



February 19, 2021

pjur group Luxembourg SA  
% Candace Cederman  
Consultant  
Candace F. Cederman  
722 Arjean Drive  
Wilmington, NC 28411

Re: K200527

Trade/Device Name: pjur® WOMAN Aloe, pjur® med Moisturising glide, pjur® BACK DOOR water-based, pjur® analyse me! water-based, pjur® med NATURAL glide, We-Vibe® Lube made by pjur®

Regulation Number: 21 CFR§ 884.5300

Regulation Name: Condom

Regulatory Class: II

Product Code: NUC

Dated: January 20, 2021

Received: January 21, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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 and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For  
Monica D. Garcia, Ph.D.  
Assistant Director  
DHT3B: Division of Reproductive,  
Gynecology and Urology Devices  
OHT3: Office of GastroRenal, ObGyn,  
General Hospital and Urology Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K200527

### Device Name

pjur® WOMAN Aloe, pjur® med Moisturising glide, pjur® BACK DOOR water-based, pjur® analyse me! water-based, pjur® med NATURAL glide, We-Vibe® Lube made by pjur®

### Indications for Use (Describe)

pjur® WOMAN Aloe is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® med Moisturising glide is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® BACK DOOR water-based is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® analyse me! water-based is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® med NATURAL glide is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

We-Vibe® Lube made by pjur® is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary  
K200527**

<b>DATE PREPARED:</b>	19 February 2021
<b>APPLICANT:</b>	pjur group Luxembourg SA 87 esplanade de la Moselle L-6637 Wasserbillig, Luxembourg Telephone: +352 74-8989 Fax: +352 74-8990
<b>CONTACT:</b>	Andrea Giebel, Quality Management Representative
<b>TRADE NAME:</b>	<ul style="list-style-type: none"> <li>• pjur® WOMAN Aloe</li> <li>• pjur® analyse me! water-based</li> <li>• pjur® BACK DOOR water-based</li> <li>• pjur® med Moisturising glide</li> <li>• pjur® med NATURAL glide</li> <li>• We-Vibe® Lube made by pjur®</li> </ul>
<b>COMMON NAME:</b>	Personal Lubricant
<b>REGULATION NUMBER:</b>	21 CFR 884.5300
<b>REGULATION NAME</b>	Condom
<b>PRODUCT CODE</b>	NUC (Lubricant, Personal)
<b>DEVICE CLASS:</b>	II
<b>PREDICATE DEVICE:</b>	KY Banksy Moisture, K183505  The predicate device has not been subject to a design-related recall.

**DEVICE DESCRIPTION:**

The pjur® WOMAN Aloe, pjur® analyse me! water-based, pjur® BACK DOOR water-based, pjur® med Moisturising glide, pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® are water-based personal lubricants provided non-sterile. These over-the-counter products have similar formulations and contain neither a contraceptive nor a spermicide. The pjur® WOMAN Aloe, pjur® analyse me! water-based, pjur® BACK DOOR water-based, and pjur® med Moisturising glide are compatible with natural rubber latex condoms. They are not compatible with polyurethane and polyisoprene condoms. The pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® are compatible with natural rubber latex and polyisoprene condoms. They are not compatible with polyurethane condoms.

The pjur® WOMAN Aloe has a formulation that consists of water, glycerin, xanthan gum, benzyl alcohol, sodium benzoate, citric acid, potassium sorbate, aloe barbadensis leaf juice powder. This lubricant is provided in 30 ml, 100 ml, and 250 ml polyethylene bottles. The pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® have the same formulation that includes the same components as the lubricant above, without aloe barbadensis leaf juice powder. The pjur® med NATURAL glide device is provided in 10 ml and 100 ml polyethylene bottles. We-Vibe® Lube made by pjur® is provided in 30 ml polyethylene bottles, and 125 ml polyethylene/polypropylene pump bottles. The pjur® analyse me! water-based, pjur® BACK DOOR water-based, and pjur® med Moisturising glide have the same formulation that consists of water, glycerin, xanthan gum, benzyl alcohol, sodium benzoate, potassium sorbate, citric acid, sodium hyaluronate. The pjur® analyse me! water-based is provided in 10 ml, 100ml, and 250 ml polyethylene bottles. pjur® BACK DOOR water-based is provided in 10 ml, 100 ml, and 250 ml polyethylene bottles. pjur® med Moisturising glide is provided in 10 ml and 100 ml polyethylene bottles.

