K080833

Abbreviated 510(k) for "Love Guard" Male Latex Condom

AUG - 7 2008

510(K) Summary for "Love Guard" Male Latex Condoms

Submitted by: Tianjin Human-care Latex Corporation
No 223, West 14 Road
Tianjin Airport Industrial Park
300308 Tianjin
People's Republic of China

Tel: 86-22-6045-7598
Fax: 86-22-6045-7578

Contact Person: Mr. Pine Stone
Director, International Trade Department
Tianjin Human-care Latex Corporation
No 223, West 14 Road
Tianjin Airport Industrial Park
300308 Tianjin
People's Republic of China
Office phone: 86-22-6045-7598

Date Revised: July 31st 2008

Proprietary Name: "Love Guard" Male Latex Condom

Common Name: Male Latex Condom

Classification Name: Condom (21 CFR §884.5300)

Predicate Device: "Lifestyles" Male Latex Condom
Ansell Healthcare Products, LLC
510(k) Document Control Number: K010371

Description of the 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. Its nominal length is 185 - 190 mm, nominal width 50.5 – 51.5 mm, and nominal thickness 0.06 – 0.08 mm. It is offered in natural latex color and lubricated with polydimethylsiloxane (silicone) with cornstarch as the

dressing material. This condom is designed to conform to established American and international voluntary standards including ASTM D3492 and ISO 4074.

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

Technological Characteristics: This condom has the same technological characteristics as the predicate condom identified above. This condom is made of natural latex. Its design is in conformance with ASTM Latex Condom Standard D3492. The "Love Guard" Male Latex Condom to be introduced to the US market is similar to the predicate device in terms of the intended use, method of operation, materials, design, etc. Therefore, there is no significant difference between the "Love Guard" Male Latex Condom and the predicate device in the areas of safety and effectiveness.

The similarities of the features and technological characteristics of "Love Guard" Male Latex Condom in comparison to the predicate condom are summarized as follows:

Features	**"Love Guard" Condom**	**"Lifestyles" Condom**
Length (mm)	185 – 190	182 -190
Width (mm)	50.5 – 51.5	51 - 52
Thickness (mm)	0.06 – 0.08	0.05
Air burst pressure (kPa)	1.35 – 2.55	0 - 2.85
Air burst volume (dm^3)	20.0 – 58.5	0 - 47
Package materials	Aluminum foil	Aluminum foil
Lubricant system	Polydimethylsiloxane (silicone) Viscosity: 300 mPa.S	Glycerin-based
Dusting agent	Cornstarch	Cornstarch
Reservoir tip	Yes	Yes

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VII. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: "Love Guard" Male Latex Condom

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Tianjin Human-Care Latex Corporation
c/o Simon Li, MD, PhD
Lift International, Inc.
56 Danville Drive
WEST WINDSOR NJ 08550

Re: K080833
Trade Name: "Love Guard" Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Male Latex Condom
Regulatory Class: II
Product Code: HIS
Dated: June 10, 2008
Received: June 12, 2008

Dear Dr. Li:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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,

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080833