MAY 15 2002 K020633

L S RUBBER SDN. BHD. (247757-A)

PLO 22, Senai Industrial Estate, Phase 1, 81400 Senai, Johor, Malaysia.
Tel : 607-599 3923 (5 Lines) Fax : 607-599 3797 E-mail: lsrsb@po.jaring.my

NOTE : *Provide the information required by 21 CFR 807.92, content and Format for a 510(k) summary (Option 1), below*
OR
the 510(k) Statement (Option 2) on the next page.

II. 510(k) SUMMARY (Option I)

[Refer to 21 CFR 807.92]

Submitted by:	LS Rubber Sdn. Bhd Plo 22, Senai Industrial Estate, Phase 1, 81400 Senai, Johor. 607-5993923.
Contact Person :	Mariza Marzih
Date Prepared :	25th October, 2001.
Proprietary Name:	Natural Rubber Latex Condoms.
Common Name :	Latex Condom
Classification :	Condom (21 CFR 884.5300)
Predicate Device :	Natural and colored latex condoms with flavors.

Description of the Device : This condom is made of a natural rubber sheath, which completely covers the penis with a closely fitted membrane. This condom has smooth or textured surface, parallel-sided ,reservoir ended condoms with an integral bead at the open end. The nominal length is minimum 180 mm, the width is 52 or 53 +/- 2 mm and 0.03 mm minimum for the thickness.

Intended Use of The Devices : 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.

Technological Characteristics : The condom has the same technological characteristic as the predicate condom 510(K) # K980964. The only modification is to delete the brand names present in the 510(K) # K980964 and to add the new flavors which are approved by the Food and Drug Authority USA and listed in the FEMA GRAS list.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2002

Ms. Mariza Marzih
LS Rubber SDN.BHD.
PLO 22, Senai Industrial Estate
Phase 1, 81400 Senai, Johor
MALAYSIA

Re: K020633
Trade Name/Device: Natural & Colored Condoms with Flavors
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: April 23, 2002
Received: April 30, 2002

Dear Ms. Marzih:

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 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). 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.

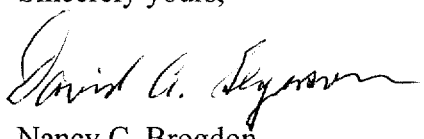
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. 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, 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/dsma/dsmamain.html".

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K020633

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VII. INDICATIONS FOR USE STATEMENTS

510(k) Number: K020633

Device Name: Colored Latex Condom with Flavored Lubricant.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segarra

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020633

Prescription Use _____ OR over-the-counter Use ✓

(Per 21 CFR 801.109)