K051273

AUG 19 2005

II. 510(k) Summary

Submitted by:
Eagle TWE, Inc.
2090 Tucker Industrial Road, Suite A-5
Tucker, GA 30084

Contact Person:
Bill Taffs
Phone (678) 937-0571
Fax (678) 937-9545
E-mail Bill@eagletwe.com

Date Prepared: May 12, 2005

Proprietary Name: Divas Dual Pleasure Male Latex Condom

Common Name: Condom

Classification Name: Condom (Rubber) Contraceptive

Predicate Device:
Durex Warming Pleasure Latex Condom
510K # K042957

KY Warming liquid personal lubricant
510K # K021492

Invigra Male Latex Condom
510K # K991374

Sheer Thin Natural Rubber Latex Condom
510K # K984488

Description of the Device: This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The device is shaped, teat ended, lubricated condom, which is lubricated with a water based warming lubricant. The device is designed to conform to national and international voluntary standards, including ISO 4074 and ASTM D3492, except where noted.

Intended Use of the Device: 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. The warming condom lubricant has the same intended use as the predicate personal lubricants when used as an accessory to a condom. It relieves friction and facilitates ease and comfort of intimate sexual activity.

Technological Characteristics: The latex condom has the same technological characteristics as the predicate condom identified above. The condom described in K042957 are manufactured of natural rubber latex with the same shape as the condoms in this application. The competitor Durex Warming Pleasure condoms are Natural Rubber Latex male condoms with "Warm Sensation" lubricant to help enhance sexual pleasure.

The K-Y Warming liquid (K021492) is a water based, condom compatible personal lubricant which provides a warming sensation. It is of similar composition as the warming lubricant on the Divas condom in this submission.

The condom design conforms to domestic and international regulations: ASTM D3942 and ISO 4074. Physical testing and release testing of the finish product revealed results in conformance with required specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2005

Mr. Bill Taffs
President
Eagle T.W.E., Inc.
P.O. Box 1511
TUCKER GA 30085-1511

Re: K051273
Trade/Device Name: Diva's Dual Pleasure Male Latex Condom with Warming Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: August 8, 2005
Received: August 9, 2005

Dear Mr. Taffs:

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

Divas Male Latex Condom with Warming Lubricant

Premarket Notification [510(k)] application

Indications for Use Statement

510(k) Number: K051273

Device name: Divas Dual Pleasure Latex Condom

Indications for Use: The Divas Dual Pleasure condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases.

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter-Use ✓
(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051273