K072236

MAY - 7 2008

Section VIII:
Durex Play™ Tingling Lubricant
Premarket approval [510(k)] Application Summary.

Section VIII.1 Submitter Information

SSL Americas
3585 Engineering Drive
Suite 200
Norcross GA 30092-9214.
Phone:770-582-2174 Fax:770-582-2226
Contact Person: Chris Robinson, Head of Regulatory Compliance.
Alternative contact person: Janice Jose, Associate Regulatory Controller
Date of summary: July 2007.

Section VIII.2 General Device Information

Device trade Name: Durex Play™ Tingling aqueous based lubricant.
Device common name: Personal Lubricant
Classification: Patient Lubricant

Section VIII.3 Predicate devices.

Durex Play™ Personal Lubricant (K032124)

Section VIII.4 Device Description

Durex Play™ Tingling aqueous based personal lubricant is a slightly hazy/clear, water soluble personal lubricant.

Section VIII.5 Intended Use

Indications: The Durex Play ™Tingling aqueous based lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2008

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

Re: K072236
Trade/Devices Name: Durex Play Tingling Aqueous Based Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Dated: April 18, 2008
Received: April 24, 2008

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 (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): K072236

Device Name: Durex Play™ Tingling aqueous based Lubricant

The Durex Play™ Tingling aqueous based Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

This product is only compatible with natural rubber latex condoms.

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 K072236