pjur® group

510(k) Summary

(as required by 21 CFR 807.92)

Submitter	pjur group Luxembourg SA
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Date Prepared	June 10, 2014

Trade Name	pjur® group silicone based lubricants: • pjur®Original • pjur®Woman • pjur®MAN Extreme Glide
Common Name	Personal Lubricant
Classification Name	Condom (21 CFR §884.5300, Product Code NUC)
Class	Class II

Predicate Devices	Erozone Glide, K040428 KY® Intrigue Premium Personal Lubricant, K062796 Wet Platinum Premium Lubricant®, K130012

Description	The pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants are non-sterile, silicone-based personal lubricants. These over-the-counter products are formulated to be clear, non-irritating, non-greasy, and odorless. The pjur® silicone based lubricants contains neither a contraceptive nor a spermicide.

Intended Use/Indications for Use	pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide are personal lubricants, for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. These products are compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Technological Characteristics	The pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants contain a blend of silicone fluid ingredients similar to ingredients found in the predicate devices.

Performance Data	Biocompatibility testing was performed in accordance with ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing" including: • Cytotoxicity • Intracutaneous Irritation • Sensitization • Vaginal Irritation and Systemic Toxicity The results of the testing show that the pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants are not cytotoxic, non-sensitizing, non-irritating, and did not show any sign of systemic toxicity or vaginal irritation. Testing per ISO 10993-10: 2010 using the Guinea Pig Maximization Study demonstrated that the subject device produced no signs of allergenic potency. The sensitization rate was 0%. All test results were satisfactory and suport that the subject device poses no undue biocompatibility risk. Condom compatibility testing was performed using the methods outlined in ASTM D7661. Testing results demonstrate that the pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants are compatible with natural latex, polyurethane, and polyisoprene condoms. .

Conclusion	The pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants have the same intended use as that of Erozone Glide, Wet Platinum Premium Lubricant® and KY® Intrigue. The ingredients in the pjur formulation are the same as in the Erozone Glide. The labeling claims of the pjur silicone based personal lubricants are similar to those of the predicates. The labeling of the pjur formulation contains the same warnings and precautions as those in the labeling of the predicates. Any differences that exist between the pjur silicone based personal lubricant formulation and the predicates have no significant effect on the safety or effectiveness. The pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide lubricants are substantially equivalent to other personal lubricant products cleared in the US in terms of biocompatibility, technology, intended use and suitability characteristics.

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

July 18, 2014

Pjur Group Luxembourg SA
Candace Cederman
Consultant
722 Arjean Drive
Wilmington, NC 28411

Re: K133233
Trade/Device Name: Pjur Original, Pjur Woman, Pjur Man Extreme Glide
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 13, 2014
Received: June 16, 2014

Dear Candace Cederman,

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 (21CFR 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 Industry and Consumer Education 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 (21CFR 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 Industry and Consumer Education 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): K133233

Device Name: pjur group silicone based lubricants
- pjur® Original
- pjur® Woman
- pjur® MAN Extreme Glide

Indications for Use:

pjur® Original, pjur® Woman, and pjur® MAN Extreme Glide are personal lubricants, for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. These products are compatible with natural rubber latex, polyurethane, and polyisoprene 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)

Benjamin R. Fisher -S
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