July 7, 2022

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

Re: K220534
Trade/Device Name: Wet Essential95 Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 7, 2022
Received: June 7, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220534

Device Name
Wet Essential95 Personal Lubricant

Indications for Use *(Describe)*
Wet Essential95 Personal Lubricant 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.

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
K220534
Wet Essential95 Personal Lubricant

1. Submitter Information

Company Name: Trigg Laboratories, Inc.
Company Address: 4220 W Windmill Lane, Suite 140
Las Vegas, NV 89139
Company Phone: (702) 957-4400
Contact Person: Marla Bolden
Regulatory and Quality Control Manager
Trigg Laboratories, Inc.
Email: marlab@trigglabs.com

Date Prepared: July 1, 2022

2. Subject Device

Device Trade Name: Wet Essential95 Personal Lubricant
Common Name: Personal Lubricant
Regulation Name: Condom
Regulation Number: 21 CFR 884.5300
Device Class: Class II
Product Code: NUC (lubricant, personal)

3. Predicate Device

Device Name Aloe Cadabra Personal Lubricant and Aloe Cadabra Flavored/Scented Lubricants
510(k) number K124044
Manufacturer Seven Oaks Ranch, Inc.

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

4. Device Description

The Wet Essential95 Personal Lubricant is a non-sterile, water-based personal lubricant 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 device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists primarily of 95% aloe barbadensis leaf juice. Wet Essential95 Personal Lubricant is sold as an over-the-counter (OTC) product and is provided in 4 oz and 6 oz HDPE bottles.

The specifications for Wet Essential95 Personal Lubricant are described in Table 1.

Table 1: Device Specifications for the Wet Essential95 Personal Lubricant

Property	Specification
Appearance	Semi-opaque, particle-free, liquid gel
Color	Light tan to brown
Odor	Vanilla
Viscosity@25°C Spindle LV#3 @20rpm (cps)	400 cps – 3,200 cps
Specific Gravity@25°C per USP <841>	0.99 – 1.04
pH per USP <791>	4.5 – 5.5
Osmolality per USP <785>	150-300 mOsm/kg, 1:10 dilution
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<100 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Absence of Pathogens per USP <62>	Absent

5. Indication for Use Statement

Wet Essential95 Personal Lubricant 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.

6. Comparison of Intended Use and Technological Characteristics

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

Table 2: Intended Use and Technological Characteristics Comparison of the Subject and Predicate Device

	K220534 Subject Device	K124044 Predicate Device	Comparison
Device Name	Wet Essential95 Personal Lubricant	Aloe Cadabra Lubricant, Aloe Cadabra Flavored/scented Lubricants	
Indications for Use	Wet Essential95 Personal Lubricant 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	Aloe Cadabra® Lubricant and Aloe Cadabra® 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	The indications for use for the subject and predicate device are the same. Therefore, the subject and predicate device have the same intended use.

	latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	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	Same
Base Type	Water	Water	Same
Sterile	No	No	Same
Primary Ingredients	Aloe Barbadensis Leaf Juice; Chamomilla Recuitita (Matricaria) Extract; Chamomilla Recuitita (Chamomile) Flower Extract; Cyamopsis Tetragonoloba (Guar) Gum; Xanthan Gum; Vanilla Flavor; Potassium Sorbate; Sodium Benzoate; Stevia Rebaudiana Extract; Citric Acid	95% organic aloe Additional formulation information is not publicly available	**Different:** The subject and predicate device have differences in formulation. These differences do not raise different questions of safety and effectiveness (S&E).
pH	4.5-5.5	Not publicly available	**Different:** The subject and predicate devices may differ in pH specification. Differences in pH specification do not raise different questions S&E.
Osmolality	150-300 mOsm/kg, 1:10 dilution	Not publicly available	**Different:** The subject and predicate devices may differ in osmolality specification. Differences in osmolality specification do not raise different questions of S&E.
Viscosity	400-3,200 cps	Not publicly available	**Different:** The subject and predicate devices may differ in

			viscosity specification. Differences in viscosity specification do not raise different questions of S&E.
Biocompatibility Tested	Yes	Yes	Same
Microbial Limits Tested (per USP <61>)	Yes	Yes	Same
Antimicrobial Effectiveness (per USP <51>)	Yes	Not tested	**Different:** The subject device underwent antimicrobial effectiveness testing. Conducting this testing to ensure that the device will not support or enhance the growth of microorganisms does not raise different questions of S&E.
Absence of Pathogenic Organisms per USP <62>	Yes	Yes	Same
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same
Shelf-Life	8.5 Months	2 years	**Different:** The subject and predicate device have different shelf-life durations. These differences do not raise different questions of S&E.

The subject and predicate devices have the same indications for use and the same intended use (i.e., to provide lubrication during intimate sexual activity). The subject and predicate devices have different technological characteristics, including different formulations, device specifications, and shelf-life. The different technological characteristics identified do not raise different questions of safety and effectiveness.

7. 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." The following testing was conducted:

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

The results of this testing demonstrate that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Condom Compatibility

The compatibility of Wet Essential95 Personal Lubricant with condoms was evaluated in accordance with ASTM D7661-10(R) 2017 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." The results of this test showed Wet Essential95 Personal Lubricant to be compatible with natural rubber latex and polyisoprene condoms. Results showed Wet Essential95 Personal Lubricant not to be compatible with polyurethane condoms.

Shelf-Life

The subject device has a shelf-life of 8.5 months. Results from accelerated testing demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

8. Conclusion

The results of the testing described above demonstrate that Wet Essential95 Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.