K120287

TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ Lubricant
Special 510(k) Notification

May 15, 2012

MAY 16 2012

510(k) Summary

Submitted by: Church & Dwight Co., Inc.
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Date Prepared: May 15, 2012

Proprietary Name: TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ Lubricant

Common Name: Natural Rubber Latex Condom with Lubricant

Classification Name: Condom [21CFR §884.5300] HIS

Predicate Device: TROJAN® THINTENSITY™ Latex Condom with Warm Sensations™ Lubricant (K073016)
Billy Boy Special Comfort Male Latex Condom (K103119)

Description of Device:
TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ Lubricant is a male condom consisting of a sheath of natural rubber latex which covers the penis with a fitted membrane, coated with a lubricant consisting of low levels of sensory ingredients to create a perception of warming and tingling. The condom is a taper-walled, non-textured, nipple-end condom with an integral formed ring at the open end.

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

(continued)

Technological Characteristics: Both the predicate TROJAN® THINTENSITY™ Latex Condom with Warm Sensations™ Lubricant (K073016) and the 510(k)-subject device are made from natural rubber latex and are coated with a glycol-based lubricant. The lubricant of the 510(k)-subject MAGNUM condom differs from that of the predicate condom in that it contains low levels of sensory ingredients to create a perception of warming and tingling

The 510(k)-subject MAGNUM condom is substantially equivalent to the predicate Billy Boy Special Comfort Male Latex Condom cleared under 510(k) K103119 both in design (taper-walled, nipple-end, lubricated condoms with an integral formed ring at the open-end) and material (natural rubber latex).

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 secondary components provide a lubricant with warming and tingling sensations for both partners.

Summary of Studies

Safety Studies – Biocompatibility studies applicable to the TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ 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. TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ Lubricant is considered safe for consumer use under normal and reasonably foreseeable misuse conditions.

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

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 male latex condoms, the TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ 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 predicates - TROJAN® THINTENSITY™ Latex Condom with Warm Sensations™ and Billy Boy Special Comfort male latex 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

Mr. Joseph A. Ciccone
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MAY 16 2012

Re: K120287
Trade/Device Name: TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ 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: K120287

Device Name: TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ Lubricant

Indications for Use: TROJAN® MAGNUM® Latex Condom with FIRE & ICE™ 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120287

TROJAN BRAND CONDOMS

CHURCH & DWIGHT CO., INC.