K041837

SEP 2 4 2004

II. 510(k) SUMMARY

Submitted By:

Innolatex SDN, BHD.
Lot 594, Persiaran Raja Lumu,
Pandamaran Industrial Estate
42000 Port Klang, Selandgor Darul Ehsan
Malaysia

Contact Persons:

Eli J. Carter
Technical Consultant
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Mr. Goh Miah Kiat
General Manager
Innolatex SDN, BHD

Date Prepared: June 30, 2004

Proprietary Name: N/A

Common Name: Male Latex Condom

Classification Name: Male Latex Condom

Predicate Devices: Thai Nippon Male Latex Condom: K011253
UNIDUS Male Latex Condom: K023175

Description of Device: This condom is made of a natural latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is straight-walled or contoured with a reservoir tip; nominal length 180mm, nominal width 52mm, and nominal thickness 0.06mm. It is lubricated with silicone and cornstarch is used as a dressing material. This condom is colored and flavored, and designed to conform to established national and international voluntary standards including ASTM D3492 and ISO 4074.

Condoms will be offered in the following Color and Flavor Combinations:

	Color	Flavor
1.	Yellow	Banana
2.	Red	Strawberry
3.	Green	Mint
4.	Black	Chocolate

Intended Use of the Device:

This latex condom has the same intended use as the predicate condoms. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

Technological Characteristics:

This condom has the same technological characteristics and uses the same color pigments and flavorings (scents) as the predicate condoms identified above. The following Table provides a description of these colors and flavorings. The design of this condom is in conformance with ASTM Latex Condom Standard D3492 and the condom is made of natural rubber latex.

Color Pigment	CI No	CAS No.
Colanyl Yellow FGL 130	19140:1	12225-21-7
Colanyl Red FGRG 100	15850:1	N/A
Colanyl Green GG 131	77289	12001-99-9
Colanyl Brown BM 100-ID	77499	1317-61-9

Flavorings	Description
Banana	Banana Flavor Concentrate #8500
Strawberry	Strawberry Flavor Concentrate #4837
Mint	Peppermint Flavor Oil #4608
Chocolate	Chocolate Flavor Oil #2141

The base formula was evaluated and confirmed to be in conformance with ISO 10993 biocompatibility requirements for cytotoxicity, and sensitization. The color pigments and flavorings have also been evaluated as part of the Predicate Device formulations and have been confirmed to be compliant with ISO 10993; and compliant with acceptable limits for oral toxicity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2004

Innolatex SDN, BHD.
c/o Mr. Eli J. Carter
Technical Consultant to Innolatex
1219 Little Creek Road
DURHAM NC 27713

Re: K041837
Trade/Device Name: Male Natural Rubber Latex Condom (with Coloring & Flavoring)
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: June 30, 2004
Received: July 7, 2004

Dear Mr. Carter:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. 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,

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

Indications for Use

510(k) Number: K041837

Device Name: Male Natural Rubber Latex Condom (with Coloring & Flavoring)

Indications for Use: The Innolatex 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 ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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