K051688

510(K) Summary

JUL 12 2006

Applicant: **TRIMENSA PHARMACEUTICALS**
1050 Lawrence Drive
Newbury Park CA 91320 USA
Phone: (805) 499-2446
Fax: (805) 499-4366
Contact: Robin James Ogilvie (ex. 102)
Email: robin@trimensa.com
Date: June 20, 2005

Device: MULTIPLE Trade Name(s):

ForPlay Personal Lubricant(s)

SLIP Personal Lubricant(s)

PrePair Personal Lubricant(s)

- Common name: Personal Lubricant(s)

- Classification name(s): Patient Lubricant
  Product Code: **85 MMS / 21CFR section 880.6375**
  Regulatory Class: **I**

  and

  Condom
  Product Code: **85 HIS / 21 CFR section 884.5300**
  Reguatory Class: **II**

Information supporting the claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic act, with respect to safety and effectiveness is summarized below: For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final ruling on,"510(K) Summaries and 510(K) Statements" (21CFR 807).

New Device Names:	ForPlay	Personal Lubricant(s)
	SLIP	Personal Lubricant(s)
	PrePair	Personal Lubricant(s)

Predicated Devices:

Lifestyles Liquid Personal Lubricant,
Ansell Healthcare, Inc. **K033076**

K-Y Liquid Personal Lubricant
McNeil-PPC, Inc. **K955648**

Technological Characteristics:

ForPlay, SLIP and **PrePair** Personal Lubricant(s) formulations contain ingredients which are **Substantially Equivalent** to the predicate devices submitted Below.

Summary of Technological Characteristics:

The table below compares the technological characteristics of ForPlay, SLIP and PrePair Personal Lubricant(s) to the predicate device brands of: **Lifestyles** Liquid Personal Lubricant, **Lifestyles** Liquid Personal Lubricant with Aloe & Vitamin E, **Lifestyles** Liquid Personal Lubricant Strawberry and **K-Y** Liquid Personal Lubricant.

Feature	ForPlay	SLIP	PrePair	Lifestyles	K-Y Liquid
510(K) #	N/A	N/A	N/A	**K033076**	**K955648**
Manufacturer	TRIMENSA Pharmaceuticals	TRIMENSA Pharmaceuticals	TRIMENSA Pharmaceuticals	Ansell Healthcare, Inc.	McNeil-PPC, Inc
Contains Purified Water	Yes	Yes	Yes	Yes	Yes
Contains Glycerine	Yes	Yes	Yes	Yes	Yes
Contains Cellulose Thickeners	Yes	Yes	Yes	Yes	Yes
Contains Methylparaben	Yes	Yes	Yes	Yes	Yes
Contains Propylparaben	Yes	Yes	Yes	Yes	Yes
Labeled Water soluble	Yes	Yes	Yes	Yes	Yes
Labeled Non-Staining	Yes	Yes	Yes	Yes	Yes
Labeled Condom Compatible	Yes	Yes	Yes	Yes	Yes
Container Material	Plastic	Plastic	Plastic	Plastic	Plastic
Sterile	No	No	No	No	No

Device Description:

"ForPlay, SLIP and PrePair Personal Lubricants" are colorless, odorless, non-sticky, non-greasy, nonirritating water based lubricants. They are water-soluble, high viscosity gels and liquids. Because they are water-soluble, ForPlay, SLIP and PrePair Personal Lubricants are easily rinsed off with water leaving NO residue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 12 2006

Mr. Robin J. Ogilvie
President
Trimensa Pharamaceuticals
1050 Lawrence Drive
NEWBURY PARK CA 91320

Re: K051688
Trade/Device Name: ForPlay, SLIP and PrePair Personal Lubricants
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 6, 2006
Received: June 7, 2006

Dear Mr. Ogilvie:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, 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/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

Indications for Use

510(k) Number (if known): K051688

Device Name: ForPlay: SLIP and PrePair

Indications For Use:

ForPlay, SLIP and PrePair personal Lubricants are medical devices intended for medical purposes to lubricate a body orifice to facilitate entry of diagnostic or therapeutic devices. ForPlay SLIP and PrePair Personal Lubricants are recommended as personal lubricants and are principally intended to supplement the body's natural lubrication, to moisturize and enhance the comfort and ease of intimacy with or without a condom.

Prescription Use NO (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use YES (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)

CONTINUE ON ANOTHER PAGE IF

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051688