May 21, 2026

Pjur Group Luxembourg S.A.
Andrea Giebel, PRRC
Person Responsible for Regulatory Compliance
87, Esplanade De La Moselle
Wasserbillig, 6637
Luxembourg

Re: K260068
Trade/Device Name: pjur NATURE Touch, 100 ml
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 8, 2025
Received: January 9, 2026

Dear Andrea Giebel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260068

Device Name
pjur® NATURE Touch, 100 ml

Indications for Use *(Describe)*
pjur® NATURE Touch, 100 ml 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K260068

1. Applicant:

Company Name: pjur group Luxembourg

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Contact Person: Andrea Giebel, PRRC
E-Mail: andreagiebel@pjur.com

Summary Preparation Date: May 20, 2026

2. Subject Device Information:

Device Trade Name: pjur® NATURE Touch, 100 ml

Common Name: Personal lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: NUC (lubricant, personal)
Device Class: II

3. Predicate Device Information:

Predicate 510(k) Number	K182027
Predicate Trade Name	Wet Organics Personal Lubricant
Predicate Manufacturer	Trigg Laboratories DBA Wet International

The predicate device has not been subject to a design-related recall.

4. Device Description

pjur® NATURE Touch, 100 ml is a non-sterile, water-based personal lubricant. It is not a contraceptive nor a spermicide. The pjur® NATURE Touch, 100 ml is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

pjur® NATURE Touch, 100 ml has a water-based formulation that consists of aqua (water), Glycerin, Xanthan Gum, Levulinic Acid, Sodium Levulinate, Sodium Anisate, Sodium Hydroxide, and Tremella Fuciformis Sporocarp Extract. pjur® NATURE Touch, 100 ml is provided in a 100 ml HD-PE / LD-PE bottle.

The device specifications for pjur® NATURE Touch, 100 ml are outlined in the table below.

pjur® NATURE Touch, 100 ml **Lubricant**		
Parameter	**Method**	**Specification**
Appearance	Visual	Clear liquid
Odor	Olfactory	Odorless
pH value	USP<791>	5.20 – 5.90
Viscosity	USP<912>	1,500 – 5,000 mPa*s
Density	USP <841>	0.900 – 1,200 g/mL
Osmolality	USP<785>	< 600 mOsmol/kg
Antimicrobial Effectiveness	USP<51>	Meets USP <51> acceptance criteria for Category 2. Bacteria: No less than 2.0 log reduction from initial count at 14 days, and no increase from the 14-day count at 28 days. Yeast and Molds: No increase from the initial calculated count at 14 days and 28 days.
Total Aerobic Microbial Count (TAMC)	USP<61>	<100 cfu/g
Total Yeast and Mold Count (TYMC)	USP<61>	<10 cfu/g
Presence of pathogenic organisms	USP<62>	Absence of: *Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans and Aspergillus brasiliensis*

5. Indication for Use

pjur® NATURE Touch 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.

6. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Parameter	Subject Device pjur®NATURE Touch, 100 ml	Predicate Device Wet Organics Personal Lubricant (K182027)	Comparison
Indications for Use	pjur®NATURE Touch, 100 ml 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.	The Wet Organics 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. The product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Similar
Rx / OTC	OTC	OTC	Same
Base Type	Water-based	Water-based	Same
Primary Ingredients	Aqua (Water), Glycerin, Xanthan Gum, Levulinic Acid, Sodium Levulinate, Sodium Anisate, Sodium Hydroxide, Tremella Fuciformis Sporocarp Extract.	Purified Water Organic aloe barbadensis leaf juice Zemea Select Propanediol Vegeluron Gel Cellosize QP-30000-H Xanthan Gum Sodium Hyaluronate Microcare SB Citric Acid Co Extract Blend	Different
Appearance	Clear liquid	Clear to slightly cloudy, semi-viscous	Similar
Odor	Odorless	Odorless (Characteristic)	Same
Viscosity	1,500 – 5,000 mPa*s	1,000 – 2,300 cps	Similar
pH value	5.20 – 5.90	4.0 - 5.0	Similar

Parameter	Subject Device pjur®NATURE Touch, 100 ml	Predicate Device Wet Organics Personal Lubricant (K182027)	Comparison
Osmolality	< 600 mOsm/kg	< 1,800 mOsm/kg	Similar
Microbial Limits	TAMC: $<10^2$ KBE/g [cfu/g] TYMC: $<10^1$ KBE/g [cfu/g] Pathogenic Organisms: Absent	TAMC: <100 cfu/g TYMC: <10 cfu/g Pathogenic Organisms: Absent	Same
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Meets USP <51> acceptance criteria for Category 2 products	Meets USP <51> acceptance criteria for Category 2 products	Same
Sterile	No	No	Same
Biocompatibility	Yes	Yes	Same
Condom Compatibility	compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms	compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms	Same
Packaging	HD-PE bottles with a polypropylene cap	polyethylene terephthalate bottle with a dispensing bottle cap with a disc top.	Different
Shelf Life	24 months	12 months	Different

The subject device, *pjur® NATURE Touch, 100 ml*, and the predicate device, *Wet Organics Personal Lubricant* (K182027) have similar indications for statements and the same intended use - to moisturize and lubricate and to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

The subject and predicate devices have different technological characteristics as shown in the table above, including different appearance, viscosity, pH, osmolality, ingredients and packaging. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Testing

Biocompatibility

Biocompatibility testing for the subject device was conducted in accordance with the 2023 FDA guidance "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 10993-10:2021
- Acute Systemic Toxicity: ISO 10993-11:2017
- Vaginal Irritation: ISO 10993-23:2021

The results of this testing demonstrated that the subject lubricant is non-cytotoxic, non-irritating, nonsensitizing, and not systemically toxic.

Condom Compatibility

The compatibility of the subject devices with condoms was evaluated in accordance with ASTM D7661-18, "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" and were determined to be:

- compatible with natural rubber latex condoms,
- compatible with polyisoprene condoms,
- not compatible with polyurethane condoms.

Shelf-Life

The subject device has a 24 month shelf life. Testing on device samples demonstrated that the subject device met all specifications listed in the device specification table across the device shelf life.

8. Conclusion

The results of the performance testing described above demonstrate that *pjur® NATURE Touch, 100 ml* is as safe and effective as the predicate device and supports a determination of substantial equivalence.