JUN 19 2012

TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant June 13, 2012
510(k) Notification

510(k) Summary
(Revised)

Submitted by: Church & Dwight Co., Inc.
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Date Prepared: June 13, 2012

Proprietary Name: TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant

Common Name: Natural Rubber Latex Condom with Lubricant

Classification Name: Condom [21CFR §884.5300] HIS

Predicate Device: TROJAN® (TM-TDB) Latex Condom with Lubricant (K912901) [Secondary Brand Name HER PLEASURE™ added when introduced to market]

Description of Device: The TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant is a male condom consisting of a sheath of natural rubber latex with a silicone-based lubricant, designed with ribs and a larger bulbous end than the predicate device. The condom has a nominal length of 200 mm and a maximum nominal flat-width of 52-54 mm, measured 30 mm from the open end. The bulbous portion at the closed end of the condom has a flat-width of 73 mm. The condom is consistent with the specifications in ASTM D3492-08 for condoms having a shaped profile about the closed end.

Intended Use of the Device: The 510(k)-subject TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant has the same intended use as the predicate TROJAN® HER PLEASURE™ Latex Condom with Lubricant (K912901). TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant is used for contraception and for prophylactic purposes (to help prevent pregnancy and other sexually transmitted infections).

(continued)

Technological Characteristics: The 510(k)-subject TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant has a similar contour-shaped condom design (shape, lubricated condoms with an integral formed ring at the open-end) and material (natural rubber latex) as the predicate HER PLEASURE™ device reviewed and cleared under 510(k) K912901. The 510(k)-subject condom has been modified to add ribs on the wall of the condom, add more room in the bulbous area by increasing the width, and remove the nipple-end at the closed-end of the condom. The nominal flat-width remains 52-54 mm, measured at 30 mm from the open-end of the condom as specified by ASTM D3492-08. 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 the added ribbing and added room in the bulbous area of the condom is based on preferred aesthetics by the consumer.

Summary of Studies

Biocompatibility Studies – Biocompatibility studies applicable to the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant were performed on the final 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® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant is considered safe for consumer use under normal and reasonably forseeable misuse conditions.

Consumer-use performance data – FDA's recognition of D3492-08 notes that, "FDA will also carefully evaluate any condom whose nominal width exceeds 58 mm" (recognition #22, 09/08/2009). Slip/Break data from a branded consumer preference study which included the 510(k)-subject condom and three other currently marketed TROJAN® latex condoms was made part of this 510(k) for FDA's review. More than 1250 couples participated in this study (500+ using over 1300 TROJAN® ECSTASY® condoms and 750+ using more than 2200 currently marketed TROJAN® latex condoms). The slippage rate for the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Condom was 1.99%, and for the control condoms was 1.09%, 0.99% and 0.00%. The breakage rate for the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Condom was 0.46%, and for the control condoms was 0.11%, 0.54%, and 0.00%. The total failure rate for TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom was 2.45%, and for the control condoms was 1.20%, 1.53%, and 0.00%. These results support that the slip and break rates of the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom is comparable to currently marketed latex condoms.

Physical testing data – Three (3) lots of the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant were tested and met 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.

Accordingly, when compared to the predicate HER PLEASURE™ male latex condom, the data from the performance and biocompatibility studies demonstrate that the TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant is substantially equivalent to the predicate.

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

JUN 19 2012

Mr. Joseph Ciccone
Manager, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543

Re: K120286
Trade/Device Name: TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: April 13, 2012
Received: April 16, 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: K120286

Device Name: TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with Lubricant

Indications for Use: TROJAN® HER PLEASURE™ (Ribbed) ECSTASY® Latex Condom with 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 K120286

TROJAN BRAND CONDOMS

CHURCH & DWIGHT CO., INC.