61> Microbiological Examination of Non-sterile Products: Microbial Enumeration
 - USP <62> Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms
 - USP <51> Antimicrobial Effectiveness Testing - category 2
- *Biocompatibility Testing* - Biocompatibility was evaluated in accordance with ISO 10993 - Biological Evaluation of Medical Devices. Tests for cytotoxicity, vaginal irritation, sensitization, and acute systemic toxicity were completed and passed.
 - Acute Systemic Toxicity: ISO 10993-11:2006
 - Cytotoxicity: ISO 10993-5:2009
 - Vaginal Irritation Testing: ISO 10993-10:2010
 - Guinea Pig Maximization Test (GPMT): ISO 10993-10:2010

- *Shelf life* - The shelf life of Love Alchemy's Love Lotion is 1 year. This is based on the results of real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life.

8. Conclusion

Based on the performance data, Love Alchemy's Love Lotion is substantially equivalent to the predicate device for safety and effectiveness.