II. 510(k) SUMMARY

Submitted by: Church & Dwight Co., Inc.
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OCT 2 4 2013

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Date Prepared: June 24, 2013

Proprietary Name: TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD)

Common Name: Natural Rubber Latex Condom with Lubricant

Classification Name: Condom (21 CFR §884.5300) HIS

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

Description of the Device: The TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) is made of a natural rubber latex sheath, which completely covers the penis with a fitted membrane and has a glycol-based lubricant containing low levels of sensory ingredients applied directly to the condom to create a perception of warming and tingling. The condom is a bulbous shaped condom consistent with ASTM D3492-08 Standard Specifications for Rubber Contraceptives (Male condom) with a reservoir end. The TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) is designed with ribs on its shank and on its bulb. The condom has a nominal length of 185 mm and a maximum nominal flat-width of 54 mm, measured 30 mm from the open end. The bulbous portion at the closed end of the condom has a flat-width of 65 mm.

Intended Use of the Device: The 510(k)-subject device, TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD), has the same intended use as the predicate TROJAN™ HER PLEASURE™ Latex Condom with Lubricant (K912901). The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections.)

Technological Characteristics: The TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) has the same bulbous-shaped condom design and material (natural rubber latex) as the predicate TROJAN™ HER PLEASURE™ Latex Condom with Lubricant (K912901). The predicate was designed with smooth wall and silicone lubricant, the 510(k)-subject device is designed with ribs on the shank and on the bulb of the condom and contains a tingling and warming lubricant. The nominal width remains 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 the warming and tingling lubricant is based on preferred aesthetics by the consumer.

Summary of Studies

Biocompatibility Studies:

Biocompatibility studies applicable to the TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) were performed on the final 510(k)-subject device. These studies include in vitro cytotoxicity study using the ISO Elution method; cytotoxicity study using the end-point titration method; rabbit vaginal irritation study; rabbit penile irritation study; acute systemic toxicity study; guinea pig maximization sensitization study; primary rabbit skin irritation study. Based on the results of these studies, TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) is considered safe for consumer use under normal and reasonably foreseeable misuse conditions.

Physical testing data

Three (3) lots of TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) were tested and met specifications of ASTM D 3492-08 Standard Specifications for Rubber Contraceptives (Male Condoms).

Shelf-life

Stability of the TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) 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 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™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 24, 2013

Church & Dwight Co., Inc.
% Emily Perez
Senior Regulatory Affairs Specialist
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K131887
Trade/Device Name: TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD)
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: August 6, 2013
Received: August 7, 2013

Dear Emily Perez,

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,

Herbert P. Lerner -S

for
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

I. INDICATIONS FOR USE STATEMENT

510(k) Number: K131887

Device Name: TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD)

Indications For Use: The TROJAN™ Jaguar Male Natural Rubber Latex Condom with Warming and Tingling Lubricant (TM-TBD) is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use____X_____
(Per 21 CFR §801.109)

Herbert P. Lerner -S
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