



March 4, 2019

United Consortium
Stephanie Morris
Global Regulatory Specialist
29000 N. Hancock Pkwy.
Valencia, CA 91355

Re: K183384
Trade/Device Name: JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant, #LubeLife Water-Based Anal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 5, 2018
Received: December 6, 2018

Dear Stephanie Morris:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K183384

Device Name

JO Agapé Original Personal Lubricant
MUSE Essence Water-Based Lubricant
#LubeLife Water-Based Lubricant
#LubeLife Water-Based Anal Lubricant

Indications for Use (Describe)

JO Agapé Original Personal Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

MUSE Essence Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Water-Based Anal Lubricant is a water-based personal lubricant for penile, anal 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 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.

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510(k) Traditional Submission

JO Agapé Original Personal Lubricant / MUSE Essence Water-Based Lubricant /
#LubeLife Water-Based Lubricant / #LubeLife Water-Based Anal Lubricant

510(k) Summary

510(k) Owner: United Consortium

Street Address: 29000 N. Hancock Parkway
Valencia, CA 91355

Contact Person: Stephanie Morris
Global Regulatory Specialist

Bruce Albert
Head of Technical Services

Contact Numbers: Phone: (661) 295-1700, ext. 232
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Summary Preparation Date: December 5, 2018

Trade Name: JO Agapé Original Personal Lubricant
MUSE Essence Water-Based Lubricant
#LubeLife Water-Based Lubricant
#LubeLife Water-Based Anal Lubricant

Device Classification:

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

Predicate Device:

Product Name:	Wet Original® Personal Lubricant
510(k) Number:	K160211
Manufacturer:	Trigg Laboratories, Inc.
Product Code:	NUC (lubricant, personal)
Device Class:	Class II

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

Device Description:

JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant and #LubeLife Water-Based Anal Lubricant are clear/water



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JO Agapé Original Personal Lubricant / MUSE Essence Water-Based Lubricant / #LubeLife Water-Based Lubricant / #LubeLife Water-Based Anal Lubricant

white, viscous personal lubricants that are compatible with condoms made of natural rubber latex and polyisoprene. These products are not compatible with polyurethane condoms. These devices are non-sterile personal lubricants for penile, anal 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. All of these devices contain the same formulation.

The JO Agapé Original Personal Lubricant product is to be sold as an over-the-counter (OTC) product in sizes of 1 fl. oz./30 mL, 2 fl. oz./60 mL and 4 fl. oz./120 mL. This product is provided in clear, Polyethylene Terephthalate (PET) cylinder bottles. The 1 oz. size bottles are capped with natural polypropylene disc tops. The 2 oz. and 4 oz. size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process. This product is also available in 3 mL and 10 mL polyester-faced laminated pouches.

The MUSE Essence Water-Based Lubricant product is to be sold as an over-the-counter (OTC) product in 4 fl. oz./120 mL size bottles. This product is provided in clear, Polyethylene Terephthalate (PET) cylinder bottles. The bottles are capped with matte black Polypropylene (PP) pump closures. The bottles are then placed in Solid Bleached Sulfate (SBS) cartons and sealed with a clear Biaxially-Oriented Polypropylene (BOPP) sticker on the top and bottom of each carton. This product is also available in 10 mL size polyester-faced laminated pouches.

#LubeLife Water-Based Lubricant product is to be sold as an over-the-counter (OTC) product in 8 fl. oz./240 mL and 12 fl. oz./360 mL sizes. This product is provided in clear, Polyethylene Terephthalate (PET) cylinder bottles and capped with natural disc tops. The individual bottles are hermetically sealed during the production process.

LubeLife Water-Based Anal Lubricant product is to be sold as an over-the-counter (OTC) product in 12 fl. oz./360 mL size bottles. This product is provided in clear, Polyethylene Terephthalate (PET) cylinder bottles and capped with natural disc tops. The individual bottles are hermetically sealed during the production process.

