K120706

October 2, 2012
(revised)

II. 510(k) Summary

OCT 4 2012

Submitter Name: Submitter Address:	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Emily Perez Regulatory Affairs Specialist Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 688-5347 Fax: (609) 497-7179
Date Prepared:	October 2, 2012
Device Trade Name:	TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Tingly Warmth 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.
Device Description:	The TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, menthol, and vanillyl butyl ether. TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

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Technological Characteristics:

There is no difference in the fundamental technological characteristics of the TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant is composed of dimethicone, dimethiconol, menthol, and vanillyl butyl ether. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol and vanillyl butyl ether, in TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant are identical to those in the predicate device. The additional ingredient, menthol, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed using TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant and ASTM D7761-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that the TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

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Shelf-life:

TROJAN™ LUBRICANTS Tingly Warmth Personal Lubricant has a two-year shelf-life based on the results of an accelerated aging study.

A Real-time aging study is being performed in order to verify results of the accelerated aging study.

Substantial Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluations of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Emily Perez
Regulatory Affairs Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543

OCT - 4 2012

Re: K120706
Trade/Device Name: TROJAN™ LUBRICANTS TINGLY WARMTH Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 29, 2012
Received: August 31, 2012

Dear Ms. Perez:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

I. Indications For Use

510(k) Number (if known): K120706

Device Name: TROJAN™ LUBRICANTS TINGLY WARMTH Personal Lubricant

INDICATIONS FOR USE:

TINGLY WARMTH 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use __X__
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120706