May 8, 2023

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

Re: K230674
Trade/Device Name: JO Water Based Anal Thick Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 7, 2023
Received: March 10, 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 (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.
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)*
K230674

Device Name
JO Water Based Anal Thick Lubricant

Indications for Use *(Describe)*
JO Water Based Anal Thick 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.

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8. 510(k) Summary

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:	May 5, 2023

Subject Device Information:

Trade Name:	JO Water Based Anal Thick 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:	The Sex Gel
	510(k) number:	K181078
	Manufacturer:	Necessaire, 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 Water Based Anal Thick Lubricant is a clear, semi-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 Water Based Anal Thick Lubricant is sold as an over-the-counter (OTC) product in 2 fl. oz./ 60 mL, 4 fl. oz./120 mL and 8 fl. oz./ 240 mL bottles. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle and capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

This device is composed of Water (Aqua), Glycerin, Polysorbate 20, Propylene Glycol, Hydroxyethyl cellulose, Chlorphenesin, Vitamin E Acetate and Sodium Hydroxide.

The device specifications are listed in the table below:

Table 1: Device Specifications for JO Water Based Anal Thick Lubricant

Property	**Specification**
Appearance	Semi-viscous liquid
Color	Clear
Odor	Odorless
Viscosity (cps) per USP <911>	6,500 – 9,000
pH per USP <971>	6.50 to 7.50
Specific Gravity per USP <841>	0.950 to 1.100
Osmolality per USP <785>	550 – 850 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**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida albicans	Absent

Indications for Use:

JO Water Based Anal Thick 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 Water Based Anal Thick Lubricant and Predicate Device – The Sex Gel

Feature	JO Water Based Anal Thick Lubricant	The Sex Gel (K181078)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	JO Water Based Anal Thick 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.	The Sex Gel 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 condoms and polyurethane condoms.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Water (Aqua), Glycerin, Polysorbate 20, Propylene Glycol, Hydroxyethylcellulose, Chlorphenisen, Vitamin E Acetate, Sodium Hydroxide	Water, Aloe Barbadensis Leaf Juice, Sorbitol, Hydroxyethylcellulose, Allantoin, Lactic Acid/Tocopherols (Vitamin E), Sodium Hyaluronate, Sodium Benzoate & Potassium Sorbate
pH	6.50 to 7.50	4.00 – 5.00
Osmolarity	550 – 850 mOsm/kg (1:1 dilution)	435 – 535 mOsm/kg
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex and Polyisoprene	Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	18 months	6 months

The subject and predicate device have similar indications for use. The indications for the subject device has been expanded to include anal application. This additional application does not represent a new intended use as the primary intended use of this device 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 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 studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Sensitization Testing were 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"* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
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- 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 an 18 month shelf-life in accordance with the results of a real time and accelerated 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 test indicated JO Water Based Anal Thick 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 Water Based Anal Thick Lubricant is safe and effective as the predicate device and supports a determination of substantial equivalence.