II. 510(k) SUMMARY

Submitted By: Shanghai Latex Factory

1700, Huangxing road, Shanghai, China, 200433

Telephone: 0086-021-55090975

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Contact Person: Mr. Lou Ji

Date Prepared: December 20, 2004

Proprietary Name: Tulip Condom

Common Name: Latex Male Condom

Classification Name: Condom (21 CFR 884.5300)

Predicate Device: Latex Condom

510(k) #K[994118]

Description of Device: This condom is made of a natural latex sheath, which completely covers the penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip, nominal length 180mm, nominal width 52mm, and nominal thickness 0.05mm. It is lubricated with silicon, with cornstarch as a dressing material. The condom is offered in natural latex color and is designed to conform to established American and international voluntary standards including ASTM D3492-02 and ISO 4074-1:1996.

Intended Use of the Device: This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases. If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. In addition, this condom will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

Technological Characteristics: This condom has the same technological characteristics as the predicate condom identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and that the condom is made of natural rubber latex. Accordingly, when compared to the predicate device, the tulip condom intended to be introduced does not incorporate any significant changes in the intended use, method of operation, materials, or design that could affect safety and effectiveness.

Feature	Tulip Condom	Predicate Device
Length (mm)	180	180
Width (mm)	52	52
Thickness (mm)	0.05	0.05
Air Burst Pressure(kPa)	2.3	2.4
Air Burst Volume (dm^3)	38.5	36
Lubricant System	Silicone	Silicone
Reservoir Tip	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2005

Shanghai Latex Factory
% Ms. Laura L. Danielson
Responsible Third Party Official
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K050360
Trade/Device Name: Tulip Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: February 11, 2005
Received: February 14, 2005

Dear Ms. Danielson:

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 (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 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 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" (21 CFR 807.97). 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 (301) 443-6597 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

VII. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K050360

Device Name: Tulip Condom

Indications For Use: The Tulip condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Prescription Use _____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050360