**Table 1: Device Specifications**

Parameter	Method	Specification	Specification	Specification	
		<ul style="list-style-type: none"> <li>pjur® WOMAN Aloe</li> </ul>	<ul style="list-style-type: none"> <li>pjur® med Moisturising glide</li> <li>pjur® BACK DOOR water-based</li> <li>pjur® analyse me! water-based</li> </ul>	<ul style="list-style-type: none"> <li>pjur® med NATURAL glide</li> <li>We-Vibe® Lube made by pjur®</li> </ul>	
Appearance	Visual	Opaque fluid	Opaque fluid	Opaque fluid	
Odor	Olfactory	Characteristic	Odorless	Odorless	
pH	USP<791>	4.0-4.5	4.0-4.5	4.0-4.5	
Viscosity (mPa*s)	USP<912>	8500-9500	9000-12000	8000-9500	
Osmolality (mOsmol/kg)	USP<785>	400 – 550 (1:9.5 dilution)	400 – 550 (1:9.8 dilution)	400 – 600 (1:9.5 dilution)	
Total Aerobic Microbial Count (TAMC)	USP<61>	<100 CFU/g	<100 CFU/g	<100 CFU/g	
Total Yeast and Mold Count (TYMC)	USP<61>	<10 CFU/g	<10 CFU/g	<10 CFU/g	
Presence of pathogenic organisms	USP<62>	<i>Pseudomonas aeruginosa</i>	Absent	<i>Pseudomonas aeruginosa</i>	Absent
		<i>Staphylococcus aureus</i>	Absent	<i>Staphylococcus aureus</i>	Absent
		<i>Candida albicans</i>	Absent	<i>Candida albicans</i>	Absent
Antimicrobial Preservation	USP<51>	Category 2 - Topical, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days.	Category 2 - Topical, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days.	Category 2 - Topical, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days.	

**INDICATIONS FOR USE:**

pjur® WOMAN Aloe is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® med Moisturising glide is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® BACK DOOR water-based is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® analyse me! water-based is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.

pjur® med NATURAL glide is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

We-Vibe® Lube made by pjur® is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

**COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES:**

**Table 2:** Comparison of Intended Use and technological characteristics of the subject and predicate devices:

	<b>pjur® WOMAN Aloe K200527 Subject Device</b>	<b>pjur® med Moisturising glide pjur® BACK DOOR water-based pjur® analyse me! water-based K200527 Subject Device</b>	<b>pjur® med NATURAL glide We-Vibe® Lube K200527 Subject Device</b>	<b>KY Banksy Moisture K183505 Predicate Device</b>	<b>Comparison</b>
Indications for Use	pjur® WOMAN Aloe is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.	<i>[Product name]</i> is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms. This product is not compatible with polyurethane and polyisoprene condoms.	<i>[Product name]</i> is a personal lubricant for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	This product is intended for penile, vaginal and/or anal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	<b>Same intended use</b>
Rx / OTC	OTC	OTC	OTC	OTC	<b>Same</b>
Base Type	Water	Water	Water	Water	<b>Same</b>
Primary Ingredients	Water, Glycerin, Xanthan Gum, Benzyl Alcohol, Sodium Benzoate, Citric Acid, Potassium Sorbate, Aloe Barbadensis	Water, Glycerin, Xanthan Gum, Benzyl Alcohol, Sodium Benzoate, Potassium Sorbate, Citric Acid, Sodium Hyaluronate	Water, Glycerin, Xanthan Gum, Benzyl Alcohol, Sodium Benzoate, Potassium Sorbate, Citric Acid	Xanthan Gum, Propanediol, Glycerin, Benzoic Acid, Purac BF P/41, Sodium hyaluronate, Water	<b>Different</b>

