K030176

II. *510(k) SUMMARY*

APR 1 7 2003

Submitted by: Ansell Healthcare Inc.
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Dothan, AL 36303
USA

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Date Prepared: January 15, 2003

Proprietary Name: LifeStyles, Contempo or private label –
Latex Condom with Male Genital Desensitizer Lubricant

Common Name: Latex condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device: Suretex Prophylactics (India) Limited, Royale Brand Latex Condoms (Silicone) Natural or Assorted Colors
510(k) Document Control Number K983320

Suretex Ltd., Latex Condoms with Spermicidal Lubricant (Natural or Assorted Colors)
510(k) Document Control Number K942858

Description of the Device:

These condoms are male contraceptive and prophylactic devices fabricated of natural rubber latex with lubricant containing Benzocaine, an over-the-counter drug generally recognized as safe and effective by the U.S. FDA as a male genital desensitizer (21 CFR Part 348 – External Analgesic Drug Products for Over-the-Counter Human Use). The condoms are designed as fitted sheaths with an integral ring at the open end and a reservoir at the closed end to contain semen. These condoms are designed to conform to established national and international voluntary standards including ASTM D3492, ISO 4074 and EN 600.

Intended Use of the Device:

These condoms have the same intended use as the predicate condoms. The condoms are used for contraception and for prophylactic purposes. Additionally, the male genital desensitizer lubricant on the condom helps in temporarily prolonging the time until ejaculation. If used properly, these condoms will help reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. In addition, these condoms will help reduce the risk of pregnancy without the serious side effects sometimes associated with other methods. However, no contraceptive can guarantee 100% effectiveness. Failure to use as directed may further result in loss of protection. Furthermore, sexually transmitted diseases can be transmitted through lesions and various body fluids during intimate contact. Therefore, the condoms should be applied before any such contact.

Technological Characteristics:

The basic design, composition (natural rubber latex) and manufacture of these condoms are the same as the predicate male latex condoms. The condom design conforms to national and international regulations: ASTM D3492, ISO 4074 and EN 600. Accordingly, when compared to the predicate male latex condoms, the condoms intended to be introduced do not incorporate any significant changes in intended use, method of operations, materials, or design that could affect safety and effectiveness. The proposed condom is a modification of the predicate device in that the condoms differ only in the lubricant applied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cynthia A. Ingram
Regulatory Affairs Administrator
Ansell Healthcare, Inc.
1500 Industrial Road
P.O. Box 1252
DOTHAN AL 36302

APR 1 7 2003

Re: K030176
Trade/Device Name: Male Latex Condom with Desensitizing Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: January 15, 2003
Received: January 17, 2003

Dear Ms. Ingram:

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.

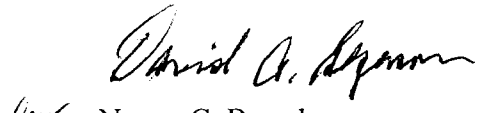
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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,



for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number: ~~None assigned as of this time~~
K030176

Device Name: LifeStyles, Contempo or private label –
Male Latex Condom with Desensitizing Lubricant

Indications for Use:

The LifeStyles, Contempo or private label Male Latex Condom with Desensitizing Lubricant is a male contraceptive device, fabricated of latex, which is designed to completely cover the penis during sexual intercourse. Additionally, the male genital desensitizer lubricant on the condom helps in temporarily prolonging the time until ejaculation. This condom is intended to be used for contraceptive and prophylactic purposes. If used properly, this condom will help reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. In addition, this condom will help reduce the risk of pregnancy without the serious side effects sometimes associated with other methods. However, no contraceptive can guarantee 100% effectiveness. Failure to use as directed may further result in loss of protection. Furthermore, sexually transmitted diseases can be transmitted through lesions and various body fluids during intimate contact. Therefore, the condom should be applied before any such contact.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030176