K023405

510(k) Summary

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

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

DEC 16 2002

Date Prepared: October 1, 2002

Proprietary Name: TROJAN® *MINT TINGLE*™ Brand Latex Condom

Common Name: Latex Condom

Classification Name: Condom [21 CFR §884.5300]

Predicate Device: TROJAN-ENZ® Lubricated Condom
(Pre-1976 Amendments Device)
and
TROJAN™ *PASSION BERRY*™ Personal Lubricant
(K013433)

Description of Device: The TROJAN® *MINT TINGLE*™ Brand Latex Condom is a male condom consisting of a sheath of natural rubber latex with a colored pigment and a flavored water-based lubricant. The condom is a straight-walled, nipple-end condom with a nominal length of 180 mm and an approximate width of 52 mm. [Refer to ASTM D-3492-97 Specification for Rubber Contraceptives (Male Condoms).]

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: Both the 510(k)-subject condom and the predicate condom are of the same basic design meeting ASTM Standard Specification for Rubber Contraceptives (Male Condoms) D3492 — both are straight-walled, nipple-ended, lubricated condoms and made using the same basic formulations of compounded natural rubber latex. The 510(k)-subject condom most notably differs from the predicate condom in that a pigment is added to the latex formulation to yield a colored condom and that the lubricant utilized with the 510(k)-subject condom is similar to the predicate flavored personal lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2002

ArmKel, LLC
% Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543-5297

Re: K023405
Trade Name/Device: TROJAN® MINT TINGLE™ Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: October 3, 2002
Received: October 10, 2002

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your 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.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

David A. Lyon

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

Indications for Use Statement

510(k) Number: K023405

Device Name: TROJAN® *MINT TINGLE*™ Male Latex Condom

Indications for Use: The TROJAN® *MINT TINGLE*™ Latex Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs).

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, **Abdominal,**
and Radiological Devices
510(k) Number K023405