510(k) Summary
K130012

TRIGG LABORATORIES, INC.
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**Submitted by:** Trigg Laboratories Inc.
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**Date Prepared:** August 19, 2013

**Propriety Name:** Wet Platinum Premium Lubricant®

**Proposed Trade Name:** Wet Platinum Premium Lubricant®

**Common Name:** Personal Lubricant

AUG 2 2 2013

**Classification Name:** Condom
21 CFR §884.5300 Class II
NUC

**Predicate Devices:** One Silicone Personal Lubricant
ONE
510(k) No.: K110690

and

K-Y® Brand Intrigue
Personal Products Co.
510(k) No.: K062796.

**Device Description:** The Wet Platinum Premium Lubricant® is a non-sterile, silicone based personal lubricant, an over-the-counter personal lubricant, formulated to be clear, non-irritating, non-greasy natural and odorless. It is a Silicone soluble, gel-like liquid for use as a personal lubricant. The Wet Platinum Premium Lubricant® contains a blend of silicone fluid ingredients similar to ingredients found in the predicate device.

The specifications for Wet Platinum include appearance, odor, viscosity, specific gravity, total aerobic microbial count, total yeast and mold count, absence of pathogenic organisms (Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Escherichia coli, Salmonella, and Clostrida), and antimicrobial effectiveness. Osmolality and pH are not applicable specifications because the subject lubricant is anhydrous.

**Intended Use:** Wet Platinum Premium Lubricant Personal Lubricant is non-sterile, an over-the-counter personal lubricant.

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**Indications For Use:** The Trigg Laboratories Wet Platinum Premium 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.

The Wet Platinum Premium Lubricant® and the predicate devices have the same Indications for Use Statement.

**Technological Characteristics:** The Wet Platinum Premium Lubricant® consists mainly of silicone based personal lubricants, contains a blend of silicone fluid ingredients similar to other lubricants currently on the U.S. markets and substantially equivalent to the predicate devices.

Wet Platinum Premium Lubricant® formula is neither a contraceptive nor a spermicide.

**BIOCOMPATIBILITY:** Biocompatibility testing was performed in accordance with ISO 10993-1 and other standards.

| Test Performed | Results |
|---|---|
| Cytotoxicity (MEM Elution Test) | Product is Non-toxic |
| ISO GUINEA PIG MAXIMIZATION SENSITIZATION TEST- (Method for Liquid Test Articles) | Product does not elicit a sensitization response |
| Vaginal Irritation and Systemic Toxicity Following Once Daily Application for Ten Consecutive Days | Product produced no macroscopic or microscopic evidence of acute systemic toxicity and it is considered a non-irritant. |

**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, two brands of Polyisoprene condoms, and one brand of Polyurethane condoms.

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

**Shelf Life Testing:** The Wet Platinum Premium Lubricant® has a one-year shelf life based on the results of an accelerated aging study.

Real-time aging studies continue to extend period to 3 years.

**Conclusion:** The performance data demonstrate that the Wet Platinum Premium Lubricant® is substantially equivalent to its proposed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Trigg Laboratories, Inc.
% Ernie Johnson
Vice President, Operations
28650 Braxton Avenue
Valencia, CA 91355

Re: K130012
Trade/Device Name: Wet Platinum Premium Lubricant®
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: July 12, 2013
Received: July 23, 2013

Dear Ernie Johnson:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -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:** **K130012**

**Device Name:** Wet Platinum Premium Lubricant®

**Indications for Use:**

"The Trigg Laboratories Wet Platinum Premium 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."

**Prescription Use** _____ **AND/OR** **Over-The-Counter Use** __X_____
**(21 CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED**

_____ _____ _____ _____ _____

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130012