K063385

Section VIII:
Durex Play™ Massage gel lubricant
Premarket approval [510(k)] Application Summary.

Section VIII.1 Submitter Information

SSL Americas
3585 Engineering Drive
Suite 200
Norcross GA 30092-9214.
Phone: 770-582-2222 Fax: 770-582-2233
Contact Person: Chris Robinson, Controller Head of Regulatory Affairs, SSL Americas.

MAR 10 2008

Date of summary: original 1 November 2006 , amended 10 March 2008.

Section VIII.2 General Device Information

Device trade Name: Durex Play™ Massage gel
Device common name: Personal Lubricant
Classification: Patient Lubricant

Section VIII.3 Predicate devices.

K-Y Jelly Personal lubricant (K955648)
Astroglide (K935299)
Durex Play™ Warmer lubricant (K042563)
Durex Play™ Personal Lubricant (K032124)

Section VIII.4 Device Description

Durex Play™ Massage gel personal lubricant is a clear, colorless, water soluble personal lubricant.

Cont.

Section VIII.5 Intended Use

Indications: Durex Play ™ Massage gel is intended as a moisturiser for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to facilitate ease and comfort during intimate sexual activity.
This lubricant has been shown to be compatible only with condoms made from natural rubber latex and synthetic polyisoprene.

Section VIII.6 Substantial Equivalence

The product Durex Play ™ Massage gel is substantially equivalent in intended use to K-Y Jelly, Astroglide and Durex Play ™ personal lubricants. The formulations are very similar to the existing Durex Play™ formulations Durex Play™ and Durex Play Warmer™ All these products are sold Over-the-Counter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2008

Mr. Chris Robinson
Controller-Head of Global Regulatory Affairs
SSL Americas, Inc.
3585 Engineering Drive, Suite 200
NORCROSS GA 30092-2891

Re: K063385
Trade/Device Name: Durex Play™ Massage Gel Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: February 19, 2008
Received: February 29, 2008

Mr. Chris 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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Section IV.3 Indications for Use

510(k) Number (if known): K063385

Device Name: Durex Play™ Massage Gel Lubricant

Durex Play™ Massage gel lubricant is intended as a moisturizer for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to facilitate ease and comfort during intimate sexual activity.

This lubricant has been shown to be compatible only with condoms made of natural rubber latex and synthetic polyisoprene.

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

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063385