

MAY 8 2007

II 510(k) SUMMARY

Submitted by : Karex Industries Sdn. Bhd.
PTD. 7906 & 7907
Taman Pontian Jaya,
Bt. 34 Jalan Johor,
82000 Pontian,
Johor, Malaysia.

Contact Persons : Mr. Leng Kian Goh Mary Goh
General Manager Quality Assurance Manager
Karex Industries Sdn. Bhd. Karex Industries Sdn. Bhd.
E-mail: lk@karex.com.my mary@karex.com.my

Date Prepared : March 7, 2007.

Proprietary Name : N/A.

Common Name : Male Latex Condom

Classification Name : Male latex Condom

Predicate Device : Latex Lubricated Condom
Innolates Sdn. Bhd.
510(k) Number = K041837

Description of Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. This condom is straight walled, contoured or flared with a reservoir tip; nominal length 180mm, nominal width 53mm, and nominal thickness 0.06mm. It is lubricated with silicone and cornstarch is used as a dressing material. The 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.	Brown	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 use 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 Pigments	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

MAY 8 2007

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Leng Kian Goh
General Manager
Karex Industries Sdn. Bhd.
PTD. 7906 & 7907 Taman Pontian Jaya
Bt. 34, Jalan Johor
82000 Pontian
JOHOR MALAYSIA

Re: K070830
Trade/Device Name: Non-spermicidal Lubricated Male Latex Condom
Colored and Scented
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 7, 2007
Received: March 26, 2007

Dear Mr. Goh:

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.



Protecting and Promoting Public Health

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.

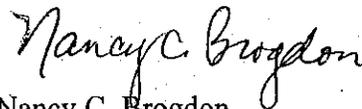
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VII INDICATIONS FOR USE STATEMENT

510(k) Number ~~Not Known~~ K070830

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

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

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070830