November 21, 2019

United Consortium
Stephanie Morris
RA/QA Specialist
29000 N. Hancock Pkwy
Valencia, California 91355

Re: K171021
Trade/Device Name: JO Agapé Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: June 29, 2017
Received: July 6, 2017

Dear Stephanie Morris:

This letter corrects our substantially equivalent letter of July 18, 2017.

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 -S

Monica D. Garcia, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171021

Device Name

JO Agapé Personal Lubricant

Indications for Use *(Describe)*

JO Agapé Personal Lubricant is a 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 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) JO Agapé Personal Lubricant Traditional Submission

510(k) Summary – K171021

510(k) Owner:	United Consortium
Street Address:	29000 Hancock Parkway Valencia, CA 91355
Establishment Registration Number:	3005691625
Contact Person:	Stephanie Morris RA/QA Specialist Bruce Albert Head of Technical Services
Contact Numbers:	Phone: (661) 295-1700, ext. 232 Phone: (661) 295-1700, ext. 231 FAX: (661) 295-1800
Summary Preparation Date:	July 18, 2017
Trade Name:	JO Agapé Personal Lubricant
Common Name:	Personal Lubricant

Device Classification:	Classification Name:	Condom
	Product Code:	NUC (lubricant, personal)
	Regulation:	21 CFR § 884.5300 (Condom)
	Device Class:	Class II
Predicate Device:	Product Name:	Wet Original® Personal Lubricant
	510(k) Number:	K160211
	Manufacturer:	Trigg Laboratories, Inc.
	Product Code:	NUC
	Device Class:	Class II

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

510(k) JO Agapé Personal Lubricant Traditional Submission

Device Description:

The JO Agapé Personal Lubricant is a clear, colorless, semi-viscous personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. It is not compatible with polyurethane condoms. The device is a non-sterile lubricant for penile and/or vaginal application, to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is provided in Polyethylene Terephthalate (PET) bottles fitted with Polypropylene caps. The individual bottles are sealed using an induction seal constructed of aluminized mylar.

The device specifications are listed in the table below:

Table 1: Device Specifications for JO Agapé Personal Lubricant

Property	**Specification**
Appearance	Clear, semi-viscous liquid
Color	Clear, colorless
Odor	Odorless
Viscosity (cps)	2400 cps to 3100 cps
Specific Gravity	1.020 to 1.026
pH	3.60 to 4.30
Osmolality	250 to 350 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>	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	Absent
Candida albicans	Absent

Indications for Use:

JO Agapé Personal Lubricant is a 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 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 intended use and technological characteristics of the subject and predicate device.

510(k) JO Agapé Personal Lubricant Traditional Submission

Table 2: Comparator Table for Subject Device – JO Agapé Personal Lubricant and Predicate Device Wet Original® Personal Lubricant

Feature	JO Agapé Personal Lubricant (K171021)	Wet Original® Personal Lubricant (K160211)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Intended Use	JO Agapé Personal Lubricant is a 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 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.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Propanedile, hydroxyethylcellulose, water, 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 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 and shelf life. 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.

510(k) JO Agapé Personal Lubricant Traditional Submission

Summary of Performance Data:

Biocompatibility

Independent third-party laboratories conducted biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Skin Sensitization testing; each were 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 10993-1:2009 as follows:

- Cytotoxicity (ISO Agarose Overlay Method, 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)
- Penile Irritation (ISO Penile Irritation Study in Rabbits, ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO Tests for Systemic Toxicity, ISO 10993-11:2006)

The results of this testing demonstrated that the subject lubricant is biocompatible.

Shelf-Life:
The proposed device, JO Agapé Personal Lubricant, is a non-sterile personal lubricant with a 36-month (three year) shelf-life in accordance with the results of a real time and accelerated aging study. All device specifications listed in Table 1 were tested at 0, 1, 2, and 3 years. The subject device met the device specifications at all time points.

Condom Compatibility:
The compatibility of the subject device, JO Agapé Personal Lubricant, was evaluated with natural rubber latex, polyisoprene and polyurethane condoms 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 indicate that the JO Agapé Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Conclusion:
The results of the performance testing described above demonstrate that the JO Agapé Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.