June 11, 2026

PR Personal Care Laboratories
Louie Goryoka
Sr. VP. Regulatory and Quality Consultant
27820 Frermont Ct. Suite 3
Valencia, California 91320

Re: K261292
Trade/Device Name: PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 20, 2026
Received: April 20, 2026

Dear Louie Goryoka:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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,

VASUDHA C. SHUKLA -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261292

Device Name
PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)

Indications for Use *(Describe)*
The PR Water-Base Lube Personal Lubricant (PR Water-Base Lube 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 PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) 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

K261292

PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)

1. Submitter Information:

PR Personal Care Laboratories

27820 Fremont Ct. Suite 3

Valencia, CA 91355, USA

2. Submission Correspondent:

Louie Goryoka

Sr. VP. Regulatory and Quality Consultant

Med-Device Consulting, Inc.

Email: mdci@m-dci.us

(818) 585-7488

3. Date of Summary:

June 11, 2026

4. Device Identification:

Device Trade Name:	PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)
Common Name:	Personal Lubricant
Regulation Name(s):	Condom
Regulation Number:	21 CFR §884.5300
Device Class:	Class II
Product Code:	NUC (lubricant, personal)

5. Predicate Device

Product Name:	Desnuda Reflect
510(k) Number:	K211998

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

6. Device Description

The PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) is a non-sterile personal lubricant. It is water-based, available over the counter, and formulated to be colorless and odorless. The subject device is compatible with natural rubber latex and lubricated polyisoprene male condoms. It is not compatible with polyurethane male condoms.

Its formulation consists of water, sodium benzoate, potassium sorbate, aloe barbadensis leaf juice, xanthan gum, propanediol, cellulose gum, hyaluronic acid, and citric acid.

The device formula is neither a contraceptive nor a spermicide. The device is packaged in a pre-filled polyethylene terephthalate (PET) bottle (118 ml).

The table below lists specifications:

Table 1: Device Specifications for PR Water-Based Personal Lubricant and Moisturizer

Property	Specification
Appearance	Clear, colorless gel
Color	Clear
Odor	Odorless
Viscosity@25°C ; Spindle #5@10rpm (cps) per USP <911>	1,067 – 12,270 cps
pH @ 25° per USP <791>	4.0 - 4.5
Osmolality (mOSm/kg) per USP <785>	840 – 1,032 mOSm/kg
Total aerobic microbial count (TAMC) per USP <61>	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61>	<10 cfu/g
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2 bacteria should show a log reduction of less than 2.0 at 14 days and no increase from the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days.
Presence of Pathogens per USP <62>	Specification
Absence of pathogenic organisms (*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, and Candida albicans*)	Absent

7. Indication for Use

The PR Water-Base Lube Personal Lubricant (PR Water-Base Lube 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 PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Table 2: Intended Use and Technological Characteristics Comparison

510(k) Summary

K261292

PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)

Characteristic/Feature	PR Water-Base Lube Personal Lubricant Subject Device K261292	Desnuda Reflect K211998
Device Name	PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant)	Desnuda Reflect
Indications for Use	The PR Water-Base Lube Personal Lubricant (PR Water-Base Lube 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 PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Desnuda Reflect 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. This product is not compatible with polyurethane condoms.
Rx/OTC	OTC	OTC
Sterile	No	No
Base type	Water-based	Water-based
Formulation	Water, sodium benzoate, potassium sorbate, aloe barbadensis leaf juice, xanthan gum, propanediol, cellulose gum, hyaluronic acid, and citric acid	Water, hyaluronic acid, hydroxyethylcellulose, xanthan gum, zemea propanediol, sodium benzoate, potassium sorbate, and dl lactic acid
Appearance	Clear, colorless gel	Gel
Color	Clear	Clear to Cloudy
Odor	Odorless	Odorless
Viscosity	1,067 – 12,270 cps	12,500 – 25,000 cps
pH@25°C	4.0 -4.5	3.5 – 4.0
Osmolality	840 -1,032 mOSm/kg	250 – 400 mOsm/kg

Absence of pathogenic organisms per USP <62>	Absent	Absent
Total mold/yeast count (TYMC) per USP <61>	<10 cfu/g	<10 cfu/g
Total aerobic microbial count (TAMC) per USP <61>	<10 cfu/g	<100 cfu/g
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Yes	Yes
Condom Compatibility	Compatible with Natural Rubber Latex and Polyisoprene Condoms. It is not compatible with lubricated polyurethane male condoms.	Compatible with Natural Rubber Latex and Polyisoprene Condoms. It is not compatible with lubricated polyurethane male condoms.
Shelf life	8.5 months	1 Year

The subject device and predicate device have the same indications for use and intended use. The subject and predicate devices differ in total aerobic microbial count (TAMC), formulation, appearance, color, viscosity, pH, osmolality, and shelf-life. These differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies were performed 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."*

The following testing was conducted:

a. Cytotoxicity (ISO 10993-5:2009)

b. Sensitization (ISO 10993-10:2010)

c. Vaginal Irritation (ISO 10993-10:2021)

d. Acute Systemic Toxicity (ISO 10993-11:2017)

The test results demonstrated that the subject device is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility:

The subject device was tested for compatibility with natural rubber latex, polyisoprene, and polyurethane condoms in accordance with the ASTM D7661-18 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.* The results show that PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) is

compatible with natural rubber latex and polyisoprene male condoms and is not compatible with lubricated polyurethane male condoms.

Shelf Life:

The subject device has a shelf-life of 8.5 months based on the results of an accelerated aging study. The shelf-life study evaluated all device specifications listed in Table 1 and met all device specifications throughout the stated shelf-life.

10. Conclusions

The results of performance testing described above demonstrate that the PR Water-Base Lube Personal Lubricant (PR Water-Base Lube Personal Lubricant) is as safe and effective as the predicate device and supports a determination of substantial equivalence.