DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 31, 2016

Church & Dwight Co., Inc.
Lisa Burns
Regulatory Affairs Manager
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K161544
Trade/Device Name: Trojan™ Chain Reaction™ Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 2, 2016
Received: June 3, 2016

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,

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

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)*
K161544

Device Name
Trojan™ Chain Reaction™ Personal Lubricant

Indications for Use *(Describe)*
Trojan™ Chain Reaction™ 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.

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510(k) Summary - K161544

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	500 Charles Ewing Boulevard Ewing, NJ 08628
Contact Person:	Lisa Burns Manager, Regulatory Affairs Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 806.1997 Fax: (609) 403.7411
Date Prepared:	August 30, 2016
Device Trade Name:	Trojan™ Chain Reaction™ Personal Lubricant
Device Common Name:	Personal Lubricant
Classification Name:	Condom (21 CFR § 884.5300)
Product Code:	NUC (lubricant, personal)
Classification:	Class II
Predicate Device:	Trojan™ Tingly Warmth Personal Lubricant (K120706), Church & Dwight Co., Inc.
Indications for Use:	Trojan™ Chain Reaction™ 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.

Device Description:

The Trojan™ Chain Reaction™ Personal Lubricant is a non-sterile anhydrous, clear silicone-based (Dimethicone, Dimethiconol) personal lubricant with sensate 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 specifications for the subject lubricant include the following:

- Appearance
- Odor
- Viscosity
- Total microbial count (total aerobic microbial count (TAMC) < 100 cfu/g per USP <61> and <1111>)
- Fungal/yeast/mold limits (total combined yeast and mold count (TYMC) < 10 cfu/g per USP <61> and <1111>)
- Absence of pathogenic organisms (Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans per USP <62>)

The Chain Reaction™ 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 packed in a carton.

Intended Use Comparison:

The subject and predicate device have identical indications for use - 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. Therefore, the intended use of the subject and predicate device are the same.

Technological Characteristics Comparison:

The following table compares the key technological characteristics of the subject and predicate device:

Device & Predicate Device(s):	**K161544**	**K120706**
Condom Compatibility	Natural rubber latex and polyisoprene	Natural rubber latex and polyisoprene
Base Type	Silicone	Silicone
Primary Ingredients	Dimethicone Dimethiconol Sensate	Dimethicone Dimethiconol Sensate
Biocompatible	yes	yes
Appearance	Clear and colorless	Viscous liquid, clear
Odor	Characteristic odor – no malodor	Menthol
Viscosity	400 – 800 cps	528 – 566 cp
Total Microbial Count	<100 cfu/g	<100 cfu/g

Fungal/Yeast/Mold Limits	<10 cfu/g	<10 cfu/g
Absence of Pathogenic Organisms	absent	absent
Sterility	Non-sterile	Non-sterile
Shelf-life	2 years	2 years

The subject and predicate device have different technological characteristics, including different formulation and specifications. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions. All personal lubricants must independently demonstrate they are biocompatible, compatible with condoms, and can maintain their specifications for their expected shelf life.

Biocompatibility:

Biocompatibility testing was performed on the final 510(k)-subject device in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009. The subject lubricant is biocompatible based on the results of the following biocompatibility studies:

Test Performed	**Standard**
Cytotoxicity	ISO 10993-5:2009
Acute Systemic Toxicity	ISO 10993-11:2006
Primary Rabbit Skin Irritation	ISO 10993-10:2010
Rabbit Vaginal Irritation	ISO 10993-10:2010
Rabbit Penile Irritation	ISO 10993-10:2010
Guinea Pig Maximum Sensitization	ISO 10993-10:2010

Condom compatibility:

Condom Compatibility Testing was performed with Chain Reaction™ 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 Chain Reaction™ Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms.

Shelf Life:

Chain Reaction™ Personal Lubricant has a two year (24 month) 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 (USP <61> and <1111>, Total Yeast and Mold count (USP <61> and <1111>), and Absence of Pathogens (USP <62>). The results were satisfactory for all parameters.

Substantial Equivalence:

The subject device is substantially equivalent to the predicate device. Both the subject and predicate device have identical intended uses and comparable technological characteristics. In addition, non-clinical performance data, biocompatibility testing, and shelf life testing further demonstrate that the subject device is substantially equivalent to the predicate device.