



October 22, 2023

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

Re: K232091
Trade/Device Name: JO Coconut Hybrid Cooling Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 17, 2023
Received: July 25, 2023

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 (the 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 available 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael T. Bailey -S

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

Indications for Use

510(k) Number (if known)

K232091

Device Name

JO Coconut Hybrid Cooling Personal Lubricant

Indications for Use (Describe)

JO Coconut Hybrid Cooling 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.

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
PRASStaff@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."



510(k) Summary

K232091

510(k) Owner: CC Wellness LLC

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

Contact Person: Marlent Perez
Regulatory Affairs Specialist II

Bruce Albert
Chief Scientific Officer

Contact Numbers: Phone: (661) 481-6390
Phone: (661) 295-1700

Summary Preparation Date: October 10, 2023

Subject Device Information:

Trade Name: JO Coconut Hybrid Cooling Personal Lubricant

Common Name: Personal Lubricant

Regulation Name: Condom

Regulation Number: 21 CFR 884.5300

Product Code: NUC (lubricant, personal)

Device Class: Class II

Predicate Device Information:

Product Name: Coconut Infused Hybrid Personal Lubricant

510 (k) number: K180712

Manufacturer: United Consortium

Product Code: NUC (lubricant, personal) Class

Device Class: II

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

Device Description:

JO Coconut Hybrid Cooling Personal Lubricant is a clear, viscous personal lubricant that is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. This device is a non-sterile personal lubricant for penile, anal and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity supplement the body's natural lubrication.



JO Coconut Hybrid Cooling Personal Lubricant is sold as an over-the-counter (OTC) product in a 1 fl. oz./ 30 mL and 4 fl. oz./ 120 mL bottle. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 1 fl. oz/ 30 mL size bottle is capped with natural disc tops. The 4 fl. oz/ 120 mL is capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

This device is composed of Water (Aqua), Propylene Glycol, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Flavor (Aroma), Phenoxyethanol, Polyacrylate 13, Cellulose Gum, Raphanus Sativus (Radish) Seed Extract, Polyisobutene, Polysorbate 20, Butyrospermum Parkii (Shea) Butter Extract, Ethyl Mentane Carboxamide, Methyl Diisopropyl Propionamide, Beeswax Glyceryl Stearate, Menthyl Lactate, PEG-100 Stearate, Stearamidopropyl Dimethylamine Lactate, PEG45M, Caprylyl Glycol, Phenethyl Alcohol, Ethylhexylglycerin and Polyquaternium-67.

The device specifications are listed in the table below:

Table 1: Device Specifications for JO Coconut Hybrid Cooling Personal Lubricant

Property	Specification
Appearance	Viscous opaque liquid
Color	Opaque, off-white
Odor	Mild Coconut
Viscosity (cps) per USP <911>	20,000 – 30,000
pH per USP <971>	5.50 – 6.50
Specific Gravity per USP <841>	0.980 – 1.050
Osmolality per USP <785>	775 - 950 mOsm/kg (1:1 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>	Less than 100 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
<i>Pseudomonas aeruginosa</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Salmonella/Shigella</i>	Absent
<i>Escherichia coli</i>	Absent
<i>Candida albicans</i>	Absent

Indications for Use:

JO Coconut Hybrid Cooling 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.



Comparison of Intended Use and Technological Characteristics with Predicate Device:

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

Table 2: Comparator Table for Subject Device – JO Coconut Hybrid Cooling Personal Lubricant and Predicate Device – Coconut Infused Hybrid Personal Lubricant

Feature	JO Coconut Hybrid Cooling Personal Lubricant	Coconut Infused Hybrid Personal Lubricant (K180712)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	JO Coconut Hybrid Cooling 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 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	Water (Aqua), Propylene Glycol, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Flavor (Aroma), Phenoxyethanol, Polyacrylate 13, Cellulose Gum, Raphanus Sativus (Radish) Seed Extract, Polyisobutene, Polysorbate 20, Butyrospermum Parkii (Shea) Butter Extract, Ethyl Mentane Carboxamide, Methyl Diisopropyl Propionamide, Beeswax Glyceryl Stearate, Menthyl Lactate, PEG-100 Stearate, Stearamidopropyl Dimethylamine Lactate, PEG45M, Caprylyl Glycol, Phenethyl Alcohol, Ethylhexylglycerin, Polyquaternium-67.	Water (Aqua), Propylene Glycol, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Flavor (Aroma), Phenoxyethanol, Polyacrylate 13, Cellulose Gum, Raphanus Sativus (Radish) Seed Extract, Polyisobutene, Polysorbate 20, PEG-45M
pH	5.50 – 6.50	5.30 – 6.30
Osmolarity	775 - 950 mOsm/kg (1:1 dilution)	300 - 950 mOsm/kg
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex and Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	3 years



The subject and predicate device have the same indications for use and intended use. The subject and predicate devices have different technological characteristics including different formulations and device specifications. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Data:

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"* as follows:

- 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 this testing demonstrated that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not acutely systemically toxic.

Shelf-Life:

The subject device is a non-sterile personal lubricant with a 3-year shelf-life in accordance with the results of a real time aging study. Results from this 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 the subject device with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-18 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this testing demonstrated JO Coconut Hybrid Cooling 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 JO Coconut Hybrid Cooling Personal Lubricant is safe and effective as the predicate device and supports a determination of substantial equivalence.