October 8, 2024

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

Re: K240379
Trade/Device Name: TROJAN SIS Synthetic Latex Condom with Silicone Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Received: September 6, 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,

Monica D. Garcia -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240379

Device Name
TROJAN SIS Synthetic Latex Condom with Silicone Lubricant

Indications for Use *(Describe)*
The TROJAN SIS Synthetic Latex Condom with Silicone Lubricant 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY – K240379

Submitter Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard
Ewing, NJ 08628

Contact Person: Lori Kordyban
Sr. Manager, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543
Phone: (920) 815-9345
E-mail: lori.kordyban@churchdwight.com

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

Date Prepared: October 10, 2024

Device Trade Name: TROJAN SIS Synthetic Latex Condom with Silicone Lubricant

Common Name: Synthetic Condom

Product Code: MOL (condom, synthetic)

Regulatory Class: Class II

Classification Name: Condom (21 CFR § 884.5300)

Predicate Device: K171639: TROJAN™ SUPRA Lubricated Polyurethane Male Condom

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

DESCRIPTION OF DEVICE

The TROJAN SIS Synthetic Latex Condom with Silicone Lubricant is made of a styrene-isoprene-styrene copolymer sheath, which covers the penis with a fitted membrane, and a silicone lubricant applied directly to the exterior of the condom. The condom is straight-walled, smooth, and has a nipple end. The condom has a nominal length of 185 mm, a nominal flat width of 55 mm, a nominal thickness of 0.065 mm, and conforms to the requirements of ISO 23409:2011(E).

INDICATIONS FOR USE

The TROJAN SIS Synthetic Latex Condom with Silicone Lubricant is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).

Comparison of Technological Characteristics

The table below includes a comparison of the subject and predicate devices.

	Subject Device **TROJAN SIS Synthetic Latex Condom with Silicone Lubricant (K240379)**	**Predicate Device** **TROJAN™ SUPRA Polyurethane lubricated condom (K171639)**
Product Code (device)	MOL (condom, synthetic)	MOL (condom, synthetic)
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Indications for Use	The TROJAN SIS Synthetic Latex Condom with Silicone Lubricant is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).	The Trojan Supra Lubricated Polyurethane Male Condom is intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections.
Prescription or Over-the-Counter	Over-the-Counter	Over-the-Counter
Condom Material	SIS (styrene-isoprene-styrene)	Polyurethane
Nominal Width	55 ± 2 mm	58 mm
Nominal Length	185 ± 20 mm	190 mm
Nominal thickness	0.065 ± 0.010 mm	0.040 mm
Lubricant	Silicone	Dimethylpoly siloxane
Shape	Straight-walled, reservoir-tip	Straight-walled, reservoir tip
Texture	Smooth (i.e., non-textured)	Non-textured
Shelf Life	1 year	5 years
Color Additives	None	None
Flavor Additives	None	None

The subject and predicate device have similar indications for use statements and the same intended use – the prevention of pregnancy and sexually transmitted infections. The technological characteristics of the subject and predicate devices are similar in that they are lubricated, the same shape and texture, and have no color or flavor additives. There are differences in material, dimension specifications, and shelf-life. These differences do not raise different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Manufacturing Processes: The manufacturing information for the subject condom was provided in accordance with 1995 FDA guidance, *Testing Guidance for Male Condoms Made From New Material (Non-Latex).*

Material Toxicity: A chemical characterization and toxicological risk assessment were performed in accordance with ISO 10993-17:2023, *Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents* and ISO 10993-18:2020, *Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process,* to assess the residual monomers and additives used in manufacturing of the subject condom.

Biocompatibility: Biocompatibility evaluations were performed on finished TROJAN™ SIS Synthetic Latex Condom with Silicone Lubricant condoms 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:

Evaluation (biological endpoint)	**ISO Standard**
Cytotoxicity	ISO 10993-5:2009
Vaginal Irritation	ISO 10993-23:2021
Acute Systemic Toxicity	ISO 10993-11:2017
Sensitization	ISO 10993-10:2021

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

Physical Testing Data

- **Airburst:** Three (3) lots of the subject condom were tested and met minimum volume and pressure airburst requirements of ISO 23409:2011, *Male condoms - Requirements and test methods for condoms made from synthetic materials*.
- **Body Temperature:** Three (3) lots of the subject condom were evaluated for physical integrity and met the tensile strength and elongation physical requirements of ASTM D3492-16, *Standard Specification for Rubber Contraceptives (Male Condoms)*, Appendix X1.
- **Tensile Properties:** The tensile properties of the subject condom were evaluated per ISO 4074:2015, *Natural latex rubber condoms – Requirements and test methods,* to evaluate force at break, tensile strength, and elongation at break.
- **Tear Resistance:** The subject condoms were evaluated for tear resistance per ASTM D624-00 (2012) *Standard Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers* with acceptable results.
- **Freedom from Holes and Visible Defects:** Three (3) lots of the subject condom were tested for freedom from holes and visible defects per ISO 23409:2011, *Male condoms - Requirements and test methods for condoms made from synthetic materials*.
- **Barrier Properties/Permeability:** A Viral Penetration Study was conducted to demonstrate the viral barrier properties of the subject condom compared to a natural rubber latex condom. Results

demonstrated that the barrier properties of the synthetic latex condom are comparable to the natural rubber latex condom per the requirements specified in Annex G of ISO 23409:2011, *Male condoms – Requirements and test methods for condoms made from synthetic materials*.

