K050913

III. 510(k) SUMMARY

APR 4 2006

Submitted by:

Dick's Formalwear, LLC
3507 W. Bethany Home Road
Phoenix, AZ 85019
480-659-1146

Contact Person: Curt Strenk

Date Prepared: April 7, 2005

Proprietary Name: Dick's Formalwear® Male Latex Condoms

Common Name: Male Latex Condom

Classification Name: Condom

Description of the Device: These condoms are made of a high quality natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. These three types of condoms (plain, ribbed, and dotted), have a nominal length of 180 mm, nominal width of 54 mm, and a nominal thickness of 0.05 mm. They are all lubricated with a silicone lubricant and have a reservoir tip for extra safety. The condoms are also printed on the exterior of the latex with a graphic design per section 11.1 of ISO 4074:2002 and have passed toxicity and biocompatibility testing.

Intended Uses of the Device: These condoms are to be used for contraception and for prophylactic purposes. they are also intended to help prevent pregnancy and the transmission of sexually transmitted diseases, including human immunodeficiency virus (HIV).

Technological Characteristics: These condoms have the same technological characteristics as condoms that are currently distributed throughout the USA. They are designed in conformance with ASTM Latex Condom Standard D3492 with an AQL of 0.25. These condoms are made of high quality natural rubber latex. Each condom is electronically tested. They are manufactured, in recognition of ISO 4074:2002, under established and implemented air burst requirements as part of good manufacturing practice procedures. The results of air burst testing yielded an AQL of 1.0. These condoms conform to domestic and international standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Mr. Curt Strenk
Managing Member
Dick's Formalwear, Inc.
3507 W. Bethany Home Road
PHOENIX AZ 85019

Re: K050913
Trade Name: Dick's Formalwear® Male Latex Condoms
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: March 22, 2006
Received: March 23, 2006

Dear Mr. Strenk:

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.

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

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

Enclosure

K050913

VIII. INDICATIONS FOR USE STATEMENT

Device Name : Dick's Formalwear® Male Latex Condoms

Indications for Use: Dick's Formalwear® Male Latex Condoms is to be used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases, including human immunodeficiency virus (HIV)).

Prescription Use _____ OR Over-The-Counter Use ✓
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K050913/S002