DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 9, 2016

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

Re: K161915
Trade/Device Name: Trojan™ XOXO™ Intense Ribbed 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: July 11, 2016
Received: July 12, 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,

For Division

Douglas Silverstein -S
2016.09.09 16:17:20 -04'00'

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)*
K161915

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

Indications for Use *(Describe)*
The Trojan XOXO Intense Ribbed Male Natural Rubber Latex Condom with Silicone and Aloe Vera OE Lubricant 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.

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II. 510(k) Summary
K161915

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:	September 9, 2016
Device Trade Name:	Trojan™ XOXO™ Intense Ribbed 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:	Trojan™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant

Device Description:

The Trojan™ XOXO™ Intense Ribbed Natural Rubber Latex Male Condom with Silicone and Aloe Vera OE Lubricant [Trojan™ XOXO™ Intense Ribbed 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 bulbous reservoir end shape and relies on ASTM D3492-08 Standard Specifications for Rubber Contraceptives (Male condom) and ISO 4074:2002 Natural Rubber Latex Condoms – Requirements and test methods. The condom has ribs on the shaft and bulb. The Trojan™ XOXO™ Intense Ribbed condom has a nominal length of 185 ± 10 mm, a nominal thickness 0.09 ± .01mm, nominal flat-width of 54 ± 2 mm measured 30 mm from the open end and 65±2 mm bulb flat width.

The Trojan™ XOXO™ Intense Ribbed condom is individually packaged into a foil container. Multiple individually foiled condoms may be packaged in a carton.

Indications for Use:

The Trojan XOXO Intense Ribbed Natural Rubber Latex Male Condom with Silicone and Aloe Vera OE Lubricant is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Technological Characteristics:

The Trojan™ XOXO™ Intense Ribbed condom has a bulbous reservoir end shape designed with 11 rows of continuous ribs on its shank and 9 rows of continuous ribs on its bulb. The Trojan™ XOXO™ Intense Ribbed 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 use in the predicate device. The Trojan™ XOXO™ Intense Ribbed condom has a silicone base lubricant with Aloe Vera OE.

Substantial Equivalence Discussion:

Characteristic	**NEW DEVICE: K161915**	**PREDICATE DEVICE: K131887**
Indications for Use	For contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).	Same
Device Composition	Pre-vulcanized Natural Rubber Latex and stabilizing additives	Natural Rubber Latex, vulcanizing additives and stabilizing additives
Lubricant	Silicone with Aloe	Glycol with sensate
Shape	Bulbous reservoir end with ribs	Same
Nominal Length	185 ± 10mm	Same
Nominal Flat Width	54 ± 2mm	Same
Bulb Flat Width	65 mm	Same
Thickness	0.09 ± .01mm	0.061 ± .01mm

The indication for use for the Trojan™ XOXO™ Intense Ribbed condom and predicate device are the same; therefore, they have the same intended use.

Although there are differences in the thickness, lubricant, and latex formulations, these differences do not raise different questions of safety and effectiveness as compared to the predicate device.

Biocompatibility:

Biocompatibility testing was performed to evaluate the biocompatibility of the Trojan™ XOXO™ Intense Ribbed condom in accordance with ISO 10993-1, Biological Evaluation of Medical Devices – Part 1(2009). The device passed each biocompatibility test identified below:

Test Performed	ISO Standard
Cytotoxicity ISO Elution Method	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)

Physical Testing:

Three (3) lots of Trojan™ XOXO™ Intense Ribbed condom were tested and met specifications of ASTM D3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms) and ISO 4074: Natural Rubber Latex Condoms Requirements and Test Methods.

Shelf Life:

The Trojan™ XOXO™ Intense Ribbed 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.

Conclusion

The Trojan™ XOXO™ Intense Ribbed condom has the same intended use as the predicate device. Based on performance data and biocompatibility review and testing and safety data, Trojan™ XOXO™ Intense Ribbed condom is substantially equivalent to the predicate device.