May 9, 2012

K120249 MAY 11 2012

510(k) Summary

Submitted by: Church & Dwight Co., Inc.
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Date Prepared: May 9, 2012

Proprietary Name: TROJAN® MAGNUM® Condom with WARMING™ Lubricant

Common Name: Natural Rubber Latex Condom with Lubricant

Classification Name: Condom [21CFR §884.5300] HIS

Predicate Device: TROJAN® MAGNUM® Latex Condom with Spermicidal Silicone Lubricant (K895640)
TROJAN® THINTENSITY™ Latex Condom with Warm Sensations™ Lubricant (K073016)
TROJAN® EXTENDED PLEASURE™ Latex Condom with Climax Control Lubricant (K000748)

Description of Device
The TROJAN® MAGNUM® Condom with WARMING™ Lubricant is a male condom consisting of a sheath of natural rubber latex with a lubricated coating consisting of a glycol-type base to create a perception of warming. The condom is a taper-walled, non-textured, nipple-end condom as described in K895640. The 510(k)-subject condom's physical specifications are substantially equivalent to the predicate device, the lubricant has been modified.

(continued)

Indications for Use: The TROJAN® MAGNUM® Condom with WARMING™ Lubricant is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Technological Characteristics: There is no difference in the fundamental technological characteristics of the 510(k)-subject MAGNUM condom and the predicate MAGNUM condom. The 510(k)-subject MAGNUM condom is substantially equivalent to the predicate MAGNUM condom cleared under 510(k) K895640 both in design (taper-walled, nipple-end, lubricated condoms with an integral formed ring at the open-end) and material (natural rubber latex). The base lubricant systems differ in that the predicate MAGNUM condom lubricant was silicone-based and the 510(k)-subject MAGNUM condom lubricant is glycol-based. This glycol-type base formulation is similar to the secondary predicates, TROJAN® THINTENSITY™ with Warm Sensations™ (K073016) and TROJAN® Extended Pleasure™ (K000748). Labeling for the 510(k)-subject device is consistent with the Special Controls provisions of 21 CFR §884.5300 and that of the predicate device. The primary purpose of lubricant on a condom is to provide vaginal lubrication during sexual intercourse; sometimes additional components are added for secondary purposes, e.g., nonoxynol-9 for spermicidal effect, benzocaine for male genital desensitizing, and in the 510(k)-subject device, the lubricant provides a mild, warm sensation for both partners.

Summary of Studies

Safety Studies – Biocompatibility studies applicable to the TROJAN® MAGNUM® Latex Condom with Warming™ Lubricant were performed on the 510(k)-subject device. These studies include *in vitro* cytotoxicity extract test; vaginal irritation test; penile irritation test; acute systemic toxicity; sensitization test; bacterial reverse mutation assay; mouse lymphoma assay. TROJAN® MAGNUM® Latex Condom with Warming™ Lubricant is considered safe for consumer use under normal and reasonably forseeable misuse conditions.

Physical testing data – Three (3) lots of condoms with the WARMING™ lubricant were tested and met the specifications of ASTM D 3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms) as recognized by the FDA.

Shelf-life – Stability of the 510(k)-subject device was established from results of physical testing data using a protocol that followed 21 CFR §801.435 as a guide. 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 date labeling requirements in 21 CFR §801.435. This testing also established the chemical compatibility between the latex condom and the lubricant.

Accordingly, when compared to the predicate MAGNUM male latex condom, the TROJAN® MAGNUM® Condom with WARMING™ Lubricant does not incorporate any significant changes in intended use, method of operations, materials, or design that could affect the safety and effectiveness; therefore, the 510(k)-subject condom is expected to perform as well, or better, than the predicate MAGNUM condom.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Church & Dwight Co., Inc.
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Re: K120249
Trade/Device Name: TROJAN® MAGNUM® Condom with WARMING™ Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: February 21, 2012
Received: February 24, 2012

Dear Mr. Ciccone:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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: K120249

Device Name: TROJAN® MAGNUM® Condom with WARMING™ Lubricant

Indications for Use: TROJAN® MAGNUM® Condom with WARMING™ Lubricant is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Prescription Use _____ OR Over-the-Counter Use X

(Per 21 CFR §8001.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine H. Bryden for Benjamin Fisher

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120249

TROJAN BRAND CONDOMS

CHURCH & DWIGHT CO., INC.