K072169

JUN 19 2008

I.4: 510(k) SUMMARY

A. Submitter Information

SSL Americas
3585 Engineering Dr.
Suite 200
Norcross, GA 30092-9214
Phone: 770 582 2174
Fax: 770 582 2226

B. Contact Person

Chris Robinson – Head of Regulatory Compliance, SSL Americas.

C. Date Prepared

9 July 2007

D. Proprietary Name

Durex synthetic polyisoprene male condom. (Trade name to be determined later)

E. Common Name

Synthetic male condom

F. Classification Name

Condom non-latex (21 CFR 884.5300, Product code M-OL)

G. Predicated Device

Durex Ultra Comfort Latex Rubber Condom [510(k) Number K980319]
Biogel Skinsense PI surgeons glove [510(k) Number K050184]

H. Description of the Device

This condom is made of a synthetic polyisoprene rubber sheath, which completely covers the penis with a closely fitted membrane. This device is a shaped, teat ended, lubricated condom. Synthetic polyisoprene is the synthetic form of natural polyisoprene rubber otherwise known as natural rubber, a material commonly used for condom manufacture. Condoms made by SSL from synthetic polyisoprene have been shown to have similar performance properties as natural rubber latex condoms and conform to the relevant physical test requirements of national and international voluntary standards for natural rubber latex male condoms, ISO 4074:2002, and ASTM D3492-03 and of the synthetic condom standard ASTM D6324-05.

I. Intended Use of the Device

This synthetic polyisoprene condom has the same intended use as the predicate condom device. The condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Physical test data, biocompatibility data, safety and clinical data included in the 510K application indicate that the differences between this condom and the predicate condom device does not adversely affect the safety and effectiveness of the device in its intended use.

J. Technological Characteristics

This condom has many similar characteristics as the predicate condom identified. The condoms described in K980319 are Durex manufactured, shaped natural rubber latex male condoms with silicone lubricant containing 'Zeus' odour masker. The synthetic polyisoprene condom is the same shape and design and uses the same silicone lubricant with 'Zeus' odour masker as the predicate device. The physical properties of the synthetic polyisoprene condom conform to relevant sections of domestic and international regulations: ASTM D3942-03, ISO 4074:2002 and ASTM D6324-05. Physical testing and final release testing revealed results in conformance with required specifications.

The synthetic polyisoprene material used to manufacture these condoms is also the same material used for the production of the predicate device, Biogel Skinsense PI surgical gloves, which are currently marketed in the USA.

The advantages of synthetic polyisoprene over natural rubber latex are the consistency of the synthetically derived material in comparison with the typical variation found in natural polyisoprene, low levels of impurities in the synthetic material and absence of natural rubber latex proteins.

K. Clinical and non clinical performance data.

Physical testing of the condom demonstrates that it meets performance standards for natural rubber condoms, which have been safely marketed worldwide for many years. This condom has also been tested in line with the requirements of the ISO10993 standard on Biological Evaluation of Medical Devices, FDA Guidance Memorandum G95-1 (1995) and FDA guidance for testing of male condoms made from new material. Results of all these biocompatibility studies support the safety of the device. Additional viral penetration studies have also been conducted with acceptable results.

A consumer user evaluation study was undertaken on the Durex synthetic polyisoprene condom in comparison with Durex natural rubber and polyurethane condoms in the UK and Italy during 2004 with favourable results for the new condom.

Subsequently a clinical investigation was conducted in 2007, in line with US FDA guidelines for clinical studies on synthetic condoms (Testing Guidance for Male Condoms made from New Material, June 29, 1995). The study was a randomised, cross over, home use study using the predicate device, (K980319 Durex Ultra Comfort condom) as the control condom. The study found no significant difference between the study condom and control condom with respect to clinical breakage or clinical slippage.

The Durex synthetic polyisoprene condom has already been launched in other markets worldwide with a low incidence of consumer complaints in these countries.

In conclusion it is considered that the Durex synthetic polyisoprene condom is as safe and effective, and performs at least as well as the predicate condom.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 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: K072169
Trade/Devices Name: SSL Synthetic Polyisoprene Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: May 16, 2008
Received: May 23, 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

I.3 Indications for Use

510(k) Number (if known): ~~Not known.~~ K072169

Device Name: Durex synthetic polyisoprene male condom

Indications for Use:

The Durex synthetic polyisoprene male condom is 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) AND/OR Over-The-Counter Use ____X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K072169