510 (k) **Summary**

APR 0 9 2013

Submitter:
Wisconsin Pharmacal Company, LLC
N168 W22223 Main Street
Jackson, WI 53037

Contact Person:
John Nygaard
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(262) 677-7112

Date Submitted:
December 6, 2012

Proprietary Names:
Warming Jelly Personal Lubricant

Common Name:
Personal Lubricant

Classification Name:

21 CFR 884.5300	Lubricant, Personal, Vaginal
Product Code:	NUC
Class:	II
Review Panel:	Obstetrics/Gynecology

Predicate Device:

Device Name:	K-Y® Brand Warming Jelly Personal Lubricant
510(k) Number:	K040164
Product Code:	MMS and HIS

Intended Use:
Warming Jelly Personal Lubricant 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 not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

Description of Device:
Warming Jelly Personal Lubricant is a clear, odorless, non-sterile, water-soluble jelly for use as a personal lubricant. The product imparts a mild warming sensation when applied to the genitalia. Warming Jelly Personal Lubricant can reduce friction during sexual intercourse thereby enhancing sexual intimacy. It is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms as defined by ASTM D7661 - 10

Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Warming Jelly Personal Lubricant is not a contraceptive or spermicide.

Technological Characteristics of the Device:
The Warming Jelly Personal Lubricant formula is proprietary and consists of water-soluble ingredients similar to the identified predicate device.

Warming Jelly Personal Lubricant is substantially equivalent to the identified previously cleared warming jelly personal lubricant predicate with respect to its design and materials, principles of operation, function, formulation, and intended use.

Summary of Non-Clinical Performance Testing:

Biocompatibility Testing: The following biocompatibility testing performed on Warming Jelly Personal Lubricant confirms it is safe for its proposed indication:

- Cytotoxicity evaluation – Direct Contact Method according to ISO 10993-5: 2009
- Maximization Test for Delayed Type Hypersensitivity test according to ISO 10993-10:2010
- Vaginal Irritation Test according to ISO 10993-10:2010
- Acute System Toxicity Test according to ISO 10993-11:2006

Condom Compatibility Testing: Condom compatibility testing as defined by ASTM D7661-10 Standard Test Method demonstrates that Warming Jelly Personal Lubricant is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

Stability Testing: Currently available stability data confirms a shelf life of 12 months for Warming Jelly Personal Lubricant.

Quality Control Release Testing: Lot release testing of Warming Jelly Personal Lubricant includes evaluation of appearance/color, odor, viscosity, microbiological safety (standard plate count, absence of gram negative bacteria, absence of Pseudomonas, absence of Staphylococcus, yeast and mold count, absence of Candida albicans), pH, osmolality and water activity.

Conclusion: Based on the information presented in this 510(k) notification, Warming Jelly Personal Lubricant is safe and effective for OTC use for its proposed indications and is substantially equivalent in intended use, formulation, safety, and technological characteristics to the identified predicate device and other similar warming lubricants.

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

April 9, 2013

Wisconsin Pharmacal Company, LLC
% Mr. John Nygaard
Director, Quality and Regulatory
1 Pharmacal Way
JACKSON WI 53037

Re: K123770
Trade/Device Name: Warming Jelly Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 5, 2013
Received: March 7, 2013

Dear Mr. Nygaard:

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 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/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,

Herbert P. Lerner -S

for

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

3.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K123770

Device Name: Warming Jelly Personal Lubricant

Indications for Use:

Warming Jelly Personal Lubricant 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 not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123770