K052974

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	September 12, 2005
Proprietary Name	PharmaPac Warming Liquid Personal Lubricant
Common Name	Personal Lubricant
Classification Name	Patient Lubricant (per 21 CFR § 880.6375)
Predicate Device	K-Y® Warming Liquid Personal Lubricant (K021492)

Description of Device

PharmaPac Warming Liquid is a non-sterile, clear, non-staining, non-greasy, liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity. Warming Liquid Personal Lubricant is not a contraceptive or spermicide. It is compatible with latex condoms.

Intended Use

Warming Liquid Personal Lubricant is primarily intended as a personal lubricant to moisturize, relieve friction, and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, or penile tissue for purposes of lubrication, and moisturization. It is also compatible with latex condoms.

Technological Characteristics of Device Compared to Predicate

The technology involved in this product has no remarkable technological characteristics consisting primarily of water soluble ingredients similar to other lubricants which are currently on the market. A comparison of technological characteristics which demonstrates the substantial equivalence of Warming Liquid Personal Lubricant with the predicate device is summarized in the Table below:

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Comparison of Characteristics

Characteristic / Feature	PharmaPac Warming Liquid Personal Lubricant	K-Y® Brand Warming Liquid (K021492)
Contains Glycerin	Yes	Yes
Contains Thickening Agents	Yes	Yes
Contains Preservative Agents	Yes	Yes
Contains Petroleum based Chemicals	No	No
Container Material	Plastic	Plastic
Sterile	No	No

Performance Data

In-Vivo studies were conducted on Warming Liquid Personal Lubricant by an outside laboratory and demonstrated the Biocompatibility of Warming Liquid Personal Lubricant by the following results.

Dermal Sensitization Study (Guinea Pig) – The product exhibited no evidence being a contact sensitizing agent in albino guinea pigs.

Penile Irritation Study (Rabbit) – Direct administration of this product to the rabbit penis and subsequent macroscopic and microscopic tissue examination showed no significant irritation.

Vaginal Irritation Study (Rabbit) – Repeated Direct administration of Warming Liquid Personal Lubricant to the rabbit vagina and subsequent macroscopic and microscopic tissue examination showed no significant irritation of the vaginal mucosa.

Systemic Injection Study (Mouse) – The product was administered to the animals at a rate of 50mL/kg and the results showed no mortality and was not associated with systemic toxicity.

Studies Condom compatibility were also conducted on Warming Liquid Personal Lubricant by a third-party laboratory which was tested in parallel with the predicate device, as well as positive and negative controls. Multiple trials were made using several brands and varieties of latex condoms were tested.

Leak testing – The condoms which had been coated with the test lubricants exhibited no evidence of being negatively affected by the test lubricants.

Burst testing – Application of the test lubricants showed no significant difference in the treatment groups' results for burst pressure or burst volume.

Tensile testing - No decrease in the break force, ultimate tensile strength, and elongation values of the condoms were noted when comparing the two lubricants.

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In an Accelerated Stability Study the Warming Liquid Personal Lubricant was stored at 40°C and tested at 0, 30, 60, and 90 day intervals. The testing showed that at every testing event the product showed no degradation, and remained within specifications for all attributes. Therefore a 24 month shelf life may be supported by this data.

The testing and evaluation of this formulation has demonstrated scientific evidence that this product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

PharmaPac, LLC
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K052974
Trade/Device Name: PharmaPac Warming Liquid Personal Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): November 12, 2005
Received (Date on orig SE ltr): November 14, 2005

Dear Mr. Job:

This letter corrects our substantially equivalent letter of December 16, 2005.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052974

Device Name: PharmaPac Warming Liquid Personal Lubricant

Indications for Use:

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

Nancy C Brogdon

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