The device specifications are listed in the table below:

Table 1: Device Specifications for JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant and #LubeLife Water-Based Anal Lubricant

Property	Specification
Appearance	Clear, viscous liquid
Color	Clear, water white
Odor	Odorless
Viscosity (cps)	2400 cps to 3100 cps
pH	3.6 to 4.5



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**JO Agapé Original Personal Lubricant / MUSE Essence Water-Based Lubricant /
#LubeLife Water-Based Lubricant / #LubeLife Water-Based Anal Lubricant**

Specific Gravity	1.020 to 1.026
Osmolality	600 to 700 mOsm/kg
Antimicrobial effectiveness per USP <51>	Meets US <51> acceptance criteria for Category 2 products.
Total aerobic microbial count (TAMC) per USP <61> and <1111>	Less than 10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	Less than 10 cfu/g
Presence of Pathogens per USP <62>	Specification
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida albicans	Absent

Indications for Use:

JO Agapé Original Personal Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

MUSE Essence Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Water-Based Anal Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Predicate Device Comparison:

The table below lists the comparative indications for use and technological characteristics of the subject and predicate devices.



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JO Agapé Original Personal Lubricant / MUSE Essence Water-Based Lubricant /
#LubeLife Water-Based Lubricant / #LubeLife Water-Based Anal Lubricant

Table 2: Comparator Table for Subject Devices – JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant, #LubeLife Water-Based Anal Lubricant and Predicate Device Wet Original® Personal Lubricant

Feature	JO Agapé Original Personal Lubricant MUSE Essence Water-Based Lubricant #LubeLife Water-Based Lubricant #LubeLife Water-Based Anal Lubricant	Wet Original® Personal Lubricant (K160211)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	JO Agapé Original Personal Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. MUSE Essence Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. #LubeLife Water-Based Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	The Trigg Laboratories Wet Original® 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, polyisoprene, and polyurethane condoms.



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JO Agapé Original Personal Lubricant / MUSE Essence Water-Based Lubricant /
#LubeLife Water-Based Lubricant / #LubeLife Water-Based Anal Lubricant

Feature	JO Agapé Original Personal Lubricant MUSE Essence Water-Based Lubricant #LubeLife Water-Based Lubricant #LubeLife Water-Based Anal Lubricant	Wet Original® Personal Lubricant (K160211)
	#LubeLife Water-Based Anal Lubricant is a water-based personal lubricant for penile, anal 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 rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Propanediol, hydroxyethylcellulose, water (aqua), gluconolactone, sodium benzoate, citric acid	Glycerin, water, pentylene glycol, potassium sorbate, sodium carboxymethylcellulose
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex, Polyisoprene	Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	2 years

The subject and predicate devices have similar indications for use. The indications for the subject devices has been expanded to also include anal use. This change does not represent a new intended use as the intended use of these devices is the same as the predicate device, i.e., lubrication of an orifice during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations, and condom compatibility. The different technological characteristics of the subject devices does not raise different types of safety and effectiveness questions.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2016 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices –*



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Part 1: Evaluation and testing within a risk management process” and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Penile Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

The results of this testing demonstrated that the subject lubricants are only slightly cytotoxic with a passing reactivity score, mildly-irritating with a passing reactivity score, non-sensitizing and non-systemically toxic.

Shelf-Life:

The subject devices are non-sterile personal lubricants with a two-year shelf-life in accordance with the results of accelerated aging studies on the various packaging types available for the lubricants, i.e., bottles with cap, bottles with pump closure and pouches. All device specifications listed in **Table 1** were evaluated for the largest volumes associated with each packaging type which were considered worst case for evaluating shelf-life.

Condom Compatibility:

The compatibility of the subject devices with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test indicated that JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant and #LubeLife Water-Based Anal Lubricant are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that the JO Agapé Original Personal Lubricant, MUSE Essence Water-Based Lubricant, #LubeLife Water-Based Lubricant and #LubeLife Water-Based Anal Lubricant are as safe and effective as the predicate device and supports a determination of substantial equivalence.