II. 510(k) SUMMARY

Submitted by: Ansell Healthcare Products LLC
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USA

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Date Prepared: December 13, 2006

Proprietary Name: LifeStyles Lubricated Polyisoprene Latex Male Condom

Common Name: Male latex condom

Classification Name: Condom (21 CFR 884.5300)

Predicate Device: Suretex Ltd., Latex Condoms with Silicone Oil Lubricant
510(k) Document Control Number K941258

Description of the Device:
The LifeStyles condom is a male contraceptive and prophylactic device fabricated from synthetic rubber polyisoprene latex with a lubricant coating. The condom is a fitted sheath with an integral ring at the open end and a reservoir (nipple-end) at the closed end to contain semen. The condom has a nominal length of 185 mm and nominal width of 53 mm. The condom is designed to conform to established national and international voluntary standards including ASTM D3492 Standard Specification for Rubber Contraceptives (Male Condoms) and ISO 4074:2002Cor.1:3002(E): Natural Latex Rubber Condoms – Requirements and Test Methods, Technical Corrigendum.

Intended Use of the Device:
The condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs).

Technological Characteristics:
The basic technological characteristics of the LifeStyles condom are the same as the predicate condom. The LifeStyles condom and the predicate condom are of the same basic design; both are straight-walled, nipple-ended, lubricated condoms with an integral ring at the open end. The condom design conforms to national

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and international standards: ASTM D3492 Standard Specification for Rubber Contraceptives (Male Condoms) and ISO 4074:2002Cor.1:3002(E): Natural Latex Rubber Condoms – Requirements and Test Methods, Technical Corrigendum.

Conclusion:

Based on intended use and technological characteristics, the LifeStyles condom is substantially equivalent to the predicate device; the Suretex Ltd. Latex Condom with Silicone Oil Lubricant (K941258).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2008

Mr. Lon McIlvain
Vice President, Regulatory Affairs Global
Ansell Healthcare Products LLC
1635 Industrial Road
DOTHAN AL 36303

Re: K070800
Trade/Device Name: LifeStyles Lubricated Polyisoprene Latex Male Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: January 25, 2008
Received: January 28, 2008

Dear Mr. McIlvain:

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

INDICATIONS FOR USE

510(k) Number: K070800

Device Name: LifeStyles Lubricated Polyisoprene Latex Male Condom

Indications for Use:

The LifeStyles Lubricated Polyisoprene Latex Male Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases, STDs).

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Per 21 CFR §801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070800