July 8, 2019

Vjuvenate, LLC
Karyn Eilber
President, CEO
3435 Santa Monica Blvd, Suite 107
Santa Monica, CA 90405

Re: K183050
Trade/Device Name: GLISSANT Intimate Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 31, 2019
Received: June 7, 2019

Dear Karyn Eilber:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Sharon Andrews
Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183050

Device Name
GLISSANT Intimate Lubricant

Indications for Use *(Describe)*
GLISSANT Intimate Lubricant Fragrance Free/Sea Salt & Caramel is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, and 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, polyisoprene, and 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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K183050 - Traditional 510(k) Premarket Notification
GLISSANT Intimate Lubricant

GLISSANT Intimate Lubricant – K183050

510(k) Summary

Submitter	VJUVENATE, LLC 3435 Ocean Park Boulevard, Suite 107 Santa Monica, CA 90405 (424) 835-4372
Contact person	Karyn S. Eilber, MD dreilber@vjuvenateyou.com (424) 835-4372 Office (310) 909-4967 Mobile
Date prepared	July 5, 2019
Device trade names	GLISSANT Intimate Lubricant GLISSANT Intimate Lubricant – Fragrance Free GLISSANT Intimate Lubricant – Sea Salt & Caramel
Device common name	Personal lubricant
Regulation number **Regulation name** **Regulatory class** **Product code**	21 CFR 884.5300 Condom Class II NUC
Classification panel	Obstetrics/gynecology
Predicate device	Aloe Cadabra® Personal Lubricant and Aloe Cadabra® Flavored/Scented Personal Lubricants (K124044) The predicate device has not been subject to a design related recall.
Indications for use	GLISSANT Intimate Lubricant Fragrance Free/Sea Salt & Caramel is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, and 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, polyisoprene, and polyurethane condoms.
Device description	GLISSANT Intimate Lubricant is a water-based, non-sterile, colorless, viscous personal lubricant. It does not contain a

	contraceptive or spermicidal component. The device is packaged in a polyethylene bottle with a lockdown pump. The primary packaging is plastic placed inside of a display box (dimensions 1.375" width x 1.375" depth x 4.75" height).

The device specifications are listed in the table below:

Parameter	**Specification acceptance criteria**
Appearance	Clear, viscous
Color	Colorless
Odor	Odorless
pH	3.9 – 4.1
Specific gravity	1.003 g/mL
Viscosity	250 – 500 cps
Osmolarity	160 - 222 mOsm/kg
Antimicrobial effectiveness	Per USP <51> (Category 2)
Total microbial count	Per USP <61> (<100 cfu/g)
Fungal/yeast/mold limits	Per USP <61> (<10 cfu/g)
Absence of pathogenic organisms (*e. coli, c. salmonella sp., pseudomonas aeruginosa, s. aureus, clostridia sp., c. albicans*)	Per USP <62> (absent)

SUBSTANTIAL EQUIVALENCE DISCUSSION

GLISSANT Intimate Lubricant has the same intended use when compared to the predicate device (Aloe Cadabra® Personal Lubricant and Aloe Cadabra® Flavored/Scented Personal Lubricants (K124044). The GLISSANT Intimate Lubricant has different technological characteristics compared to the predicate device; however, these differences do not raise different questions of safety or effectiveness. The following table compares GLISSANT™ Intimate Lubricant to the predicate device.

	DEVICE	**PREDICATE DEVICE**
Trade Name	GLISSANT Intimate Lubricant Fragrance free and Sea Salt & Caramel (K183050)	ALOE CADABRA® Personal Lubricant and Flavored/Scented Lubricants (K124044)
Regulation number **Regulation name** **Regulatory class** **Product code**	21 CFR 884.5300 Condom Class II NUC	SAME
Indications for use	GLISSANT Intimate Lubricant Fragrance Free/Sea Salt and Caramel	Aloe Cadabra® Lubricant and Aloe Cadabra®

	is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, and 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, polyisoprene, and polyurethane condoms.	Flavored/Scented Lubricants are personal lubricants, 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.
Device description	Water-based, non-sterile, unscented and flavored/scented personal lubricant	Aloe-based, non-sterile, flavored/scented personal lubricant
Common ingredients	Organic aloe barbadensis leaf juice, potassium sorbate, hydroxyethylcellulose, stevia, flavor	Aloe
Biocompatibility tests per ISO-10993	Meets acceptance requirements for all biocompatibility tests	SAME
Condom compatibility per ASTM D7661-10	Compatible with natural rubber latex, polyisoprene, and polyurethane	Not compatible with polyurethane condoms
Packaging	PETG plastic bottle with lockdown pump packaged in a carton	HDPE plastic bottle with flip top cap packaged in a carton
Shelf life	1 year	2 years
Stability tests per USP <51>, <61>, and <62>	Meets acceptance requirements for microbial testing at baseline and at 1 year (accelerated aging)	SAME

SUMMARY OFNON-CLINICAL PERFORMANCE DATA

Biocompatibility

The subject device was evaluated for biocompatibility in accordance with the 2016 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
- Acute systemic toxicity per ISO 10993-11:2006
- Sensitization per ISO 10993-10:2010
- Vaginal irritation per ISO 10993-10:2010

The results of this testing demonstrated that the subject lubricants are non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Condom compatibility

Condom compatibility was performed according to the FDA recognized consensus standard ASTM D7661-10 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this test indicate that JO subject lubricants are compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf life (stability) testing

The shelf life of GLISSANT™ Intimate Lubricant is 12 months based on an accelerated aging study per ASTM F1980-16 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*.

At baseline and following aging, the device met its specifications for appearance, color, odor, pH, specific gravity, viscosity, osmolarity, antimicrobial preservative effectiveness based on USP <51>, total aerobic microbial count and total yeast and mold count based on USP <61>, and absence of pathogenic organisms based on USP <62>.

CONCLUSION

The results of the performance testing described above demonstrate that the GLISSANT Intimate Lubricants are as safe and effective as the predicate device and support a determination of substantial equivalence.