September 26, 2024

Westridge Laboratories, Inc.
% Erica Loring
Regulatory Consultant
Erica Loring
3506 6th ave
San Diego, California 92103

Re: K240745
Trade/Device Name: ID Free Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Received: August 27, 2024

Dear Erica Loring:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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, PhD
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)*
K240745

Device Name
ID Free® Personal Lubricant

Indications for Use *(Describe)*
ID Free® Personal Lubricant is for or penile, anal 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 polyisoprenecondoms. 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.

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510(K) Summary – K240745

ID Free® Personal Lubricant

I. Submitter

Applicant	Westridge Laboratories, Inc
Address:	1671 E Andrew Pl Santa Ana, CA 92706
Telephone	714-259-9400
Contact Person:	Erica Loring
Contact Title:	Regulatory Consultant
Email:	Erica.Loring@yahoo.com
Date Prepared	September 25, 2024

II. Subject Device Information

Trade Name:	**ID Free Personal Lubricant**
Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Regulatory Class:	II
Product Code:	NUC (Lubricant, Personal)

III. Predicate Device Information

Proprietary Name:	Astroglide® Glycerin & Paraben Free
501(k) number:	K220653
Manufacturer:	BioFilm Inc.
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Regulatory Class:	II
Product Code:	NUC (Lubricant, Personal)

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

IV. Device Description

ID Free® Personal Lubricant is a personal lubricant, for penile, anal 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 intended for over-the-counter use.

The device is a non-sterile water based personal lubricant with a clear, odorless formulation. The device is packaged in nonsterile 8.5 fl. oz/250 ml plastic/PET bottles

with a screw-on cap and flip top closure, or in 0.14 fl. oz/4 ml foil sachets.

The device is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. This product is not a contraceptive and does not contain a spermicide.

The device formulation consists of water, propanediol, hydroxyethyl cellulose, carbomer, PEG-45M, tetrahydroxypropyl ethylenediamine, EDTA, caprylhydroxamic acid, and sucralose.

The specifications for ID Free Personal Lubricant are described in **Table 1.**

Table 1. Device Specifications

Parameter	**Specification (Test Method)**
Color	No color to slight yellow tint
Appearance	Clear viscous gel
Odor	Odorless
Viscosity Spindle #63 @ 30 RPM	2,200 - 4,400 cps
pH	5.0 - 5.5
Osmolality	250 - 500 mOsm/kg
Total yeast/mold count (TYMC) (USP <61>)	<10 cfu/mL
Total aerobic microbial count (TAMC) (USP <61>)	<100 cfu/mL
Presence of Pathogenic Organisms (USP <62>) *(Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans)*	Absent
Antimicrobial effectiveness (USP <51>)	Meets USP <51> acceptance criteria for Category 2 products.

v. Indications for Use

ID Free® Personal Lubricant is a personal lubricant, for penile, anal 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.

vi. Substantial Equivalence Discussion

The following table compares the intended use and key technological characteristics of the subject and predicate device:

Product Name	ID FREE® Personal Lubricant (Subject Device)	Astroglide Glycerin & Paraben Free (Predicate Device)
Device Classification	Lubricant, personal	Lubricant, personal
Product Code	NUC	NUC
Classification	Class II	Class II
Indications for Use	ID Free® Personal Lubricant is a personal lubricant, for penile, anal 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.	Astroglide Glycerin & Paraben Free is a personal lubricant for penile, vaginal, and/or anal 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
Over the Counter use	Yes	Yes
Ingredients	Water, Propanediol, Hydroxyethylcellulose, Carbomer, PEG 45M, EDTA, Tetrahydroxypropyl Ethylenediamene, Caprylhydroxamic acid, Sucrose	Purified Water, Xylitol, Butylene Glycol, Methyl Gluceth-20, Propylene Glycol, Polyquaternium-7, Hydroxyethylcellulose, Potassium Sorbate, Sodium Benzoate, Citric Acid
Condom compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex and Polyisoprene
pH	5.0-5.5	3.5-5.5
Osmolality	200-500 mOsm/Kg	230-300 mOsm/kg, 1:5 dilution factor
Sterile	No	No
Water based	Yes	Yes
Antimicrobial Test (USP <51>, USP <61>, USP <62>)	Yes	Yes

The subject and predicate device have the same indications for use and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate device are both water-based, non-sterile lubricants with differences in technological characteristics, including different formulations and device specifications. The technological characteristics differences do not raise different questions of safety and effectiveness.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the subject lubricant was 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" and ISO 10993-1:2009 as follows:

- Cytotoxicity (per ISO 10993-5:2009)
- Guinea Pig Maximization Sensitization (per ISO 10993-10:2010)
- Vaginal Irritation (per ISO 10993-10:2010)
- Acute Systemic Toxicity (per ISO 10993-11:2017)

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

Shelf Life

The subject device is a non-sterile personal lubricant packaged in a 2.5 oz. bottle with a 24-month shelf-life in accordance with the results of real time aging study, conducted for 24 months at 25°C. The device specifications listed in **Table 1** were tested across the device shelf-life and the subject device met the specifications at all time points.

Condom Compatibility

ID FREE® Personal Lubricant 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 of the testing demonstrate that the subject device is compatible with natural rubber latex and polyisoprene condoms. The subject device is not compatible with polyurethane condoms.

VIII. Conclusion

The results of the performance testing described above demonstrate that the ID FREE® Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.