September 28, 2022

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

Re: K221906
Trade/Device Name: TROJAN™ Fire & Ice lubricated male natural rubber latex condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: June 22, 2022
Received: June 30, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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, 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)*
K221906

Device Name
TROJAN™ Fire & Ice lubricated male natural rubber latex condom

Indications for Use *(Describe)*
The TROJAN™ Fire & Ice male natural rubber latex condom with 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.

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510(k) Summary – K221906

Submitter Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard, Ewing, NJ 08628

Contact Person: Supreet Sahota-Bhatti
Sr. Manager, Global Regulatory Affairs (US)
Church & Dwight Co., Inc., 469 North Harrison Street, Princeton, NJ 08543
Tel: (609)806-7893

Date Prepared: September 15, 2022

Trade Name: TROJAN™ Fire & Ice lubricated male natural rubber latex condom

Common Name: Male Natural Rubber Latex Condom

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Regulatory Class: Class II

Product Code: HIS (condom)

Predicate Device: K131887: TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant

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

Description of Device:

The TROJAN™ Fire & Ice lubricated male natural rubber latex condom is made of a natural rubber latex sheath, which completely covers the penis with a fitted membrane, and a lubricant applied directly to the exterior of the condom that creates a perception of warming and cooling. The condom is bulbous shaped and smooth (no ribs) with a reservoir tip and meets the specifications of ASTM D3492-16. The condom has a nominal length of 185 mm and a nominal flat width of 54 mm, measured 30 mm from the open end. The bulbous part at the closed end of the condom has a flat width of 65 mm.

Indications for Use:

The TROJAN™ Fire & Ice male natural rubber latex condom with lubricant is used for contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).

Predicate Device Comparison:

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

	Subject Device TROJAN™ Fire & Ice lubricated male natural rubber latex condom	**Predicate Device** TROJAN™ Jaguar male natural rubber latex condom with Warming and Tingling Lubricant
510(k) Number	K221906	K131887
Product Code	HIS	HIS
Regulation	21 CFR 884.5300	21 CFR 884.5300
Indications for Use	For contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).	For contraception and for prophylactic purposes (to prevent pregnancy and the transmission of sexually transmitted infections).
Prescription or Over-the-Counter	Over-the-counter	Over-the-counter
Condom Material	Natural rubber latex	Natural rubber latex
Nominal Length	185 mm	185 mm
Nominal Width	54 mm	54 mm
Nominal Thickness	0.085 mm	0.088 mm
Texture	Smooth	Ribbed
Lubricant	Glycol-based	Glycol-based
Air Burst Test Pressure	$\geq$ 1.0 kPa	$\geq$ 1.0 kPa
Air Burst Test Volume	$\geq$ 18 L	$\geq$ 18 L
Shelf-Life	3 years	3 years

The subject and predicate device have the same intended use and indications for use. The subject and predicate device share the same shape, dimensions, shelf-life, and primary packaging. Both are lubricated natural rubber latex condoms, but the formulations of their natural rubber latex and lubricant

differ. Additionally, the predicate device is ribbed, the subject device is smooth without ribbing. These differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing

Physical Testing: Three (3) lots of TROJAN™ Fire & Ice lubricated male natural rubber latex condoms were tested at baseline and met met all the requirements of ISO 4074:2015 - *Natural rubber latex male condoms – Requirements and test method*s and ASTM D3492-16 - *Standard Specification for Rubber Contraceptives (Male Condoms).*

Shelf Life: Stability of the TROJAN™ Fire & Ice lubricated male natural rubber latex condom was established from results of physical testing data using a protocol that followed 21 CFR §801.435 and met the requirements of both ASTM D3492-16 and ISO 4074:2015. Based on the evaluation of the results of the physical testing data, the expiration date has been initially set at 36 months and will be then verified through real-time stability through five (5) years in compliance with FDA expiration labeling requirements in 21 CFR §801.435.

Biocompatibility: Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2020 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"* and ISO 10993-1:2009 as follows:

Table 1: Biocompatibility Evaluations Conducted

Evaluation (biological endpoint)	ISO Standard
Cytotoxicity ISO Elution Method	ISO 10993-5
Rabbit Vaginal Irritation	ISO 10993-10
Guinea Pig Maximization Sensitization	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11

The results of this testing demonstrated that the subject devices are non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Conclusion:

Based on the results of the testing described above, the TROJAN™ Fire & Ice lubricated male natural rubber latex condom is as safe and effective as the predicate device and supports a determination of substantial equivalence.