July 6, 2026

PCCA, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K261909
Trade/Device Name: Plum Vagiceuticals™ Vaginal Moisturizing Suppositories
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Received: June 8, 2026

Dear Dave Yungvirt:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261909

Device Name
Plum Vagiceuticals™ Vaginal Moisturizing Suppositories

Indications for Use *(Describe)*
Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene 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

Plum Vagiceuticals™ Vaginal Moisturizing Suppositories

K261909

I. General Information

Submitter/Owner: PCCA
9901 South Wilcrest Drive
Houston, Texas, 77099
United States

Contact Person: Daniel Banov
Vice President of Research and Development
PCCA

Phone: 832-295-4426
Email: DBanov@pccarx.com

Preparation Date: July 6, 2026

II. Device Information

Trade Name:	Plum Vagiceuticals™ Vaginal Moisturizing Suppositories
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	Class II
Product Code:	NUC (Lubricant, Personal)

III. Predicate Device

Revaree Plus Vaginal Suppositories (K213220)

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

IV. Device Description

Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are non-hormonal, non-sterile, glyceride-based personal lubricant, designed for over-the-counter use to alleviate vaginal dryness, enhance comfort during intimate activity, and support the body's natural lubrication.

The suppositories are solid, off-white, 1.8 g each, and the shape is designed for easy intravaginal administration. Each vaginal suppository is individually packaged in a polyvinyl chloride (PVC) /polyethylene (PE) blister and marketed in cartons containing 10 vaginal suppositories (two blister packs of 5 vaginal suppositories each).

Each vaginal suppository contains 1% sodium hyaluronate in combination with lipid excipients, self-emulsifying agent, and additional hydrating and mucoadhesive agents. The suppositories do not contain hormones or pharmacologically active drug substances.

Upon insertion into the vaginal cavity, the suppository melts at body temperature. The viscous lipid matrix disperses over the mucosal surface and provides lubrication in a dry environment. In the presence of vaginal fluid, the formulation undergoes self-emulsification, forming a viscous emulsion. The emulsion system remains in contact with the vaginal mucosa for the intended period of action and is ultimately cleared by gravity and the natural self-cleaning mechanisms of the vagina.

The specifications for Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are provided in **Table 1.**

Table 1. Device specifications

Parameter	Test Method	Specification
Appearance	Visual	Solid
Color	Visual	White to off-white
Odor	Organoleptic	Practically odorless
Osmolality	USP <785> Osmolality/ after dilution	100-300 mOsm/kg (after taking account of dilution factor of 1:10)
Disintegration Time	Eu.Ph 2.9.2	≤ 30 minutes
Melting Point	USP <741> Class III	30°C - 37°C
Water Activity	USP <1112>	< 0.600
Average Weight	Gravimetry	1.8 g
Content of Sodium Hyaluronate	HPLC	10 mg/g
TAMC	USP <61>	≤ 100 cfu/g
TYMC	USP <61>	≤ 10 cfu/g
Pseudomonas Aeruginosa, Staphylococcus Aureus, Candida Albicans	USP <62>	Absent /g

V. Indications for Use

Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

VI. Substantial Equivalence Discussion

A comparison of the intended use and key technological characteristics of the subject and predicate device is provided in **Table 2** below.

Table 2. Intended Use and Technological Characteristics of Subject Device Compared to Predicate Device

	Plum Vagiceuticals™ Vaginal Moisturizing Suppositories	**Revaree Plus Vaginal Suppositories (K213220)**	**Comparison**
Indications for Use	Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Revaree plus vaginal suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Similar
Over the counter	Yes	Yes	Same
Base type	Fat-based	Glyceride	Similar
Ingredients	Hard fat, stearoyl polyoxyl-32 glycerides, polyoxyl 20 cetostearyl ether, sodium hyaluronate, Hippophae Rhamnoides Fruit Oil, sodium polyglutamate, sh-polypeptide-123, tocopheryl acetate, zinc hydrolyzed hyaluronate	HA, glycerides, and sweet almond oil	Different
Appearance	Off-white opaque vaginal suppositories	Off-white opaque vaginal suppositories	Same
Average Weight	1.8 g	2 g	Different

TAMC	≤100 cfu/g	≤100 cfu/g	Same
TYMC	≤10 cfu/g	≤10 cfu/g	Same
Absence of *Pseudomonas Aeruginosa, Staphylococcus Aureus, Candida Albicans*	Absent/g	Absent/g	Same
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Same
Packaging	PVC/PE blister of 5 vaginal suppositories	PVC/PE blister of 3 or 5 vaginal suppositories	Same

The subject and predicate device have the similar indications for use and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations and device specifications. The different technological characteristics do not raise different questions of safety and effectiveness.

VII. Summary of Non-Clinical Performance Data

Biocompatibility

Biocompatibility testing on the subject lubricant was performed in accordance with the 2023 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"* and ISO 10993-1:2018 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2021)
- Vaginal Irritation (ISO 10993-12: 2021; ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Shelf-Life

The shelf-life of Plum Vagiceuticals™ Vaginal Moisturizing Suppositories is 12 months. This is based on the results of an intermediate accelerated aging study conducted at 30°C in accordance with ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*.

Condom Compatibility

Condom compatibility testing was not conducted for the subject device. Therefore, Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are not compatible with natural rubber latex, polyisoprene, and polyurethane condoms

VIII. Conclusions

The results of the testing described above demonstrate that Plum Vagiceuticals™ Vaginal Moisturizing Suppositories are as safe and effective as the predicate device and supports a determination of substantial equivalence.