



Food and Drug Administration
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February 5, 2016

The Kama Sutra Company
Louie Goryoka
Regulatory Consultant
5804 Rainbow Hill Rd.
Agoura Hills, CA 91301

Re: K152168
Trade/Device Name: Love Liquid Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: January 6, 2016
Received: January 8, 2016

Dear Louie Goryoka,

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)

K152168

Device Name

Love Liquid® Personal Lubricant

Indications for Use (Describe)

The Love Liquid® 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. It 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.

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

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510(K) SUMMARY
K152168
Love Liquid® Personal Lubricant

Company Name:	The Kama Sutra Company
Company Address:	2151 Anchor Court Thousand Oaks, California 91320
Contact Person:	Med-Device Consulting Inc. Louie Goryoka – Regulatory Consultant
Contact Numbers:	Phone 1 (818) 735-0488 mdci@m-dci.us
Summary Preparation Date:	February 3, 2016
Trade Name:	Love Liquid® Personal Lubricant
Common Name:	Personal Lubricant
Classification Name(s):	Condom
Product Code:	NUC (lubricant, Personal) 21 CFR § 884.5300 Class II
Predicate Devices	ONE Personal Lubricant
510 (k) Number:	K110691
Manufacturer:	ONE Personal Lubricant

Device Description

The Love Liquid® Personal Lubricant is a non-sterile; water based personal lubricant, an over-the-counter personal lubricant, formulated to be a clear, non-irritating, non-greasy, liquid and odorless, aqueous-based.

The proposed device contains a blend of ingredients similar to ingredients found in the predicate device. The device is designed to supplement the body's own natural lubrication fluids and is compatible for use with or without a latex condom during intimate sexual activity as evidenced by condom compatibility testing. The device formula is neither a contraceptive nor a spermicide.

Indication for Use Statement

The Love Liquid® 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. It is not compatible with polyurethane condoms.

Technological Characteristics

The technology involved in this product, Love Liquid® Personal Lubricant, has no exceptional technological characteristics.

The Love Liquid® Personal Lubricant contains mainly of ingredients that are substantially similar to other lubricants currently on the U.S. markets and substantially equivalent to the predicate device. All ingredients are either NF, USP, or are considered "generally recognized as safe for their intended use."

510(K) SUMMARY
K152168
Love Liquid® Personal Lubricant

Performance Data

Biocompatibility: The Love Liquid® Personal Lubricant is a mucosal membrane contacting device with limited contact duration (<24 hours) in accordance with ISO 10993-1:2009. Biocompatibility testing was performed in accordance with ISO 10993 standards. The results provided scientific evidence that this product is safe for its intended use.

Test Performed	Results
Cytotoxicity (Direct Contact)	Product is Non-toxic
ISO GUINEA PIG MAXIMIZATION SENSITIZATION TEST- (Method for Liquid Test Articles)	Product does not elicit a sensitization response
Vaginal Mucosa Irritation with Histopathology	Product is considered a non-irritant to vaginal tissue
Acute Systemic Toxicity	There is no evidence of system toxicity

Condom Compatibility: The testing was performed in accordance with ASTM D7661-10 (Air Burst and Tensile); “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms” on three marketed brands of Natural Rubber Latex condoms, one brand of Polyisoprene condoms, and one brand of Polyurethane condoms. The result showed that the product is compatible with natural rubber latex and Polyisoprene condoms and is not compatible with polyurethane condoms.

Microbiology: The Love Liquid® Personal Lubricant has passed the tests for Antimicrobial Effectiveness based on USP <51>, Total Microbial Count and Total Yeast and Mold Count based on USP <61>, and Absence of Pathogenic organism based on USP <62>.

Shelf-life: The real-time and accelerated shelf-life testing have been conducted on Love Liquid® Personal Lubricant. The results showed that the product maintained its appearance, color, odor, pH, osmolality, viscosity and microbiology specifications over a period of nine (9) months. Ongoing shelf-life testing will support extension of shelf-life to three years.

Conclusion

Laboratory and safety testing conducted on the product has provided scientific evidence that this product is safe for its intended use, and that it is substantially equivalent to predicate devices.