September 20, 2022

CC Wellness LLC
Marlent Perez
Quality/Regulatory Specialist
29000 N. Hancock Pkwy.
Valencia, CA 91355

Re: K221908
Trade/Device Name: JO CUMPLAY Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 27, 2022
Received: June 30, 2022

Dear Marlent Perez:

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)*
K221908

Device Name
JO CUMPLAY Personal Lubricant

Indications for Use *(Describe)*
JO CUMPLAY Personal Lubricant is a 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K221908
JO CUMPLAY Personal Lubricant

1. **Submitter Information**

Applicant: CC Wellness LLC
Contact: Marlent Perez
Regulatory Affairs Specialist
Bruce Albert
Chief Scientific Officer
Address: 29000 N. Hancock Parkway Valencia, CA 91355
Phone: (661) 481-6390
Phone: (661) 295-1700, ext. 231

2. **Correspondent Information**

Contact: Marlent Perez
Address: 29000 N. Hancock Parkway Valencia, CA 91355
Phone: (661) 481-6390
Email: mperez@ccwellness.com

3. **Date prepared:** August 26, 2022

4. **Subject Device Information**

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

5. **Predicate Device Information**

Device Name: Coconut Infused Hybrid Personal Lubricant
510(k) Number: K180712
Manufacturer: United Consortium

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

6. **Device Description**

JO CUMPLAY Personal Lubricant is a non-sterile, 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 device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

Its formulation consists of Water (Aqua), Propylene Glycol, Dimethicone, Dimethiconol, Lauryl Glucoside, Aloe Barbadensis Leaf Powder, Vitamin E Acetate, Hydroxyethylcellulose, PEG-90M, Hydrogenated Polydecene, Acrylic Copolymer, Sodium Acrylates/Beheneth-25 Metharylate Crosspolymer, and Chlorphenesin.

JO CUMPLAY Personal Lubricant is sold as an over-the-counter (OTC) product and is provided in a 4 fl. Oz./120 mL polyethylene terephthalate bottle and capped with matte black Polypropylene (PP) pump closure.

Device specifications for the JO CUMPLAY Personal Lubricant are listed in Table 1.

Table 1: Device Specifications for JO CUMPLAY Personal Lubricant

Property	**Specification**
Appearance	Viscous liquid
Color	White to off-white
Odor	Odorless
Viscosity (per USP<911>)	7800 – 8800 cps
pH (per USP<791>)	6.8 – 8.0
Osmolality (per USP<785>)	700 – 1000 mOsm/kg
Total Aerobic Microbial Count (TAMC, per USP <61>)	<100 cfu/g
Total Yeast and Mold Count (TYMC, per USP <61>)	<10 cfu/g
Presence of Pathogens (per USP <62>)	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli	Absent
Salmonella/Shigella	Absent
Antimicrobial Effectiveness Testing (per USP <51>)	**Specification**
Bacteria	Meets USP <51> criteria for category 2. No less than 2.0 log reduction from initial count at 14 days and no increase from the 14-day count at 28 days
Yeast and Molds	No increase from the initial calculated count at 14 and 28 days

7. Indications for Use

JO CUMPLAY Personal Lubricant is a 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.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below 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

	JO CUMPLAY Personal Lubricant K221908 Subject Device	**Coconut Infused Hybrid Personal Lubricant K180712 Predicate Device**
Indications for Use	JO CUMPLAY Personal Lubricant is a 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.	Coconut Infused Hybrid 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
Base type	Water	Water
Primary ingredients	Water (Aqua), Propylene Glycol, Dimethicone, Dimethiconol, Lauryl Glucoside, Aloe Barbadensis Leaf Powder, Vitamin E Acetate, Hydroxyethylcellulose, PEG-90M, Hydrogenated Polydecene, Acrylic Copolymer, Sodium Acrylates/Beheneth-25 Metharylate Crosspolymer, Chlorphenesin	Water (Aqua), Propylene Glycol, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Flavor (Aroma), Phenoxyethanol, Polyacrylate 13, Cellulose Gum (sodium carboxymethylcellulose), Raphanus Sativus (Radish) Seed Extract, Polyisobutene, Polysorbate 20, PEG-45M
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance	Viscous liquid	Translucent, semi-viscous cream
Color	White to off-white	White to off-white
Odor	Odorless	Odorless
Viscosity	7,800 – 8800 cps	20,000 – 31,000 cps
pH	6.8 – 8.0	5.7 – 6.3
Osmolality	700 – 1000 mOsm/Kg	450-900 mOsm/kg
Total Aerobic Microbial count (TAMC)	<100 cfu/g	<10 cfu/g
Total Yeast and Mold Count (TYMC)	<10 cfu/g	<10 CFU/g
Absence of Pathogenic Organisms	Yes	Yes

Antimicrobial Effectiveness Tested	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex and polyisoprene condoms
Biocompatibility Tested	Yes	Yes
Shelf life	2.5 years	3 years

The subject and predicate device indications for use and intended use are the same. The subject and predicate device have different technological characteristics, including formulations, shelf-life, and specifications for appearance, TAMC, viscosity, pH, and osmolality. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing 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:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing support the biocompatibility of the device materials.

Shelf-Life

The subject device has a shelf-life of 2.5 years. Results from real-time testing demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

The compatibility of JO CUMPLAY 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 JO CUMPLAY Personal Lubricant to be compatible with natural rubber latex and polyisoprene condoms. Results showed JO CUMPLAY Personal Lubricant not to be compatible with polyurethane condoms.

10. Conclusion

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