August 1, 2018

Church & Dwight Co., Inc.
Joelle Reinson
Senior Regulatory Affairs Specialist
500 Charles Ewing Blvd.
Ewing, NJ 08628

Re: K180764
Trade/Device Name: Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 27, 2018
Received: June 28, 2018

Dear Joelle Reinson:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -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)*

K180764

Device Name

Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)

Indications for Use *(Describe)*

Trojan™ Azul Personal Lubricant (H2O Sensitive Touch 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. This product is not compatible with 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 Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard
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Phone: 609-806 1200

Contact Person: Joelle Reinson
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Date Prepared: July 31, 2018

Device Trade Name: Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)
Device Common Name: Personal Lubricant
Product Code: NUC (lubricant, personal)
Classification: Class II, Condom (21 CFR § 884.5300)

Predicate Device: K141034: TROJAN™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant)

The predicate device has not been subject to a design related recall.

Description of Device:
The Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant) is a hydrous, clear water-based personal lubricant with aloe and vitamin E that is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is a clear, colorless viscous gel. The lubricant formula is thickened using sodium hyaluronate and hydroxyethylcellulose. It contains a pH buffer system to maintain a slightly acidic pH of 5.9 to 6.9, and is preserved using Symocide pH (Phenoxyethanol, Hydroxyacetophenone, Caprylyl Glycol, and Water).

The Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant) may be packaged in two (2) types of polyethylene terephthalate (PET) bottles. One bottle (PET), 5.5 fl. oz. with a screw on, flip-top polypropylene (PP) closure. An induction seal will be placed over the bottle. The second bottle (PET), 4.5 fl. oz., will be the same bottle material with a pump in the bottle. The pump and nozzle will be made of the same material as the flip-top cap (PP). The pump bottle will have a shrink band over the pump.

The following parameters are included as part of the device specifications:

- Appearance
- Color
- Odor
- pH
- Viscosity
- SymOcide pH Assay
- Osmolality
- Antimicrobial effectiveness
- Total Aerobic Microbial Count (TAMC)
- Total Yeast and Mold Count (TYMC)
- Absence of Pathogenic Organisms (at minimum Pseudomonas aeruginosa, Staphylococcus aureus, and Candida albicans)

Device & Predicate Device(s):	K180764	K141034
Indication for Use	Trojan Azul personal lubricant (H2O sensitive touch personal lubricant) is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, to enhance to 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. This product is not compatible with polyurethane condoms.	Azul personal lubricant is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, to enhance to 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. This product is not compatible with polyurethane condoms.
General Device Characteristics		
Sponsor	Church & Dwight Co., Inc.	Church & Dwight Co., Inc.
Regulation Number Product Code Device Class	884.5300 NUC II	884.5300 NUC II
Condom Compatibility	NRL and polyisoprene	NRL and polyisoprene

Base Type	Water	Water
Primary Ingredients	Deionized Water	Deionized Water
	Glycerin, USP	Glycerin, USP
	Symocide pH (Phenoxyethanol, Hydroxyacetophenone, Caprylyl Glycol, Water)	Methylparaben, NF
	Hydroxyethyl-Cellulose	Hydroxyethyl Cellulose (Natrosol 250 HX PHARM)
	Sodium Hyaluronate	Sodium Hyaluronate
	Sodium Citrate, USP	Sodium Citrate, USP
	Sodium Chloride, USP	Sodium Chloride, USP
	Citric Acid, USP	Citric Acid, USP
	Sodium Hydroxide	Sodium Hydroxide
	Vitamin E TPGS (Tocophersolan)	Vitamin E TPGS
	Veragel 200 Standardized (Aloe Barbadensis Leaf Extract)	Aloe
Appearance	Clear Gel	Clear Gel
Color	Clear and colorless	Clear and colorless
Odor	Characteristic odor	Characteristic odor
pH	5.9-6.9	5.9-6.9
Viscosity	1500-7500	1500-7500
Osmolality	250 – 550 (S001)	
Antimicrobial effectiveness	Meets Requirement	Meets Requirement
TAMC	< 100 cfu/g	< 100 cfu/g
TYMC	<10 cfu/g	<10 cfu/g
Absence of pathogenic organisms	Absent	Absent

The indication for use statement of the subject device is identical to that of the predicate device.

The only difference in the technological characteristics between the subject and predicate device is the inclusion of Symocide instead of Methylparaben. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions as compared to the predicate device. These differences can be address through non-clinical testing.

Performance Data:
The performance testing results are summarized below.

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

Test Performed	**Standard**
Cytotoxicity with Agarose Overlay	ISO 10993-5
Rabbit Vaginal Irritation Study	ISO 10993-10
Acute Systemic Toxicity Study	ISO 10993-11
Guinea Pig Maximization Sensitization Study	ISO 10993-10

Condom Compatibility:
The results for laboratory testing used a modification of the methodology found in ASTM D7661; Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Laboratory test results demonstrated that the proposed device is compatible with leading commercial brands of natural rubber latex and polyisoprene condoms, but not compatible with polyurethane condoms.

Shelf Life:
The Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant) has a validated shelf life based on results of an accelerated aging stability study. Evaluation of Odor, Color, Viscosity, Osmolality, and pH was conducted. Microbial evaluation was conducted via USP testing and results were met for all parameters

Substantial Equivalence:
Based on the results of performance testing, the Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant) is substantially equivalent to the predicate device, Trojan™ Azul Personal Lubricant (H2O Sensitive Touch Personal Lubricant), K141034.