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 6, 2015

pjur group Luxembourg SA
% Cheryl Wagoner
Consultant
Wagoner Consulting LLC
PO Box 15729
Wilmington, NC 28408

Re: K141913
Trade/Device Name: pjur® Backdoor Anal Glide and pjur® Analyse Me!
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: July 14, 2014
Received: July 17, 2014

Dear Cheryl Wagoner,

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 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" (21 CFR 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 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,

Herbert P. Lerner -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141913

Device Name
pjur® Backdoor Anal Glide or pjur® Analyse Me!

Indications for Use *(Describe)*

pjur® Backdoor Anal Glide and pjur® Analyse Me! are personal lubricants for penile, vaginal, and/or anal application intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. These products are compatible with natural rubber latex, synthetic polyisoprene, and polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	pjur group Luxembourg SA
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	Telephone: +352 74-8989
	Fax: +352 74-8990
Contact Person	Patrick Giebel
	Quality Manager
	pgiebel@pjur.com
Date Prepared	2/23/2015

Trade Name	pjur® silicone based lubricant under the brand names of pjur® Backdoor Anal Glide or pjur® Analyse Me!
Common Name	Personal Lubricant
Classification Name	Condom (21 CFR §884.5300, Product Code NUC)
Class	Class II

Predicate Devices	Wet Platinum Premium Lubricant®, K130012

Description	The pjur® Backdoor Anal Glide or pjur® Analyse Me! device is a non-sterile, silicone-based personal lubricant. This over-the-counter product is formulated to be clear, non-irritating, non-greasy, and odorless. The pjur® Backdoor Anal Glide or pjur® Analyse Me! Device is a silicone based lubricant contains neither a contraceptive nor a spermicide. The product contains Cyclopentasiloxane, Dimethicone, Dimethiconol, and jojoba.

Indications for Use	pjur® Backdoor Anal Glide and pjur® Analyse Me! are personal lubricants for penile, vaginal, and/or anal application intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. These products are compatible with natural rubber latex, synthetic polyisoprene, and polyurethane condoms.

Technological Characteristics	The pjur® Backdoor Anal Glide or pjur® Analyse Me! device is a silicone based lubricant that contains a blend of silicone fluid ingredients similar to ingredients found in other lubricants currently on the U.S. markets and substantially equivalent to the predicat device. Both the Subject and predicate devices contain Cyclopentasiloxane, Dimethicone, Dimethiconol. Both devices also contained a plant-derived oil additive that is present in very small amounts and has no impact upon safety or effectiveness. In the case of The pjur® Backdoor Anal Glide or pjur® Analyse Me! device the additive is jojoba which is commonly used in food and cosmetic devices. The additive for Wet Platinum Premium Lubricant®, K130012 is Vitamin E. This plant based additive, as with the Subject device, does not negatively impact risk or biocompatibility. The presence of jojoba oil in the Subject device and Vitamin E in the Predicate device do not raise any new questions of safety or effectiveness nor does it represent a new technology. These products are compatible with natural rubber latex, synthetic polyisoprene, and polyurethane condoms. The intended use of the Subject device is the same as its predicate. Both are intended as non-sterile, over-the-counter personal lubricants. The indications for use for the Subject and Predicate devices are not identical, but are substantially equivalent. Both the Subject device and the predicate are indicated as a personal lubricant for intimate sexual activity and have been fully tested to ensure that there are no new questions of safety or effectiveness related to this usage nor does it represent new technology.

<table>
<tr><td>Performance Data</td><td>Biocompatibility testing was performed in accordance with ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing” including:

<table>
<tr><th>Test Performed</th><th>Results</th></tr>
<tr><td>ISO 10993-5 Cytotoxicity (Direct contact)</td><td>Non-cytotoxic</td></tr>
<tr><td>ISO 10993-10 Guinea Pig Maximization Sensitization test</td><td>No sensitization response.</td></tr>
<tr><td>ISO 10993-10
• Irritation (Direct contact)
• Irritation(Intracutanteous injection)
• Vaginal Irritation (repeat insult)</td><td>Non-irritant</td></tr>
<tr><td>Shelf-Life Testing</td><td>At least 1 year</td></tr>
<tr><td>Viscosity</td><td>600-1000 cps</td></tr>
<tr><td>Density</td><td>0.900-0.950 g/ml</td></tr>
<tr><td>Appearance</td><td>Viscous liquid</td></tr>
<tr><td>Turbidity</td><td>Clear, no turbidity</td></tr>
<tr><td>Color</td><td>Slightly yellow</td></tr>
<tr><td>Odor</td><td>None</td></tr>
<tr><td>Microbial Limits</td><td><100 cfu/g TAMC, <10 cfu/g TYMC, absence of pathogenic organisms</td></tr>
<tr><td>Water Activity</td><td><0.3 A_w</td></tr>
<tr><td>pH and Osmolaltity</td><td>N/A since product is anhydrous</td></tr>
</table>

Condom compatibility testing was performed using the methods outlined in ASTM D7661-10 including burst volume, burst pressure, force of break and elongation until break. Testing results demonstrate that the pjur® pjur® Backdoor Anal Glide or pjur® Analyse Me! device is compatible with natural latex, , polyurethane, and polyisoprene condoms.</td></tr>
</table>

Conclusion	The pjur® Backdoor Anal Glide or pjur® Analyse Me! device has the same intended use as that of its predicate. The ingredients in the pjur formulation are the similar to the Wet Platinum Premium Lubricant, K130012. The labeling claims and indications for use of the pjur® Backdoor Anal Glide or pjur® Analyse Me! device are the similar to those of the predicates. The labeling of the pjur® Backdoor Anal Glide or pjur® Analyse Me! device formulation contains the same warnings and precautions as those in the labeling of the predicate. Any differences that exist between t The pjur® Backdoor Anal Glide or pjur® Analyse Me! device and the predicates have no significant effect on the safety or effectiveness.

	T The pjur® Backdoor Anal Glide or pjur® Analyse Me! device is substantially equivalent to other personal lubricant products cleared in the US in terms of biocompatibility, technology, intended use, indications, and suitability characteristics.