DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 26, 2016

Church & Dwight Co., Inc.
Lisa Burns
Manager, Regulatory Affairs
500 Charles Ewing Blvd
Ewing, New Jersey 08628

Re: K161545
Trade/Device Name: Trojan™ XOXO™ Thin Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: HIS
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,

Joyce M. Whang -S

for Benjamin 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)*
K161545

Device Name
Trojan(TM) XOXO(TM) Thin Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant

Indications for Use *(Describe)*
The Trojan XOXO Thin condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

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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II. 510(k) Summary – K161545

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	500 Charles Ewing Boulevard Ewing, NJ 08628
Contact Person:	Lisa Burns Regulatory Affairs Manager Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 806.1997 Fax: (609) 403.7411
Date Prepared:	June 2, 2016
Device Trade Name:	Trojan™ XOXO™ Thin Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant
Device Common Name:	Natural Rubber Latex Condom with Lubricant
Product Code:	HIS – Condom (21 CFR § 884.5300)
Classification:	Class II
Predicate Device: (K912901)	Trojan™ (TM-TBD) Latex Condom with Lubricant [Secondary Brand name HER PLEASURE™ added when introduced on market]
Indications for Use:	The Trojan XOXO Thin condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Device Description:

The Trojan™ XOXO™ Thin Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant [Trojan™ XOXO™ Thin condom] is a natural rubber latex sheath, which completely covers the penis with a fitted membrane. A silicone base lubricant containing Aloe Vera OE is applied directly to the condom. The condom is a straight wall nipple end shape consistent with ASTM D3492-08

Standard Specifications for Rubber Contraceptives (Male condom). The Trojan™ XOXO™ Thin condom has a nominal length of 180 ± 10 mm, a nominal thickness of 0.07 ± 0.01 mm, and a nominal flat- width of 52 ±2 mm, measured 30 mm from the open end.

The Trojan™ XOXO™ Thin condom is packaged in a primary foil. Multiple individually foiled condoms may be packaged in a carton.

Technological Characteristics:

The Trojan™ XOXO™ Thin condom is a straight wall nipple end condom with lubricant. The predicate and 510(k) subject device are both smooth walled with similar dimensions and contain a silicone based lubricant. The Trojan™ XOXO™ Thin condom is made from a pre-vulcanized natural rubber latex. The purpose and technological function of the pre-vulcanized natural rubber latex in the latex condom formulation is the same as the current natural rubber latex. The Trojan™ XOXO™ Thin condom has an additional ingredient to the silicone based lubricant versus the plain silicone lubricant on the predicate device. This difference does not raise different questions of safety or effectiveness as all condoms must demonstrate biocompatibility and physical testing.

Biocompatibility:

Biocompatibility testing was performed to evaluate the biocompatibility of the Trojan™ XOXO™ Thin condom in accordance with ISO 10993-1, Biological Evaluation of Medical Devices, 2009 and the device is considered safe for consumers based on the results of the biocompatibility testing.

Test Performed	ISO Standard
Cytotoxicity ISO Elution Method	ISO 10993-5
Acute Systemic Toxicity	ISO 10993-11
Primary Rabbit Skin Irritation	ISO 10993-10
Rabbit Vaginal Irritation	ISO 10993-10
Rabbit Penile Irritation	ISO 10993-10
Guinea Pig Maximum Sensitization	ISO 10993-10

Physical Testing:

Three (3) lots of Trojan™ XOXO™ Thin condom were tested and met specifications of ASTM D3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms).

Shelf Life:

The Trojan™ XOXO™ Thin condom has a three year (36 month) shelf-life based on the results of an accelerated stability study protocol created with reference to 21 CFR 801.435. Five year (60 month) expiration dating will be verified with real-time stability according to 21 CFR 801.435.

Substantial Equivalence:

The Trojan™ XOXO™ Thin Condom has the same intended use as the predicate device. Based on performance data and biocompatibility review and testing and safety data, Trojan™ XOXO™ Thin Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant is substantially equivalent to the predicate device in technology, intended use, safety and effectiveness.