FEB - 6 2009

K081886

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
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Mary Goh
Quality Assurance Manager
Karex Industries Sdn. Bhd.
mary@karex.com.my

Date Prepared : December 9, 2008.

Proprietary Name : N/A.

Common Name : Male Latex Condom

Classification Name : Male latex Condom

Predicate Devices :

Latex Lubricated Condom
Innolatex Sdn. Bhd.
510(k) Number = K012962 (Dotted Condoms)
510(k) Number = K010919 (Ribbed Condoms)
510(k) Number = K053367 (Non Lubricated Condoms)

Karex Industries Sdn. Bhd.
510(k) Number=K070830 (Colored and Flavored Condoms)

Dongkuk Techco Rubber Industries
510(k) Number = K002060 (Ribbed, Dotted & Contoured)

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 sided or contoured , textured or non textured ,with a reservoir tip; nominal length 180mm, nominal width 53mm, and nominal thickness 0.07mm. It is non-lubricated or lubricated with silicone and cornstarch is used as a dressing material. The condom is either colored or non colored, flavored or non 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 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	11767	12225-21-7
Colanyl Red FGRG 100	15850:1	N/A
Colanyl Green GG 131	77260	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

FEB - 6 2009

Ms. Mary Goh
QA Manager
Karex Industries SDN. BHD.
PTD. 7906 & 7907
Taman Pontian Jaya
Bt. 34 Jalan Johor,
82000 Pontian, Johor
MALAYSIA

Re: K081886
Trade/Device Name: Male Natural Rubber Latex Condom
(Straight sided or Contoured in shape, either Textured or Non-Textured, Lubricated or Non-Lubricated, Non-colored or Colored and Flavored or Non-Flavored)
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: January 22, 2009
Received: January 26, 2009

Dear Ms. 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 (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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting 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 K081886

Device Name Male Natural Rubber Latex Condom .
(Straight sided or Contoured in shape, either Textured or Non-Textured, Lubricated or Non-Lubricated, Non-colored or Colored and Flavored or Non-Flavored).

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 X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081886