



Food and Drug Administration
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July 20, 2015

Charles & Dwight Co., Inc.
Lisa Burns
Senior Regulatory Affairs Specialist
500 Charles Ewing Blvd.
Ewing, NJ 08628

Re: K150886
Trade/Device Name: Trojan Riviera Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 22, 2015
Received: June 23, 2015

Dear Lisa Burns,

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,


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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K150886

Device Name
Trojan Riviera Personal Lubricant

Indications for Use (Describe)

Trojan Riviera Personal Lubricant is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other 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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II. 510(k) Summary
Trojan™ Riviera™ Personal Lubricant

Submitter Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard
Ewing, NJ 08628

Contact Person: Lisa Burns
Senior Regulatory Affairs Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543
Tel: (609) 806.1997
Fax: (609) 403.7411

Date Prepared: March 31, 2015

Device Trade Name: Trojan™ Riviera™ Personal Lubricant

Device Common Name: Personal Lubricant

Product Code: NUC – Condom (21 CFR § 884.5300)

Classification: Class II

Predicate Device: Trojan™ Tingly Warmth Personal Lubricant (K120706)

Intended Use: A personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane or other condoms.

Device Description:

The Trojan™ Riviera™ Personal Lubricant is an anhydrous, clear silicone-based personal lubricant with fragrance that is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane or other condoms. This product is not a spermicide or contraceptive.

The Riviera™ Personal Lubricant is packaged in a polyethylene terephthalate (PET) bottle with a screw on, flip top polypropylene (PP) closure. An induction seal will be placed over the bottle for tamper resistance. One bottle is packaged in a carton.

Technological Characteristics:

There is no difference in the fundamental technological characteristics of Riviera™ Personal Lubricant and the predicate Trojan™ Tingly Warmth Personal Lubricant (K120706). The 510(k)-subject device contains a similar silicone base as the legally marketed predicate, and the addition of fragrance does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed on the final 510(k)-subject device in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Test Performed	Results
Cytotoxicity	Mild Reactivity (Grade 2)
Acute Systemic Toxicity	Non-systemically toxic
Primary Rabbit Skin Irritation	Negligible irritant
Rabbit Vaginal Irritation	Non-irritant
Rabbit Penile Irritation	Non-irritant
Guinea Pig Maximum Sensitization	Non-sensitizer

Condom compatibility:

Condom Compatibility Testing was performed with Riviera™ Personal Lubricant according to ASTM D7761-10 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms” with a modification to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of natural rubber latex condoms and two brands of polyisoprene condoms were tested. Condoms made from polyisoprene were included to represent an alternative to natural rubber latex that may be used with the 510(k)-subject lubricant.

Condom compatibility testing demonstrates that Riviera™ Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms.

Shelf Life:

Riviera™ Personal Lubricant has a two year shelf-life based on the results of an accelerated stability study. Evaluation of viscosity, odor, color and appearance was conducted. Microbial evaluation was conducted via USP testing for Total Microbial Count, Total Yeast and Mold count, and Absence of Pathogens. The results were satisfactory for all parameters.

A real-time stability study is being performed in order to verify results.

Substantial Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, Riviera™ Personal Lubricant is substantially equivalent to the predicate device, Trojan™ Tingly Warmth Personal Lubricant in technology, intended use, safety and effectiveness.