APR 2 7 2004

K040185

Durex studded/ribbed Latex Condom Premarket approval [510(k)]

Section I General Information

A. Name and address of applicant

SSL Americas
3585 Engineering Drive, Norcross, GA 30092-9214.
The general phone number for SSL Americas is 770-582-2222, fax number is 770-582-2204.

B. Contact Person

Chris Robinson
Controller – Head of Global Regulatory Affairs, SSL Americas
Phone: 770-582-2152
Fax: 770-582-2204
Email: chris.robinson@ssl-international.com

C. Establishment Registration of Submitter

1065445

D. Name and address of SSL manufacturing facility

TTK-LIG LTD.
Located at: 35 Old Trunk Rd., Pallavaram, Chennai, India 600 043
Establishment registration number: 3003878048.

TTK-LIG LTD
Located at: 20 Perali Road, Virudhungar, India 626 001
Establishment registration number: 9680394

E. Name of Device

Proprietary Name: Durex studded/ribbed lubricated Latex Condom
(commercial name Pleasuremax Condom)
Common Name: Male Latex Condom
Classification Name: Condom (21 CFR 884.5300)

F. Classification of Device

Class II Condom 21 CFR 884.5300

G. Action Taken to Comply with Section 514 of the Act

The Durex latex condoms conforms to the ASTM D3492 , ISO 10993 and ISO 4074:2002 standards, except were variances are noted. Conformance to these standards is described on the following pages.

Office of Regulatory Affairs
3585 Engineering Drive, Suite 200
Norcross, GA 30092-9214
Tel: 770-582-2222
Fax: 770-582-2204

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

January 14, 2004

D. Proprietary Name

Durex studded and ribbed Male Latex Condom
Trade name to be determined later

E. Common Name

Male Latex Condom

F. Classification Name

HIS

G. Predicated Device

Dotted Condom [510(k) Number K012962]
Ribbed Condoms [510(k) Number K902509]
Durex Latex Rubber Condom [510(k) Number K980319]

H. Description of the Device

This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This device is a parallel sided, teat ended, lubricated condom and is designed to conform to national and international voluntary standards, including ISO 4074, EN600 and ASTM D3492.

Durex studded and ribbed Male 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 condoms described in K012962 are manufactured of natural rubber latex with raised studs. The condoms described in K902509 are Durex manufactured ribbed Natural Rubber Latex male condoms with silicone lubricant. The condoms described in K980319 are Durex manufactured natural rubber latex male condoms with silicone lubricant. The condom design conforms to domestic and international regulations: ASTM D3942, 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

APR 2 7 2004

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: K040185
Trade/Device Name: Durex Pleasuremax Condom – Male latex condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: January 20, 2004
Received: January 28, 2004

Dear Mr. Robinson:

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.

Your device is classified (see above) into class II (Special Controls) and is 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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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

03 3163

Indications for Use

510(k) Number (if known): K040185

Device Name: Durex ~~Mutual Pleasure~~ pleasuremax 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040185