



Food and Drug Administration
10903 New Hampshire Avenue
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August 1, 2017

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

Re: K171639
Trade/Device Name: Trojan Supra Lubricated Polyurethane Male Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: June 1, 2017
Received: June 2, 2017

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,


Charles Viviano -S

For 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

Indications for Use

510(k) Number (if known)

K171639

Device Name

Trojan Supra Lubricated Polyurethane Male Condom

Indications for Use (Describe)

The Trojan Supra Lubricated Polyurethane Male Condom is intended to prevent pregnancy, HIV/AIDS, and other 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:

Submitter Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard
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Contact Person: Lisa Burns
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Date Prepared: August 1, 2017

Device Trade Name: TROJAN SUPRA™ Lubricated Polyurethane Male Condom

Device Common Name: Polyurethane Condom

Product Code: MOL

Classification: Class II, Condom (21 CFR § 884.5300)

Predicate Device: K100767: TROJAN SUPRA Polyurethane Condom

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

Reason for 510(k) Submission:

The subject device is identical to the predicate device (K100767). The purpose of this submission is to change the personal lubricant compatibility statement in the labeling.

Description of Device:

The TROJAN SUPRA™ Lubricated Polyurethane Condom is a male condom consisting of a sheath of polyurethane with a lubricated coating. The condom is a straight-walled, non-textured, nipple-end condom with a nominal length of 190 mm and a nominal flat-width of 58 mm. This product has a 5-year shelf-life.

Intended use of the Device:

The Trojan Supra Lubricated Polyurethane Male Condom is intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections. The IFU statement is similar to the predicate device.

Comparison of Technological Characteristics:

Device & Predicate Device(s):	K171639	K100767
Condom		
Condom Material	Same as the predicate	Emulsified polyurethane containing polyoxyethylene alkylether emulsifier
Nominal Width	Same as the predicate	58 mm
Nominal Length	Same as the predicate	190mm
Nominal Thickness	Same as the predicate	0.04 mm
Lubricant	Same as the predicate	Dimethylpoly siloxane (400 mg/unit max)
Color Additives	Same as the predicate	Non-colored
Dusting agent	Same as the predicate	Hydrated amorphous silica < 20 mg/unit
Shape	Same as the predicate	Straight walled with a reservoir tip at the closed end and ring at the open end
Texture	Same as the predicate	Non-textured
Burst properties	Same as the predicate	Burst volume 9.4 dm ³ Burst pressure 10.31 kPa

There is no difference in the technological characteristics of the subject 510(k) condom and the predicate condom. Both the 510(k) subject condom and the predicate condom have the same design, dimensions, and materials. The 510(k) subject condom labeling is the same except for the device labeling has been revised to replace the existing warning of: “DO NOT USE WITH ANY ADDITIONAL PERSONAL LUBRICANTS, as they may damage the condom.” This warning is being replaced with: “May be used with

personal lubricants labeled compatible with polyurethane condoms.”

Performance Testing:

Compatibility Testing of Polyurethane Condoms with Cleared Personal Lubricants:

Condom compatibility testing was performed on Polyurethane condoms (subject device) with current commercial lubricant per ASTM D7661-10.

The results did not support that all personal lubricants are compatible with polyurethane condoms. However, a personal lubricant cleared by FDA with labeling for use with polyurethane condoms would be permissible to use.

Substantial Equivalence:

Based on the Compatibility Testing of Polyurethane Condoms with Current Commercial Lubricant, Trojan Supra Lubricated Polyurethane Male Condoms are substantially equivalent to the predicate device.