

K070623

510(k) Summary

<u>Submitter</u>	PharmaPac, LLC 110 Industrial Park Road DeKalb, MS 39328	
<u>Contact Person</u>	Tom Otto (601) 743-9771 phone (601) 743-9772 fax	AUG 31 2007
<u>Date Prepared</u>	January 26, 2007	
<u>Proprietary Name</u>	PharmaPac Lubricating Jelly Personal Lubricant	
<u>Common Name</u>	Personal Lubricant	
<u>Classification Name</u>	Patient Lubricant	
<u>Predicate Device</u>	K-Y [®] Brand Lubricating Jelly (K810310)	

Description of Device

PharmaPac Lubricating Jelly is a water-based personal lubricant containing chlorhexidine gluconate and methylparaben as preservatives in a vehicle for glucono delta lactone, glycerin, hydroxyethylcellulose, sodium hydroxide, and purified water.

Intended Use

Lubricating Jelly Personal Lubricant is primarily intended for personal lubrication, and eases insertion of rectal thermometers, enemas, tampons, and diagnostic or therapeutic devices. It is also compatible with latex condoms.

Technological Characteristics of Device Compared to Predicate

The technological characteristics of the PharmaPac Lubricating Jelly are identical to those of the predicate device.

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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 31 2007

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

Re: K070623
Trade Name: PharmaPac Lubricating Jelly
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 16, 2007
Received: August 17, 2007

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 (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.



Protecting and Promoting Public Health

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.

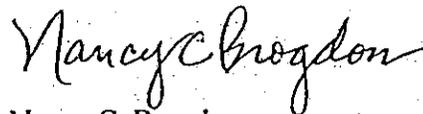
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
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): K070623

Device Name: PharmaPac Lubricating Jelly

Indications for Use:

Lubricating Jelly Personal Lubricant is primarily intended for personal lubrication, and eases insertion of rectal thermometers, enemas, and tampons and similar type nozzles. It is also compatible with latex 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)

JWhe
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070623