September 23, 2022

Trigg Laboratories, Inc.
Marla Bolden
Regulatory/Quality Control Manager
4220 West Windmill Lane, Suite 140
Las Vegas, NV 89139

Re: K221829
Trade/Device Name: Wet Flavored Personal Lubricants
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 24, 2022
Received: June 27, 2022

Dear Marla Bolden:

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,

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)*
K221829

Device Name
Wet Flavored Personal Lubricants

Indications for Use *(Describe)*
Wet Flavored Personal 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. The product is compatible with natural rubber latex and polyisoprene condoms. The 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Wet Flavored Personal Lubricants
510(k) Summary - K22189

510(k) Owner:	TRIGG LABORATORIES, INC.
Street Address:	4220 W WINDMILL LANE, SUITE 140 LAS VEGAS, NV 89139
Establishment Registration Number:	3003963141
Contact Person:	Marla Bolden Regulatory and Quality Control Manager
Contact Number:	Phone: (702) 957-4421
Summary Preparation Date:	August 23, 2022

Device Trade Name: Wet Flavored Personal Lubricants

Device Versions:
Wet Sultry Strawberry Flavored Personal Lubricant
Wet Juicy Watermelon Flavored Personal Lubricant
Wet Tropical Explosion Flavored Personal Lubricant
Wet Popp'n Cherry Flavored Personal Lubricant
Wet Desserts Frosted Cupcake Flavored Personal Lubricant
Wet Desserts Whipped Cream Flavored Personal Lubricant

Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR §884.5300
Product Code:	NUC (lubricant, personal)
Regulatory Class:	Class II

Predicate Device:

Product Name:	JO Gelato Flavored Personal Lubricants
510(k) Number:	K172447
Manufacturer:	United Consortium

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

Device Description:

The Wet Flavored Personal Lubricants are clear, non-sterile, over-the-counter personal lubricants, formulated to be clear, particle-free, and colorless to slight yellow.

The device is designed to supplement the body's own natural lubrication fluids during intimate sexual activity. The product is compatible with natural rubber latex and polyisoprene condoms. The product is not compatible with polyurethane condoms. The device formula is neither a contraceptive nor a spermicide.

The device specifications are listed in Table 1 below:

Table 1: Device Specifications for Subject Device - Wet Flavored Personal Lubricants

Property	Specification
Appearance	Particle free
Color	Colorless to Slight Yellow
Odor	Sweet/Characteristic
Viscosity (cps)	200– 700 cps
Specific Gravity	1.05 – 1.15
pH	5.5-6.8
Osmolality	400-800 mOsm/kg
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Presence of Pathogens per USP <62>	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella	Absent
Escherichia coli	Absent
Candida Albicans	Absent

Indications for Use:
Wet Flavored Personal 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. The product is compatible with natural rubber latex and polyisoprene condoms. The product is not compatible with polyurethane condoms.

Substantial Equivalence Discussion:
The table below lists the comparative intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject Device - Wet Flavored Personal Lubricants and Predicate Device JO Gelato Flavored Personal Lubricants

Characteristic/Feature	Wet Flavored Personal Lubricants	JO Gelato Flavored Personal Lubricants (K172447)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Intended Use	Wet Flavored Personal 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. The product is compatible with natural rubber latex and polyisoprene condoms. The product is	JO Gelato Flavored Personal Lubricants are water-based personal lubricants for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural

	not compatible with polyurethane condoms.	rubber latex, polyurethane and polyisoprene condoms.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Water/Eau, Glycerin, Pentylene Glycol, Flavor/Aroma, Cellulose Gum, Potassium Sorbate, Sucralose	Water (Aqua), Glycerin, Potassium Sorbate, Hydroxyethylcellulose, Flavor(Aroma), Sodium Chloride, Sucralose, Citric Acid
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	2 years	2 years
Appearance	Particle free	Clear, semi-viscous liquid
Color	Colorless to Slight Yellow	Color
Odor	Sweet/Characteristic	Sweet/Characteristic
Viscosity (cps)	200– 700 cps	2000 – 3700 cps
Specific Gravity	1.05 – 1.15	0.900 - 1.050
pH	5.5-6.8	5.0 – 6.0
Osmolality	400-800 mOsm/kg	1350 – 1550 mOsm/kg
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products	Meets USP <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<10 cfu/g	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g	<10 cfu/g
Presence of Pathogens per USP <62>	Absent	Absent

The subject and predicate device have the same intended use - for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The subject and predicate device have different technological characteristics, including different formulation, viscosity, specific gravity, pH and osmolality. The different specifications of the subject device do not raise different types of safety and effectiveness questions. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions. All personal lubricants must independently demonstrate they are biocompatible, compatible with condoms, and can maintain their specifications for their expected shelf life.

Summary of Performance Data:

Biocompatibility:

Biocompatibility testing was performed in accordance with 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 10993-1:2018 as follows:

- Acute Systemic Toxicity (ISO Tests for Systemic Toxicity, ISO 10993-11:2017)
- Cytotoxicity (ISO Direct Contact, ISO 10993-5:2009)
- Sensitization (ISO Guinea Pig Maximization Sensitization, ISO 10993-10:2010)
- Vaginal Irritation (ISO Vaginal Irritation Study in Rabbits, ISO 10993-10:2010/10993-23:2021)

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

Shelf-Life:
The Wet Flavored Personal Lubricant is shown to have a two-year shelf life per ICH Guideline "EVALUATION FOR STABILITY DATA Q1E" 2003, for Accelerated Aging. Testing on samples with accelerated aging showed that the subject device met the device specifications at baseline and at the end of the proposed shelf life. In addition, a real-time aging study is being conducted to confirm results of the accelerated aging study through the proposed two-year shelf life of the product.

Condom Compatibility:

Compatibility Testing was performed per ASTM D7661-18 (Air Burst and Tensile); "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" and ASTM D3492-16: "Standard Specification for Rubber Contraceptives (Male Condoms)." The results show that Wet Flavored Personal Lubricants are compatible with natural rubber latex and polyisoprene condoms. The subject device is not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that the Wet Flavored Personal Lubricants are as safe and effective as the predicate device and supports a determination of substantial equivalence.