JAN 2 7 2006

K052959

Durex Male Latex Colored Condom with Scented Lubricants
Premarket Notification [510(k)] application

Section II: Summary

A. Submitter Information

SSL Americas
3585 Engineering Dr.
Suite 200
Norcross, GA 30092-9214
Phone: 770 – 582 – 2222
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B. Contact Person

Chris Robinson, Controller Head of Global Regulatory Affairs, SSL Americas

C. Date Prepared

September 2005

D. Proprietary Name

Durex male latex colored shaped condoms with scented lubricants
Trade name: Durex Tropical

E. Common Name

Male latex condom

F. Classification Name

HIS

G. Predicate Devices

Durex Colors and Scents – 510(k) Number K980174
Durex Mint Scented Condom – 510(k) Number K900679
(plus 'note to file' line extension dated 30.09.2003)

H. Description of the Device

The condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The device is a straight walled , teat ended, coloured condom containing either red, yellow, orange or green pigment. The condoms are lubricated with a water based flavoured lubricant containing either lychee, guava, pineapple, mango or kiwi scent.

The device is designed to conform to national and international voluntary standards, including ISO 4074:2002 and ASTM D3492-03.

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I. Intended Use of the Device

This latex condom has the same intended use as the predicate condoms. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

J. Technological Characteristics

This condom has the same technological characteristics as the predicate condoms identified.

The condoms described in **K980174** are natural rubber latex, straight walled, teat ended condoms containing pigments (red, yellow, orange) lubricated with scented lubricants (strawberry, banana, tangerine). This application is also concerned with straight walled, teat ended, colored natural rubber latex condoms of the same basic formulation containing the same pigments as used in the predicate devices, but with aqueous based lubricants with the alternative scents of lychee, guava, pineapple, mango.

The condoms described in **K900679** are straight walled, teat ended, natural rubber latex condoms lubricated with a spearmint flavor. An 'Add to File' was prepared in September 2003 to cover a natural rubber latex condom containing green pigment and lubricated with spearmint flavour sourced from a new supplier. This application is also concerned with the same green pigmented natural rubber latex condom with an alternative scented (kiwi) lubricant.

The condom design conforms to domestic and international regulations: ASTM D3942-03 and ISO 4074:2002. Physical testing and release testing of the finished product revealed results in conformance with required specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2006

Mr. Chris Robinson
Controller Head of Global Regulatory Affairs
SSL Americas, Inc.
Office of Regulatory Affairs
3585 Engineering Drive, Suite 200
NORCROSS GA 30092-9214

Re: K052959
Trade/Device Name: Durex Male Latex Colored Condom with Scented Lubricants
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: October 10, 2005
Received: November 7, 2005

Dear Mr. Robinson:

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.

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 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); 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.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

Durex Male Latex Colored Condom with Scented Lubricants
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Indications for Use

510(k) Number (if known): K052959

Device Name: Durex Tropical (male latex colored condom with scented lubricants)

Indications For Use: Durex latex condom used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted disease).

Prescription Use _____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052959