



April 16, 2026

Golden Isles Medical, Inc.  
% Louie Goryoka  
Sr. Consultant QA/RA  
Med-Device Consulting, Inc.  
5804 Rainbow Hill Rd.  
Agoura Hills, California 91301

Re: K254101  
Trade/Device Name: Julva Velvé Water-Based Personal Lubricant  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: December 23, 2025  
Received: January 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](mailto: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

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)  
K254101

Device Name  
Julva Velvé Water-Based Personal Lubricant

### Indications for Use (Describe)

Julva Velvé Water-Based Personal Lubricant is a water-based personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. Julva Velvé Water-Based 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

### Julva Velvé Water-Based Personal Lubricant

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#### 1. Submitter Information:

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Brunswick, GA 31525-6854, USA  
TEL: (912) 388-6707

#### 2. Submission Correspondent:

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Med-Device Consulting, Inc.  
Email: [mdci@m-dci.us](mailto:mdci@m-dci.us)  
(818) 585-7488

#### 3. Date of Preparation:

April 16, 2026

#### 4. Device Identification:

Device Trade Name:	Julva Velvé Water-Based Personal Lubricant
Common Name:	Personal lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR §884.5300
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

#### 5. Predicate Devices

Desnuda Reflect - K211998

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

#### 6. Device Description

Julva Velvé Water-Based Personal Lubricant is a non-sterile personal lubricant. It is water-based, available over the counter, and formulated to be colorless to pale yellow and odorless. The subject device is compatible with natural rubber latex and lubricated polyisoprene male condoms and is incompatible with polyurethane male condoms.

Its formulation consists of water, Sodium Benzoate, Potassium Sorbate, Aloe Barbadensis Leaf Juice, Zemea Propanediol, Hydroxyethylcellulose, Hyaluronic Acid, Citric Acid, Paullinia Cupana Seed Extract, Oryza Sativa (Rice) Bran Extract, Panax Ginseng Root Extract.

The device formula is neither a contraceptive nor a spermicide.

**Julva Velvé Water-Based Personal Lubricant**

**Table 1: Device Specifications for Julva Velvé Water-Based Personal Lubricant**

Property	Specification
Appearance	Translucent Viscous Gel
Color	Colorless to Pale Yellow
Odor	Odorless
Viscosity	2,100 cps – 3,900 cps
pH	4.0 – 5.0
Osmolality	1000 – 2000 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> criteria for Category 2. Bacteria show 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 show no increase from the initial calculated count at 14 and 28 days.
Presence of Pathogens per USP <62>	Specification
Absence of pathogenic organisms ( <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> , and <i>Candida albicans</i> )	Absent

**7. Indication for Use**

The Julva Velvé Water-Based Personal Lubricant is a water-based personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The Julva Velvé Water-Based Personal Lubricant is compatible with natural rubber latex and polyisoprene male condoms, but is incompatible with lubricated polyurethane male 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**

Characteristic/Feature	Julva Velvé Water-Based Personal Lubricant Subject Device K254101	Desnuda Reflect K211998
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**Julva Velvé Water-Based Personal Lubricant**

Indications for Use	Julva Velvé Water-Based Personal Lubricant is a water-based 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. Julva Velvé Water-Based 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
Primary ingredients	Purified Water, Sodium Benzoate, Potassium Sorbate, Aloe Barbadensis Leaf Juice, Zemea Propanediol, Hydroxyethylcellulose, Hyaluronic Acid, Citric Acid, Paullinia Cupana Seed Extract, Oryza Sativa (Rice) Bran Extract, Panax Ginseng Root Extract	Water, Hyaluronic Acid, Hydroxyethylcellulose, Xanthan Gum, Zemea Propanediol, Sodium Benzoate, Potassium Sorbate, DL Lactic Acid
Appearance	Clear, viscous liquid	Gel
Color	Colorless to Pale Yellow	Clear to Cloudy
Odor	Odorless	Characteristic
Viscosity	2,100 cps – 3,900 cps	12,500 – 25,000 cps
pH	4.0 - 5.0	3.5 – 4.0
Osmolality	1000 – 2000 mOSm/kg	250 – 400 mOsm/kg
Antimicrobial Effectiveness Tested per USP <62>	Yes	Yes
Total aerobic microbial count (TAMC) per USP <61>	<10 cfu/g	<100 cfu/g
Total mold/yeast count (TYMC) per USP <61>	<10 cfu/g	<10 cfu/g
Antimicrobial Effectiveness Testing (USP<51> Category 2)	Yes	Yes

**Julva Velvé Water-Based Personal Lubricant**

Condom Compatibility	Compatible with Natural Rubber Latex and Polyisoprene Condoms.	Compatible with Natural Rubber Latex and Polyisoprene Condoms.
Biocompatibility Tested	Yes	Yes
Shelf life	8.5 month	1 Year

The subject device and predicate device have the same indications for use and intended use. As shown in the table, there are differences in the technological characteristics of the subject and predicate devices, including packaging, formulation, specifications (appearance/color, pH, viscosity, osmolality, and TAMC), and device 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 10993-23:2021)
- 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 using ASTM D7661-18 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results show that Julva Velvé Water-Based 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 Julva Velvé Water-Based Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.