Durex 'Tingling Pleasure' Male Latex Condom Premarket approval [510(k)]

K042470

Section II Summary

A. Submitter Information

SSL Americas
3585 Engineering Dr.
Suite 200
Norcross, GA 30092-9214
Phone: 770 – 582 – 2222
Fax: 770 – 582 – 2233

B. Contact Person

Chris Robinson: Controller Head of Global Regulatory Affairs.

C. Date Prepared

July 26, 2004

D. Proprietary Name

Durex spearmint scented lubricated Male Latex Condom
Trade name Durex 'Tingling Pleasure'

E. Common Name

Male Latex Condom

F. Classification Name

HIS

G. Predicated Device

Durex Ultra Comfort Latex Rubber Condom [510(k) Number K980319].
Spearmint scented green condom [510(k) Number K900679].

H. Description of the Device

This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This device is a shaped, teat ended, transparent condom lubricated with a spearmint scented lubricant, and is designed to conform to national and international voluntary standards, including ISO 4074:2002 and ASTM D3492 except where noted.

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 K980319 are shaped, transparent Durex manufactured natural rubber latex condoms with silicone lubricant, and are of the same dimensions, and have the same lubricant dosage as the condom in this application. The only difference between these two condoms is the addition of the spearmint scent in 'Tingling Pleasure'.

The condom described in K900679 is a green pigmented, parallel sided condom which is lubricated with the same spearmint scented silicone fluid lubricant as the 'Tingling Pleasure' condom. The dosage of spearmint scented lubricant on the Tingling Pleasure condom is 520mg. (400mg for the parallel sided condom in K900679).
All three condoms are of the same base latex formulation (with addition of green pigment in the case of K900679).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2005

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: K042470
Trade/Device Name: Durex® Spearment Scented Lubricated Male Latex Condom (Durex® 'Tingling Pleasure')
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: February 7, 2005
Received: February 10, 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

Indications for Use

510(k) Number (if known): K042470

Device Name: Durex 'Tingling Pleasure' condom

Indications For Use: This Durex latex condom is 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 K042470