



Food and Drug Administration
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September 23, 2015

Uberlube, LLC
% John Ziobro
Principal Consultant
SpectraMedEx, LLC
117 West South Street
Oconomowoc, WI 53066

Re: K151647
Trade/Device Name: Überlube®
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 16, 2015
Received: June 25, 2015

Dear John Ziobro,

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)

K151647

Device Name

Überlube

Indications for Use (Describe)

Überlube 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. This product 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.

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

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**Überlube LLC®
Personal Lubricant
Traditional 510(k) Summary**

K151647

1. **Applicant Name:** Überlube LLC
2611 Hartzell St.
Evanston, IL 60201
Phone: 847-372-3127
Establishment Registration Number: pending
2. **Submission Correspondent:** On behalf of Überlube LLC, the following consultant is assigned the responsibility of submission correspondence:
John F. Ziobro
Principal Consultant
SpectraMedEx, LLC
117 W. South Street
Oconomowoc, WI 53066
262-719-8922
3. **Trade Name:** Überlube
4. **Common Name:** Personal Lubricant
5. **Description:** Überlube is a clear, colorless, semi-viscous silicone-based personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. The device is not compatible for use with polyurethane condoms. The device is a non-sterile lubricant designed to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is normally packaged in glass bottles with pump tops or in foil samples. It may also be packaged in stoppered glass vials or plastic bottles. The specifications for Überlube include appearance, odor, viscosity, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms.
6. **Classification Regulation, Class & Product Code & Panel:**
Regulation: 21 CFR 884.5300, Condom
Classification: Class II
Product Code: NUC
Panel: Obstetrics/Gynecology
7. **Reason for Traditional 510(k):**
New Device
8. **Predicate Device(s):** 510(k) Number: K132954
Manufacture: United Consortium
Trade Name: JO Premium Personal Lubricant
Product Code: NUC
Classification: Class II
9. **Summary Date:** May 15, 2015
10. **Indication for Use**
Überlube 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. This product is not compatible with polyurethane condoms.



**Überlube LLC®
Personal Lubricant
Traditional 510(k) Summary**

11. Comparison to Predicates

Überlube has the same intended use and technological characteristics as the predicate device.

12. Performance Data

Testing per ASTM D7661-10 indicated that Überlube is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

Biocompatibility testing per ISO 10993-1, including cytotoxicity, vaginal irritation, sensitization and systemic toxicity, demonstrate that Überlube is biocompatible.

Microbial limits testing conducted per USP <61> and USP <62> indicated microbial quality.

Real-time aging tests indicate a 3-year shelf life for the lubricant.

13. Conclusion

Überlube is substantially equivalent to the predicate device.