K071313

III. 510(k) SUMMARY

Submitter's Name and Address:	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Stephen C. Kolakowsky Director, Regulatory Affairs
Date Prepared:	May 2007
Proprietary Name:	TROJAN-ENZ® brand
Common Name:	Male Latex Condom
Classification Name:	Condom
Predicate Device:	TROJAN-ENZ® Male Latex Condoms Church & Dwight Co., Inc. Pre-1976 Device and Multiple Brands Sagami Rubber Industries Co., Ltd K897129
Description of the Device:	The condoms are made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The condoms are smooth surface straight-walled nipple-end (SWNE) style within ASTM standard specifications D-3492 Table 1 requirements, *e.g.*, minimum length 160 mm, maximum width 54 mm, and minimum thickness of 30 μM.
Intended Use of the Device:	This latex condom product has the same intended use as the predicates. It is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases.)
Technological Characteristics:	The proposed modified condom product would have the same technological characteristics as the predicate condom product identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and the condoms are made of natural rubber latex. The proposed modified condom product are equivalent to the current TROJAN-ENZ® brand male latex condoms in all respects except they would be manufactured by a contract manufacturer utilizing the contract manufacturer's compounded latex formulation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2007

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

Re: K071313
Trade Name: TROJAN-ENZ® Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: October 16, 2007
Received: October 17, 2007

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

VIII. INDICATIONS FOR USE STATEMENT

510(k) Number: K071313
Device Name: TROJAN-ENZ® brand Male Latex Condom
Indications For Use: The TROJAN-ENZ® brand condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Prescription Use _____
(Per 21 CFR §801.109)

Over-The-Counter Use ✓

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____