

Durex Male Latex Condom with Warming Lubricant
Premarket Notification [510(k)] application

IC 092957

FEB 17 2005

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, SSL Americas

C. Date Prepared

October 8, 2004

D. Proprietary Name

Durex Male Latex Condom with warming lubricant.
Trade name: Durex Warming Pleasure.

E. Common Name

Male Latex Condom

F. Classification Name

HIS

G. Predicate Device

Durex Latex Rubber Condom - 510(k) Number K980319
Trojan Shared Pleasure condom – 510(K) Number unknown.
KY Warming liquid personal lubricant – 510(k) Number K021492

H. Description of the Device

The condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The device is a shaped, teat ended, lubricated condom which is lubricated with a water based warming lubricant.

The device is designed to conform to national and international voluntary standards, including ISO 4074 and ASTM D3492, except where noted.

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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). The warming condom lubricant has the same intended use as the predicate personal lubricants when used as an accessory to a condom. It relieves friction and facilitates ease and comfort of intimate sexual activity.

J. Technological Characteristics

This condom has the same technological characteristics as the predicate condoms identified. The condoms described in K980319 are manufactured of natural rubber latex with the same shape as the condoms in this application. The competitor Trojan Shared Pleasure condoms are Natural Rubber Latex male condoms with 'Warm Sensations' lubricant to help enhance sexual pleasure.

The K-Y Warming liquid (K021492) is a water based, condom compatible personal lubricant which provides a warming sensation. It is of similar composition as the warming lubricant on the Durex condom in this submission.

The condom design conforms to domestic and international regulations: ASTM D3942 and ISO 4074. Physical testing and release testing of the finished product revealed results in conformance with required specifications.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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: K042957
Trade/Device Name: Durex Male Latex Condom
with Warming Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: January 31, 2005
Received: February 9, 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.

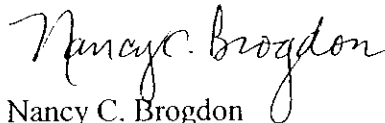
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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/dsma/dsmamain.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 Male Latex Condom with Warming Lubricant
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Indications for Use

510(k) Number (if known): K042957

Device Name: Durex male latex condom with warming lubricant

Indications For Use: Durex latex condom used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted disease).

Prescription Use _____
(Part 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-Counter Use
(21 CFR 807)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Edward M. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042957