January 21, 2021

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

Re: K200731
Trade/Device Name: pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, pjur® AQUA ProVitamin B5
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 21, 2020
Received: December 22, 2020

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing 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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200731

Device Name
pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, pjur® AQUA ProVitamin B5

Indications for Use *(Describe)*
pjur® AQUA Baseline 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® AQUA Guarana 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® BACK DOOR anal Provitamin B5 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® AQUA ProVitamin B5 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 not compatible with natural rubber latex, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K200731

DATE PREPARED:	19 January 2021
SUBMITTER INFORMATION:	pjur group Luxembourg SA 87 esplanade de la Moselle L-6637 Wasserbillig, Luxembourg Telephone: +352 74-8989 Fax: +352 74-8990 Contact: Andrea Giebel, Quality Management Representative
DEVICE INFORMATION:	Trade name: • pjur® AQUA Baseline • pjur® AQUA Guarana • pjur® BACK DOOR anal Provitamin B5 • pjur® AQUA ProVitamin B5 Common name: Personal Lubricant Regulation Number: 21 CFR 884.5300 Regulation Name: Condom Product Code: NUC (Lubricant, Personal) Class: II
PREDICATE DEVICE:	Astroglide® Organix® Liquid, K200114 The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:

The pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 are water-based personal lubricants provided non-sterile. These personal lubricants are for over-the-counter use. They are not compatible with natural rubber latex, polyurethane, and polyisoprene condoms. The products are provided in 30 mL and 100 mL polyethylene bottles.

The pjur® AQUA Baseline consists of water, glycerin, ethoxydiglycol, phenoxyethanol, hydroxypropyl guar hydroxypropyltrimonium chloride, hydroxyethylcellulose, and citric acid. The pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 have the same formulation and consist of water, glycerin, ethoxydiglycol, phenoxyethanol, hydroxypropyl guar hydroxypropyltrimonium chloride, propylene glycol, hydroxyethylcellulose, panthenol, polysorbate 20, citric acid, chamomilla recrutita (matricaria) flower extract, paullinia cupana seed extract, cananga odorata flower oil, alcohol, 1,2-hexanediol, decylene glycol, lactic acid, sodium benzoate, and potassium sorbate.

Table 1: Device Specifications

Parameter	**Method**	**Specifications for pjur® AQUA Baseline**		**Specifications for pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5**	
Appearance		Clear fluid		Clear fluid	
Odor		Product typical		Product typical	
pH	USP<791>	4.1-4.7		4.1-4.7	
Viscosity (mPa*s)	USP<912>	750 – 1250		690 – 1100	
Osmolality (mOsmol/kg)	USP <785>	500-625 (diluted 1:3.9)		500-625 (diluted 1:4.1)	
Total Yeast and Mold Count (TYMC)	USP<61>	<10 cfu/g		<10 cfu/g	
Total Aerobic Microbial Count (TAMC)	USP<61>	<100 cfu/g		<100 cfu/g	
Presence of Pathogenic Organisms	USP<62>	*Pseudomonas aeruginosa*	Absent	*Pseudomonas aeruginosa*	Absent
		Staphylococcus aureus	Absent	*Staphylococcus aureus*	Absent
		Candida albicans	Absent	*Candida albicans*	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.	

INDICATIONS FOR USE:

pjur® AQUA Baseline 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® AQUA Guarana 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® BACK DOOR anal Provitamin B5 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

pjur® AQUA ProVitamin B5 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 not compatible with natural rubber latex, polyisoprene, and 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:

	pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 K200731 Subject Devices	**Astroglide® Organix® Liquid K200114 Predicate Device**	**Comparison**
Indications for Use	pjur® AQUA Baseline 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms. pjur AQUA Guarana 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms. pjur BACK DOOR anal Provitamin B5 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms. pjur® AQUA ProVitamin B5 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 not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	Astroglide® Organix® Liquid 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 compatible with natural rubber latex and polyisoprene condoms. The product is not compatible with polyurethane condoms.	**Same intended use**
Rx / OTC	OTC	OTC	**Same**
Base Type	Water	Water	**Same**
Primary Ingredients	pjur® AQUA Baseline: Water, Glycerin, Ethoxydiglycol, Phenoxyethanol, Hydroxypropyl Guar Hydroxypropyltrimonium	Water, Glycerin, Xanthan Gum, Aloe Barbabensis Powder, Chamomilla Recutita (Matricaria) Flower Extract, Calendula Officinalis Flower Extract,	**Different**

	pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 K200731 Subject Devices	**Astroglide® Organix® Liquid K200114 Predicate Device**	**Comparison**
	Chloride, Hydroxyethylcellulose, and Citric acid pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5: Water, Glycerin, Ethoxydiglycol, Phenoxyethanol, Hydroxypropyl Guar Hydroxypropyltrimonium Chloride, Propylene Glycol, Hydroxyethylcellulose, Panthenol, Polysorbate 20, Citric Acid, Chamomilla Recrutita (Matricaria) Flower Extract, Paullinia Cupana Seed Extract, Cananga Odorata Flower Oil, Alcohol, 1,2-Hexanediol, Decylene Glycol, Lactic Acid, Sodium Benzoate, Potassium Sorbate	Vaccinium Macrocarpon (Cranberry) Fruit Extract, Passiflora Incarnata Flower Extract, Sodium Benzoate, Potassium Sorbate, Citric Acid	
Appearance	Clear Liquid	Colorless to slightly yellow, hazy liquid	**Different**
Odor	Product typical (characteristic)	Odorless	**Different**
Viscosity	pjur® AQUA Baseline: 750-1250 mPa*s pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5: 690-1100 mPa*s	250-310 cps	**Different**
pH	4.1-4.7 (all versions)	3.5-5.5	**Similar**
Osmolality	pjur® AQUA Baseline: 500-625 mOsm/kg (diluted 1:3.9) pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5: 500-625 mOsm/kg (diluted 1:4.1)	500-800 mOsm/kg (diluted1:5)	**Different**
Microbial Limits	Total aerobic microbial count (TAMC): <100 cfu/g Total yeast and mold count (TYMC): <10 cfu/g	TAMC: <100 cfu/g TYMC: <10 cfu/g	**Same**
Absence of Pathogenic Organisms per USP <62>	Absent	Absent	**Same**

	pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 K200731 Subject Devices	**Astroglide® Organix® Liquid K200114 Predicate Device**	**Comparison**
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Yes	Yes	**Same**
Sterile	No	No	**Same**
Biocompatibility Tested	Yes	Yes	**Same**
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene and polyurethane condoms	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms	**Different**
Packaging	Polyethylene bottles	Polyethylene terephthalate bottles and foils	**Different**
Shelf Life	18 months	17 months (bottles) 9 months (foils)	**Different**

The subject and predicate device indications for use are not identical due to differences in application area and condom compatibility. The subject device is intended to be used for penile, vaginal and/or anal applications while the predicate device is for penile and/or vaginal application. The subject device is not compatible with natural rubber latex (NRL), polyisoprene, and polyurethane condoms while the predicate device is compatible with NRL and 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, packaging, specifications, shelf-life, and condom compatibility. 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 D7661-10 “Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.” Testing demonstrated that the subject devices are not compatible with natural rubber latex, polyisoprene, and 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 within a risk management process” as follows:

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

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

SHELF-LIFE:

pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 lubricants demonstrated a shelf-life of 18 months in accordance with the results of accelerated and real-time aged stability studies. Results from testing demonstrated that the device can maintain its specifications as shown in Table 1 over the duration of its shelf-life.

CONCLUSION:

The results of the non-clinical testing described above demonstrate that the pjur® AQUA Baseline, pjur® AQUA Guarana, pjur® BACK DOOR anal Provitamin B5, and pjur® AQUA ProVitamin B5 personal lubricants are as safe and effective as the predicate and support a determination of substantial equivalence.