AUG 19 1999

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II. 510(k) SUMMARY

Submitted by:

Suretex Prophylactics (India) Limited
74-91, KIADB Industrial Estate
Jigani II Phase, Anekal Taluk
Bangalore – 562 106
India
Telephone: 91-80-426-222
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Contact Person: Dr. V. V. Ramana Rao

Date Prepared: June 2, 1999

Proprietary Name: Ansell trade names (LifeStyles, Midnight) or private label – silicone lubricated – black color

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

Sime Health Ltd., Lubricated (Silicone) Latex Condom (Coloured)
510(k) Document Control Number K932983

Description of the Device:

This condom is a male contraceptive and prophylactic device which is fabricated of a natural rubber latex. The condom is designed as a fitted sheath with an integral ring at the open end and a reservoir at the closed end to contain semen. This condom is designed to conform to established national and international voluntary standards including ASTM D3492, ISO 4074, and EN 600.

Intended Use of the Device:

This condom has the same intended use as the predicate condoms. The condom is used for contraception and for prophylactic purposes. 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 design, composition (natural rubber latex) and manufacture of this condom are the same as the predicate male latex condoms except for the pigment used for coloring the product. The condom design conforms to domestic and international regulations: ASTM D3492, ISO 4074, and EN 600. All physical testing, air inflation testing, colorfastness testing, including other in-process and final release testing, revealed results in conformance with required specifications.

The High Purity Furnace Black (CAS Reg. No. 1333-86-4)™colorant supplied to Ansell and/or Suretex was approved effective May 9, 1997 as a colorant for polymers (CFR §178.3297). This black colorant is formulated into an aqueous dispersion called Permablak 2949 for use in coloring the compounded latex formulation.

Biocompatibility testing of the finished condom has been conducted in conformance with test methods of ISO 10993 Biological Evaluation of Medical Devices and ODE Guidance Memorandum G95-1 dated May 1, 1995, for a Device in Contact for 24 hours or less with a Skin/Mucosal Membrane Surface. The condom is not toxic (local or systemic), sensitizing, locally irritating or otherwise harmful.

Therefore, when compared to the predicate male latex condoms, the condom did not incorporate any significant changes in intended use, method of operations, materials, or design that could affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Suretex Prophylactics (India) LTD.
c/o Mr. Lon D. McIlvain
Quality Assurance/Regulatory Manager
Ansell Healthcare Products Inc.
1500 Industrial Road
Post Office Box 1252
Dothan, Alabama 36302

Re: K992081
LifeStyles® and Tuxedo® Black Color Male Latex Condoms
Dated: June 18, 1999
Received: June 21, 1999
Regulatory Class: II
21 CFR §884.5300/Procode: 85 HIS

Dear Mr. McIlvain:

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 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,

CAPT. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K992081

INDICATIONS FOR USE STATEMENT

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

Device Name: Various Ansell or private label tradename
male latex condoms with silicone lubricant – black color

Indications for Use:

The Ansell or private label black condom is a male contraceptive device, fabricated of latex, which is designed to completely cover the penis during sexual intercourse. 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992081