- **Package Integrity:** The subject condom packaging was tested per ISO 23409:2011, , *Male condoms – Requirements and test methods for condoms made from synthetic materials*.

Shelf Life: The subject condom has a 1-year shelf life based on the results of stability evaluations conducted as required in 21 CFR 801.435 and met the applicable requirements of ISO 23409:2011, *Male condoms – Requirements and test methods for condoms made from synthetic materials,* and per the 1995 FDA guidance, *Testing Guidance for Male Condoms Made From New Material (Non-Latex),* including mechanical testing and an analysis of chemical degradation byproducts and physical properties over time. All samples met predefined acceptance criteria.

SUMMARY OF CLINICAL TESTING

Design: A multisite clinical break-slip investigation (NCT05370196) was completed to evaluate the performance of the subject synthetic latex (SIS) condom conforming to ISO 23409:2011 as compared to a legally marketed natural rubber latex (NRL) control condom conforming to ISO 4074:2015. This randomized crossover clinical trial was conducted in California, according to the clinical failure noninferiority study requirements of ISO 29943-1:2017, *Condoms Guidance on Clinical Studies, Part 1: Male condoms, clinical function studies based on self-reports*.

Study Population: Three hundred (300) couples were enrolled, and two hundred eighty-nine (289) couples completed the study. All but 2 individuals had prior condom use.

Study population demographics

	Male		Female		Combined	
	n=300	%	n= 300	%	n= 600	%
Age						
21 or under	17	*6*	23	*8*	40	*7*
22-24	46	*15*	51	*17*	97	*16*
25-29	97	*32*	122	*41*	219	*37*
30-34	78	*26*	61	*20*	139	*23*
35-39	62	*21*	43	*14*	105	*18*
Mean age (yrs.)	29.6		28.3		28.9	
Race/ethnicity						
White	134	*45*	133	*44*	267	*45*
Hispanic	78	*26*	74	*25*	152	*25*
African-American	18	*6*	10	*3*	28	*5*
Asian	28	*9*	40	*13*	68	*11*
Other, multiple	42	*14*	43	*14*	85	*14*

Couples were asked to use four condoms of each condom type, with 1,200 condoms of each type available for use and a goal of completing ≥1,000 uses of each type. A total of 1,129 SIS condom and 1,130 NRL control condom uses contributed to the clinical breakage/slippage analysis.

Objectives and Endpoints: The primary objective of the study was to determine whether the total clinical failure rate of the SIS condom is non-inferior to that of the NRL control condom. The synthetic

latex condom was considered non-inferior if the upper limit of the one-sided 95% confidence interval of the SIS condom total clinical failure rate minus the NRL control condom total clinical failure rate did not exceed 2.5%.

The secondary objectives were to determine whether the failure rates of individual failure modes (clinical breakage and clinical complete slippage) for the SIS condom are non-inferior to that of the NRL control condom. For each failure mode, the SIS condom was considered non-inferior if the upper limit of the one-sided 95% confidence interval of the SIS condom total clinical failure rate minus the NRL control condom total clinical failure rate did not exceed 2%.

Results: The SIS condom was demonstrated to be non-inferior to the control NRL condom in clinical breakage, slippage, and total clinical failure rates. Ten adverse events were reported by nine female participants and one adverse event reported by a male participant. Four of the events were deemed unrelated to the study condoms, three were possibly related to the NRL control condom, two probably related to the NRL control condom, and two probably related to the subject condom. These events included genital itching, vaginal swelling, and vaginal burning. No serious adverse events were reported during the study.

The total clinical failure rate of the SIS condom (2.39%) was statistically non-inferior to the total clinical failure rate of the NRL control condom (1.77%), with the upper bound of 1.70% below the limit of 2.5%. The SIS condom was also non-inferior to the NRL control condom with respect to both the clinical breakage rate (1.42% SIS, 0.44% latex, upper bound 1.67%) and the clinical complete slippage rate (0.97% SIS, 1.33% latex, upper bound 0.44%), both upper bounds below the limit of 2.0%.

Summary of Clinical Trial Results (N = uses; Upper Bound is based upon 1-sided 95% CI)

Inferiority Analysis Summary by Population						
Population	**Outcome**	**Product**	**N**	**Events**	**Percent**	**Upper Bound**
Per Protocol	Breakage	Test	1129	16	1.42%	1.67%
		Control	1130	5	0.44%	
	Slippage	Test	1129	11	0.97%	0.44%
		Control	1130	15	1.33%	
	Total Failure	Test	1129	27	2.39%	1.70%
		Control	1130	20	1.77%	
Intent To Treat	Breakage	Test	1149	16	1.39%	1.64%
		Control	1143	5	0.44%	
	Slippage	Test	1149	11	0.96%	0.43%
		Control	1143	15	1.31%	
	Total Failure	Test	1149	27	2.35%	1.66%
		Control	1143	20	1.75%	

CONCLUSION

The results of the performance testing described above demonstrate that the TROJAN SIS Synthetic Latex Condom with Silicone Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.