Section VIII:
Durex Play™ Temptations Assorted lubricants
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.
Date of summary: 22nd December 2005.

Section VIII.2 General Device Information

Device trade Name: Durex Play™ Temptations Assorted lubricants.
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™ Temptations Assorted personal lubricants are clear, colorless, water soluble personal lubricants.

The Tingle and Warming lubricants are already covered under K042958 and K042563 respectively.
Section VIII.5 Intended Use

Indications: Durex Play™ Temptations Assorted Lubricants are intended as moisturizers for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to facilitate ease and comfort during intimate sexual activity.

Section VIII.6 Substantial Equivalence

The product Durex Play™ Temptations Assorted Lubricants 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 and are condom compatible formulations.
Mr. Chris Robinson  
Head of Regulatory Compliance  
SSL Americas, Inc.  
Office of Regulatory Affairs  
3585 Engineering Drive, Suite 200  
NORCROSS GA 30092-9214  

Re: K060098  
Trade/Device Name: Durex Play™ Temptations Assorted Personal Lubricant  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: May 11, 2006  
Received: May 15, 2006  

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.xxx (Gastroenterology/Renal/Urology) 240-276-0115
- 21 CFR 884.xxx (Obstetrics/Gynecology) 240-276-0115
- 21 CFR 894.xxx (Radiology) 240-276-0120
- Other 240-276-0100

Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure
Durex Play™ Temptations Assorted Lubricants Premarket Approval 510(K) Application.

Section IV.3 Indications for Use

510(k) Number (if known): K066098

Device Name: Durex Play™ Temptations Assorted Lubricants

Durex Temptations Assorted Lubricants are 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.

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)

[Signature]

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K066098

Section V. Substantial Equivalence

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