	Leaf Juice Powder (Aloe Vera)				
Appearance	Opaque Liquid	Opaque Liquid	Opaque Liquid	Clear	<b>Different</b>
Odor	Characteristic	Odorless	Odorless	Odorless	<b>Similar</b>
Viscosity	8500 – 9500 mPas	9000 – 12000 mPas	8000 – 9500 mPas	3000 – 8000 cps	<b>Different</b>
pH	4.0-4.5	4.0-4.5	4.0-4.5	3.5-4.5	<b>Similar</b>
Osmolality	400-550 mOsm/kg (1:9.5 dilution)	400-550 mOsm/kg (1:9.8 dilution)	400-600 mOsm/kg (1:9.5 dilution)	850-1200 mOsm/kg	<b>Different</b>
Microbial Limits	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	<b>Same</b>
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Yes	Yes	Yes	Yes	<b>Same</b>
Sterile	No	No	No	No	<b>Same</b>
Biocompatibility Tested	Yes	Yes	Yes	Yes	<b>Same</b>
Condom Compatibility	Compatible with natural rubber latex condoms. Not compatible with polyurethane and polyisoprene condoms	Compatible with natural rubber latex condoms. Not compatible with polyurethane and polyisoprene condoms	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms	<b>Similar</b>
Packaging	Polyethylene bottles	Polyethylene bottles	Polyethylene bottles Polyethylene/ Polypropylene Pump bottles	Polyethylene bottles	<b>Similar</b>
Shelf Life	4 years (bottles)	4 years (bottles)	4 years (bottles) 3 years (pump bottles)	2 years	<b>Different</b>

The indications for use for the subject and predicate devices are not identical as there are differences in condom compatibility for some of the predicate devices (i.e., not compatible with polyisoprene condoms). These differences do not represent a new intended use as both the subject and predicate devices are intended to provide lubrication during intimate sexual activity.

The subject and predicate devices have different technological characteristics, including different formulations, specifications, shelf-life, packaging, etc. as identified in the table above. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

#### **NON-CLINICAL TESTING/PERFORMANCE DATA:**

##### **CONDOM COMPATIBILITY:**

Condom compatibility testing was performed in accordance with ASTM D7661 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.” Testing demonstrated that the pjur® WOMAN Aloe, pjur® analyse me! water-based, pjur® BACK DOOR water-based, and pjur® med Moisturising glide are compatible with natural rubber latex condoms. They are not compatible with polyurethane and polyisoprene condoms. The pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® are compatible with natural rubber latex and polyisoprene condoms. They are not compatible with polyurethane condoms.



## **BIOCOMPATIBILITY:**

Biocompatibility studies were performed in accordance with the 2020 FDA guidance document “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing” as follows:

- Cytotoxicity: ISO 10993-5:2009
- Sensitization: ISO 10993-10:2010
- Systemic Toxicity: ISO 10993-11:2017
- Vaginal Irritation: ISO 10993-10:2010

The results of the testing show that the formulations of the subject devices are biocompatible.

## **SHELF-LIFE:**

pjur® WOMAN Aloe, pjur® med Moisturising glide, pjur® BACK DOOR water-based, pjur® analyse me! water-based, pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® have a shelf-life of 4 years when packaged in polyethylene bottles and a shelf-life of 3 years when packaged in polyethylene/polypropylene pump bottles, in accordance with the results of real-time aged stability studies. Results from testing demonstrated that the devices can maintain their specifications as shown in Table 1 over the stated shelf-life duration.

## **CONCLUSION:**

The results of the performance testing demonstrate that the pjur® WOMAN Aloe, pjur® med Moisturising glide, pjur® BACK DOOR water-based, pjur® analyse me! water-based, pjur® med NATURAL glide, and We-Vibe® Lube made by pjur® personal lubricants are as safe and effective as the predicate device and support a substantial equivalence determination.