



Food and Drug Administration
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April 27, 2016

Trigg Laboratories D/B/A Wet International
Erica Loring
Vice President, Regulatory Affairs and Quality Assurance
28650 Braxton Avenue
Valencia, CA 91355

Re: K160211
Trade/Device Name: Wet Original[®] Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: January 25, 2016
Received: January 28, 2016

Dear Erica Loring,

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

Indications for Use

510(k) Number (if known)

K160211

Device Name

WET ORIGINAL® Personal Lubricant

Indications for Use (Describe)

The Trigg Laboratories WET ORIGINAL® 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, polyisoprene, and 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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510(k) SUMMARY

Submitter Information:

Date Prepared: April 27, 2016

Company Name: Trigg Laboratories Inc.

Company Address: 28650 Braxton Avenue
Valencia CA 91355

Company Phone: 1 (800) 248-4811

Company Facsimile: 1 (661) 775-3143

Contact Person: Erica Loring; Vice President, Regulatory & Quality
EricaL@trigglabs.com

Device Trade Name: **WET ORIGINAL® Personal Lubricant**

Common Name: Personal Lubricant

Classification Name(s): Condom

Classification Regulation: 21 CFR §884.5300, Class II

Device Product Code: NUC

Advisory Panel: Obstetrics and Gynecology

Predicate device:

K150480
JO H2O Water Based Personal
Lubricant
UNITED CONSORTIUM INC.
29000 Hancock Pkwy
Valencia, CA 91355

Indications for Use:

The Trigg Laboratories WET ORIGINAL® Personal Lubricant is 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, polyisoprene, and polyurethane condoms.

Device Description:

The WET ORIGINAL® Personal Lubricant is a non-sterile device. It is a water based personal lubricant, an over-the-counter personal lubricant, formulated to be a clear, non-irritating, non-greasy, gel-like, 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.

Ingredients of the device:

Ingredient	Function
Glycerin	Humectant
Water (Aqua)	Solvent
Pentylene Glycol	Preservative
Potassium Sorbate	Preservative
Sodium Carboxymethylcellulose	Thickener

Technological Characteristics:

The technology involved in this product (WET ORIGINAL® Personal Lubricant) has no exceptional technological characteristics. The WET ORIGINAL® contains similar ingredients to other lubricants currently on the U.S. market.

This product is designed and packaged in a convenient low density polyethylene (LDPE) tube with a disk top cap, and peel seal.

Bench testing indicated that the lubricant has an appropriate viscosity, specific gravity, appearance, color and odor for substantial equivalence to the predicate. USP testing for Total Aerobic Microbial Counts, Total Yeast and mold Counts; absence of microbial pathogens, and antimicrobial effectiveness indicated microbial quality.

Summary of Performance Data:

Biocompatibility studies and condom compatibility were conducted on the WET ORIGINAL® by an outside laboratory, in compliance with Good Laboratory Practices (GLPs). The subject device was evaluated for Biocompatibility according to the following FDA recognized ISO 10993 standards:

- Cytotoxicity per ISO 10993-5:2009
- Guinea Pig Maximization Sensitization per ISO 10993-10:2010
- Vaginal Irritation per ISO 10993-10:2010
- Systemic Toxicity per to ISO 10993-11:2006 (2010)

The results of testing demonstrated that this formula meets acceptance requirements for all tests.

Bench testing indicated that the WET ORIGINAL® Personal Lubricant meets its specifications (i.e. pH, viscosity, specific gravity, osmolality, color and odor) for substantial equivalence to the predicate. USP testing for total aerobic microbial count, total yeast and mold counts; absence of pathogenic organisms, and antimicrobial effectiveness indicated microbial quality.

Condom Compatibility:

Compatibility 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 results demonstrated that the condom compatibility testing of the lubricant is compatible with commercially available male condoms made from natural rubber latex, polyurethane, and polyisoprene materials.

Shelf Life Testing:

The WET ORIGINAL® Personal Lubricant has a two-year shelf life based on the results of a real-time aging study.

Conclusion:

The WET ORIGINAL® Personal Lubricant is substantially equivalent to its proposed predicate device.