February 21, 2025

Church & Dwight Co., Inc.
% Dawn Reilly-O'Dell
Principal
Full Circle Regulatory Consulting, LLC
107 Casablanca Court
Cary, North Carolina 27519

Re: K243640
Trade/Device Name: Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: November 25, 2024
Received: November 25, 2024

Dear Dawn Reilly-O'dell:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

For
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243640

Device Name
Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)

Indications for Use *(Describe)*
The Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) is used for contraception and for prophylactic purposes (to 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K243640
Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)

1. Submitter Information

Applicant:	Church & Dwight Co., Inc.
Address:	500 Charles Ewing Boulevard Ewing, NJ 08628
Contact:	Lori Kordyban Sr. Manager, Regulatory Affairs 469 North Harrison Street Princeton, NJ 08543
Phone:	(920) 815-9345
Email:	lori.kordyban@churchdwight.com

2. Correspondent Information

Company:	Full Circle Regulatory Consulting, LLC
Contact:	Dawn Reilly-O'Dell, RAC, MPH
Email:	dreilly@fullcirclereg.com

3. Date prepared: February 19, 2025

4. Device Information

Device Name:	Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)
Common Name:	Male Natural Rubber Latex Condom
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	HIS (Condom)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	TROJAN™ Her Pleasure (Ribbed) Ecstasy latex condom with silicone lubricant
510(k) Number:	K120286
Sponsor:	Church & Dwight Co., Inc.

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

6. Device Description

The Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) is made of a natural rubber latex sheath, which covers the penis with a fitted membrane. A silicone-based lubricant is applied directly to the condom during packaging. The condom is a bulbous shaped condom with 7 rows of continuous ribs on the shaft and 9 rows of continuous ribs on the bulb. The condom meets the specifications of ASTM D3492-16. The condom has a nominal length of 200

mm, a nominal thickness of 0.095 mm, nominal flat widths of 53 mm measured 30 mm from the open end and 71 mm at the bulbous, closed end, and 800 mg of silicone lubricant per condom.

The condoms are packaged in individually sealed laminate (plastic inner layer, foil middle layer, and cellophane outer layer). The foils are packaged in an outer consumer cardboard carton. The Trojan™ Ultra Ribbed Ecstasy condoms are intended for over-the-counter (OTC) use. These condoms conform with FDA-recognized standards ASTM D3492-16 and ISO 4074:2015.

Device specifications are listed in Table 1 below.

7. Indications for Use Statement

The Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

Table 1. Comparison of Intended Use and Technological Characteristics

	Subject Device Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) K243640	**Predicate Device TROJAN™ Her Pleasure (Ribbed) Ecstasy latex condom with silicone lubricant K120286**
Device & Predicate Device	Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)	TROJAN™ Her Pleasure (Ribbed) Ecstasy latex condom with silicone lubricant
510(K) Number	K243640	K120286
Product Code	HIS	HIS
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	The Trojan™ ultra ribbed ecstasy latex condom with silicone lubricant (trojan™ ultra ribbed ecstasy) is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).	TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections)
Prescription or Over-The-Counter Use	Over-The-Counter	Over-The-Counter
Condom Material	Natural Rubber Latex	Natural Rubber Latex

Width	53 ± 2 mm (30 mm from open end) 71 ± 2 mm (75 ± 5 mm from closed end)	53 mm (30 mm from open end) 73 mm (bulbous, closed end)
Nominal Length	200 ± 10 mm	200 ± 10 mm
Nominal Thickness	0.095 ± 0.010 mm	0.094 ± 0.010 mm
Lubricant	Silicone	Silicone
Lubricant Quantity	800 ± 200 mg	Not specified
Air Burst Pressure	> 1.0 kPa	Not specified
Air Burst Volume	28.0 L	Not specified
Sterilization	Non-Sterile	Non-sterile
Texture	Ribbed	Ribbed
Shelf Life	3 Years	3 Years
Color Additives	N/A	N/A
Flavor Additives	N/A	N/A

The subject and predicate device have similar indications for use and have the same intended use. The technological characteristics of the subject device and predicate device are similar in that they are natural rubber latex-based, are lubricated with silicone, and have the same shelf-life duration. The subject and predicate devices do have different technological characteristics, including different dimensions and specifications. However, the different technological characteristics of the subject devices do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility:
Biocompatibility studies were performed in accordance with the 2023 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* as follows:

- Cytotoxicity (ISO 10993-5:2009/R 2014)
- Sensitization (ISO 10993-10:2010/R 2014)
- Vaginal Irritation (ISO 10993-23:2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not acutely, systemically toxic.

Physical Performance Testing:
The Trojan™ ultra ribbed ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) was tested and met all the requirements of ISO 4074:2015 - Natural rubber latex male condoms – Requirements and test methods and ASTM D3492-16 - Standard Specification for Rubber Contraceptives (Male Condoms).

Shelf Life:
The Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy)

has a three-year shelf life based on the results of accelerated stability evaluations conducted as required in 21 CFR 801.435. All samples met predefined acceptance criteria.

10. Conclusion

The results of the performance testing described above demonstrate that the Trojan™ Ultra Ribbed Ecstasy latex condom with silicone lubricant (Trojan™ Ultra Ribbed Ecstasy) is as safe and effective as the predicate device and supports a determination of substantial equivalence.