

K971132

P192

**510(K) SUMMARY**

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

The assigned 510(k) number is: \_\_\_\_\_.

SEP - 3 1997

**1. Submitter's Identification:**

G. Premjee (USA) Inc.  
304 B East Lawrence Blvd.  
Avondale, Arizona 85323

Date Summary Prepared: March 26, 1997

**2. Name of the Device:**

Royale<sup>®</sup> Brand Latex Condoms - (Silicone)- Colored and Assorted Colors

**3. Predicate Device Information:**

Suretex Ltd., K#910284, Latex Rubber Condoms (Silicone)  
Sime Health Ltd., K#932983, Lubricated (Silicone) Latex Condoms (Colored)  
(Essential<sup>™</sup>, Mi Vida<sup>™</sup> and Jiffi<sup>™</sup>).

**4. Device Description:**

A condom is a sheath which completely covers the penis with a closely fitting 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 Royale<sup>®</sup> Brand Latex Condoms - (Silicone) - Colored or Assorted Colors, is identical in all aspects to the Suretex Ltd. Latex Rubber Condoms (Silicone) and similar in design, composition (latex) and function to the Sime Health Ltd. Lubricated (Silicone) Latex Condoms (Colored).

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

- a. ASTM-D-3492-96
- 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<sup>®</sup> Brand Latex Condoms - (Silicone) - Colored and Assorted Colors has the same intended use and similar technological characteristics as the Sime Heath Ltd. Condom and identical technological characteristics as the 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<sup>®</sup> Brand Latex Condoms - (Silicone) - Colored and Assorted Colors did not incorporate any significant changes in intended use, method of operations, material, or design that could affect safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

G. Premjee (USA), Inc.  
c/o Ms. Susan D. Goldstein-Falk  
mdi Consultants, Inc.  
55 Northern Boulevard, Suite 410  
Great Neck, New York 11021

SEP - 3 1997

Re: K971132  
Royale® Brand Latex Condoms (Silicone)  
Colored or Assorted Colors  
Dated: July 28, 1997  
Received: July 30, 1997  
Regulatory class: II  
21 CFR §884.5300/Product code: 85 HIS

Dear Ms. Goldstein-Falk:

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 requirement, 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/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): \_\_\_\_\_

Device Name: Royale ® Brand Latex Condoms (Silicone) - 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)

Robert R. Sathiy  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K971132

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use