510(k) SUMMARY

K081413

OCT 24 2008

Submitters Name and Address:
Dalian Latex Company, LTD.
No. 188 Malan North Street
Shahekou District
Dalian City, Liaoning Province
China 116021

Contact Person:
Mrs. Chunli Zhao

Date Prepared:
January 19, 2008

Proprietary Name:
Twinlotus
Shields

Common Name:
Male Latex Condom

Classification Name:
Condom

Predicate Device:
Durex condom

Description of Device:

This condom is made of high quality natural rubber latex, which completely covers the penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip ; nominal length 160mm, nominal width 52 +/- 2mm, and nominal thickness 0.07 +/- 0.01mm. It is lubricated with methyl silicone and white carbon black is used as a dressing material. The condom is colored and flavored, and designed to conform to the latest national and international voluntary standards including ISO 4074 、 ISO 10993 and ASTM D3492.
The condoms will be offered in a variety of colors and flavors. The condoms also are offered in ribbed and studded configurations.

Intended Use of Device:

The Twinlotus or Shield condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of 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 D3492 and ISO 4074.And the condom is made from the same natural rubber latex. Accordingly, when compared to the predicate device, the Twinlotus and Shield condom intended to be introduced does not incorporate any significant changes in the intended use, method of operations, materials, or design that could affect safety and effectiveness.

Substantially Equivalence Statement

The Dalian twinlotus and shield condoms are of the same materials, have undergone the same testing and are substantially equivalent to the Durex flavored condoms, K032227.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dailian Latex Co., Ltd.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

OCT 24 2008

Re: K081413
Trade/Device Name: "TWINLOTUS" and "SHIELD" Male Natural Rubber Latex Condom (with Coloring and Flavoring)
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: October 8, 2008
Received: October 9, 2008

Dear Mr. Job:

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 (PMA), 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081413

Device Name: TWINLOTUS and SHIELD Male Natural Rubber Latex Condom (with Coloring and Flavoring)

The condoms will be offered in the following type, color and flavor,

Available types:

Type	*Color*	*Flavor*
Plain	Red	Banana
Dotty	Yellow	Strawberry
Ribbed	Green	Orange
Combination	Blue	Chocolate
	Violet	Mint
	Black	Vanilla
	Orange	Juicy Peach
		Pineapple
		Apple
		Cherry

Indications For Use: The Twinlotus or Shield condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

Prescription Use _____ **AND/OR** **Over-The-Counter Use** X

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081413