510(k) Summary

K050828

Submitted by: Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

Contact Person: Stephen C. Kolakowsky
Director, Regulatory Affairs
(609) 279-7748

Date Prepared: April 1, 2005

Proprietary Name: TROJAN SUPRA® Lubricated Polyurethane Male Condom

Common Name: Polyurethane Condom

Classification Name: Condom [21 CFR §884.5300]

Predicate Device: TROJAN SUPRA® Lubricated Polyurethane Male Condom
510(k) #K942697

Description of Device: The TROJAN SUPRA® Lubricated Polyurethane Condom is a male condom consisting of a sheath of polyurethane with a lubricant coating. The condom is a straight-walled, nipple-end condom with a nominal length of 190 mm and an approximate flat-width of 58 mm.

Intended Use of the Device: The 510(k)-subject condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs).

Technological Characteristics: There is no difference in the basic technological characteristics of the 510(k)-subject condom and the predicate condom. Both the 510(k)-subject condom and the predicate condom are of the same basic design, both are straight-walled, nipple-ended, lubricated condoms with an integral formed ring at the open-end. The 510(k)-subject condom differs from the predicate condom in the polyurethane resin material used to manufacture each condom. The labeling for the subject 510(k) device is the same as the predicate device except for the addition of the disclosure of foreign origin and name of the contract manufacturer.

Summary of Studies

Safety Studies — Safety information regarding the component materials and the finished product are provided in the 510(k) Notification and raise no safety concerns. Biocompatibility studies on the non-lubricated condom and on the lubricated finished product include *in vitro* cytotoxicity extract test and direct contact test; sensitization test; vaginal irritation test; acute systemic toxicity; and penile irritation test.

In-Use Study — A slippage and breakage study following a protocol prepared to meet the FDA guidance: "Clinical Testing Guidance for New Material Male Condoms," was conducted in France using the 510(k) subject condom with a standard latex condom serving as a control. Among the 206 couples included in the study, the clinical breakage rate for the polyurethane condom was 0.6% compared to 1.3% for the control. Clinically significant slippage was 1.1% for the polyurethane condom and 0.5% for the control. Neither difference was significantly difference. The polyurethane condom was therefore significant equivalent to the latex control condom in terms of clinical failure rate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2006

Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Law Department, Building 100
PRINCETON NJ 08543

Re: K050828
Trade/Device Name: TROJAN® SUPRA® Polyurethane Male Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: January 13, 2006
Received: January 17, 2006

Dear Mr. Kolakowsky:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K050828

Device Name: TROJAN SUPRA® Lubricated Polyurethane Male Condom

Indications for Use: The TROJAN SUPRA® Lubricate Polyurethane Male Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs).

Prescription Use _____ OR Over-the-Counter Use ___X___
(Per 21 CFR §8001.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050828