May 22, 2020

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

Re: K200457
Trade/Device Name: Premium Warming Personal Lubricant, Premium Anal Warming Lubricant, All-In-One Warming
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: February 21, 2020
Received: February 25, 2020

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200457

Device Name
Premium Warming Personal Lubricant
Premium Anal Warming Lubricant
All-In-One Warming

Indications for Use *(Describe)*

Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming are 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. These products are compatible with natural rubber latex, polyisoprene and 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.

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510(k) Summary – K200457

510(k) Owner:	CC Wellness LLC
Street Address:	29000 N. Hancock Parkway Valencia, CA 91355
Contact Person:	Marlent Perez Quality Specialist Bruce Albert Head of Technical Services
Contact Numbers:	Phone: (661) 295-1700, ext. 1007 Phone: (661) 295-1700, ext. 231
Summary Preparation Date:	May 4, 2020
Trade Name:	Premium Warming Personal Lubricant Premium Anal Warming Lubricant All-In-One Warming
Common Name:	Personal 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:	JO Premium Personal Lubricant
	510(k) Number:	K132954
	Manufacturer:	United Consortium
	Product Code:	NUC (lubricant, personal)
	Device Class:	Class II

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

Device Description:

Premium Warming Personal Lubricant is sold as an over-the-counter (OTC) product in 1 fl. oz./30 mL and 2 fl. oz./60 mL sizes. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 1 fl. oz./30 mL size bottles are capped with natural disc tops. The 2 fl. oz./60 mL size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

Premium Anal Warming Lubricant is sold as an over-the-counter (OTC) product in 2 fl. oz./60 mL size. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 2 fl. oz./60 mL size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

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

This device is composed of Dimethicone, Dimethiconol and Capsicum Frutescens Fruit Extract.

The device specifications are listed in the table below:

Table 1: Device Specifications for Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming

Property	**Specification**
Appearance	Semi-viscous liquid
Color	Colorless
Odor	Odorless
Viscosity (cps) per USP <911>	800 to 1,075
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:

Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming are 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. These products are compatible with natural rubber latex, polyisoprene and polyurethane

condoms.

Predicate Device Comparison:

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

Table 2: Comparator Table for Subject Device – Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming and Predicate Device – JO Premium Personal Lubricant

Feature	Premium Warming Personal Lubricant Premium Anal Warming Lubricant All-In-One Warming (K200457)	JO Premium Personal Lubricant (K132954)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming are 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. These products are compatible with natural rubber latex, polyisoprene and polyurethane condoms.	JO Premium Personal Lubricant is a 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.
Water soluble	No	No
Ingredients	Dimethicone, Dimethiconol and Capsicum Frutescens Fruit Extract	Dimethicone, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethiconol
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex, Polyisoprene and Polyurethane	Latex, Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	3 years

The subjects and predicate device have similar indications for use. The indication for the subject device has been expanded to also include anal use. This change 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; for example, different formulations. The different technological characteristics of the subject device do 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 – Part 1: Evaluation and testing within a risk management process"* and ISO 10993-1:20019 as follows:

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

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

Shelf-Life:

The subject devices are non-sterile personal lubricants with a three-year shelf-life in accordance with the results of a real time 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 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 that Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming are compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that Premium Warming Personal Lubricant, Premium Anal Warming Lubricant and All-In-One Warming are as safe and effective as the predicate device and supports a determination of substantial equivalence.