K091554

510(k) Summary

Submitter	PharmaPac, LLC 110 Industrial Park Road DeKalb, MS 39328
Contact Person	Tom Otto (601) 743-9771 phone (601) 743-9772 fax
Date Prepared	29 April 2009
Proprietary Name	PharmaPac Personal Lubricant
Common Name	Personal Lubricant
Classification Name	Patient Lubricant
Predicate Device	K-Y® Brand Personal Lubricant (K955648)

AUG 0 7 2009

Description of Device
PharmaPac Personal Lubricant is a water-based personal lubricant formulated to be a non-greasy, non-sticky, non-staining clear gel-like liquid. The water-soluble formula allows this product to be rinsed off with water.

Intended Use
Lubricating Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Technological Characteristics of Device Compared to Predicate
The technological characteristics of the PharmaPac Lubricating Jelly are identical to those of the predicate devices. This includes being formulated with only United States Pharmacopeia (USP) or National Formulary (NF) ingredients, all of which are listed as "Generally Recognized As Safe" (GRAS) with the exception of Hydroxyethyl Cellulose. As also noted in the predicate device, Hydroxyethyl cellulose is listed in the FDA's Inactive Ingredient Guide and has been historically been widely used in many drug products e.g. oral syrups and tablets, also otic and ophthalmic solutions.

Performance Data
Stability of the PharmaPac Lubricating Jelly was confirmed throughout its labeled shelf life (24 Months) by an accelerated stability study for 90 days at 40°C / 75% R.H. and parallel microbial study in accordance with USP standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

PharmaPac LLC
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 0 7 2009

Re: K091554
Trade/Device Name: PharmaPac Personal Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Product Code: NUC
Regulatory Class: II
Dated: July 22, 2009
Received: July 23, 2009

Dear Mr. Job:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting 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): K091554

Device Name: PharmaPac Personal Lubricant

Indications for Use:

Lubricating Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091554