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Durex Flavored Latex Condom Premarket approval [510(k)]

K032227

## 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

Kathleen Harris, Regulatory Affairs Manager, SSL Americas

### C. Date Prepared

July 11, 2003

### D. Proprietary Name

Durex Flavored Latex Condom

### E. Common Name

Latex Condom

### F. Classification Name

Condom (21 CFR 884.5300)

### G. Predicated Device

Natural and Colored Condoms with Flavors [510(k) Number K020633]
One Touch (or private label) Flavored Male Latex Condom [510(k) Number K011253]
Durex Lubragel Latex Rubber Condom [510(k) Number K983380]

### H. Description of the Device

This condom is made of a natural rubber colored latex sheath, which completely covers the penis with a closely fitted membrane. This device is a parallel sided, teat ended, flavored condom and is designed to conform to national and international voluntary standards, including ISO 4074, EN600 and ASTM D3492. The condom is offered in Chocolate, Chocolate/coconut, Chocolate/peppermint, and Chocolate/orange.

# Durex Flavored Latex Condom Premarket approval [510(k)]

## 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 LS Rubber SDN and Thai Nippon Rubber Industry products are manufactured of natural rubber latex with flavor additives in lubricant . The Durex Lubragel product is the same condom and base lubricant as the product submitted in this 510(k). The condom design conforms to domestic and international regulations: ASTM D3492, ISO 4074 and EN 600. All physical testing and final release testing 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

Ms. Kathleen Harris
Regulatory Affairs Manager
SSL Americas, Inc.
Office of Regulatory Affairs
3585 Engineering Drive, Suite 200
NORCROSS GA 30092-9214

MAR 2 9 2004

Re: K032227
Trade Name/Device: Durex flavored Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: 85 HIS
Dated: January 6, 2004
Received: January 8, 2004

Dear Ms. Harris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your 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.
Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. 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/dsma/dsmamain.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

# Indications for Use

510(k) Number (if known): K032227

Device Name: Durex flavored natural rubber latex condom

Indications For Use: 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 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032227