

K983320

DEC 11 1998

Exhibit #1
2 pages

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The assigned 510(K) number is : _____.

1. Submitter's Identification:

Suretex Prophylactics (India) Limited
74-91, KIADB Industrial Estate,
Jigani II Phase, Anekal Taluk
Bangalore - 562 106
Tel - 91-80-426 222
Fax - 91-80-426 219

Date summary Prepared: 10th September 1998.

2. Name of the Device:

Latex Condoms - silicone lubricated - Natural and assorted colors in Royale brand or in any other private label.

3. Predicate Device Information:

Suretex Ltd., K# 942858A, Latex condoms with Spermicidal Lubricant.
Sime Health Ltd., K# 932982, Spermicidal lubricated condoms
(Essential, Mi Vida and Jiffi).

4. Device Description

A condom with silicone lubricant is a sheath which covers the penis with a closely fitted membrane

5. Intended Use

The intended use of this condom is for contraception and prophylactic purposes (preventing transmission of venereal diseases).

6. Comparison to Predicate Devices:

The Latex condoms in Royale or any other private label - Silicone lubricated natural colored or assorted colors, will be identical in all aspects to the Suretex Ltd. Latex Condoms with silicone Lubricant and similar in design, composition (latex) and function to the silicone lubricated condoms of Sime Health Ltd.

The Following voluntary standards were adhered to and their device was tested in accordance with all requirements of these standards.

- a. ASTM D3492-96
- b. ISO 4074, part 1 and part 6
- c. May 1, 1995 FDA biocompatibility guidance, FDA modified matrix of ISO - 10893.

All Physical testing, air inflation testing and color fastness testing, including all other in-process, and final release testing, revealed results that conformed to the required specifications. In addition, a shelf life of 5 years is claimed, with real-time testing data to support such claim.

8. Discussion of clinical tests performed

Not applicable.

9. Conclusions

The Royale latex condoms or any private labelled condoms – silicone lubricant - natural colored and assorted colors - to be sold by Suretex Prophylactics (India) Ltd, has the same intended use and similar technological characteristics as that of Sime Health Ltd. Condoms and identical technological characteristics as that of Suretex Ltd. Condom. All non-clinical testing and biocompatibility testing revealed no new questions of safety or effectiveness. Thus, when compared to the predicate devices, the Royale brand condoms or any other private labelled condoms - silicone lubricant - colored and assorted colors did not incorporate any significant changes in intended use, method of operations, material, or design that could effect safety or effectiveness.



DEC 11 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. V.V. Ramana Rao
Senior Manager QA and R&D
Suretex Prophylactics (India) Limited
74-91, KIADB Industrial Estate
Jigani II Phase, Anekal Taluk
Bangalore - 562 106

Re: K983320
Royale®Brand Latex Condoms (Silicone)Natural
or Assorted Colors
Dated: September 10, 1998
Received: September 21, 1998
Regulatory Class: II
CFR 884.5300/Procode: 85 HIS

Dear Dr. Ramana Rao:

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 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number (if known): K983320

Device Name: Royale Brand Latex Condoms Silicone Lubricant Colored -
Or Assorted Colors

Indications For Use:

The intended use of this condom is for contraception and prophylactic purposes (preventing transmission of venereal disease).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Segeman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K983320