



June 10, 2021

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

Re: K210986
Trade/Device Name: H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling, #LubeLife Sensations Pleasure Kit for Two
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 30, 2021
Received: April 1, 2021

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.
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)

K210986

Device Name

H2O Cooling Personal Lubricant

JO 2 To Tango Couples Pleasure Kit

H2O Anal Cooling Personal Lubricant

#LubeLife Sensations Cooling

JO 2 To Tango for Me

#LubeLife Sensations Pleasure Kit for Two

Indications for Use (Describe)

H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two 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 and polyisoprene condoms. These products are 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.

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510(k) Summary – K210986

**H2O Cooling Personal Lubricant/ H2O Anal Cooling Personal Lubricant/
JO 2 To Tango for Me/ JO 2 To Tango Couples Pleasure Kit/ #LubeLife
Sensations Cooling/ #LubeLife Sensations Pleasure Kit for Two**

510(k) Owner: CC Wellness LLC

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

Contact Person: Marlent Perez
Quality/Regulatory Affairs Specialist

Bruce Albert
Chief Scientific Officer

Contact Numbers: Phone: (661) 295-1700, ext. 1007
Phone: (661) 295-1700, ext. 231

Summary Preparation Date: May 25, 2021

Trade Name: H2O Cooling Personal Lubricant
H2O Anal Cooling Personal Lubricant
JO 2 To Tango for Me
JO 2 To Tango Couples Pleasure Kit
#LubeLife Sensations Cooling
#LubeLife Sensations Pleasure Kit for Two

Common Name: Personal Lubricant

Device Classification: Regulation Name: Condom
Regulation Number: 21 CFR § 884.5300
Product Code: NUC (lubricant, personal)
Device Class: Class II

Predicate Device: Product Name: Agape Cooling Personal Lubricant
510(k) Number: K200894
Manufacturer: CC Wellness LLC
Product Code: NUC (lubricant, personal)
Device Class: Class II

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



**H2O Cooling Personal Lubricant/ H2O Anal Cooling Personal Lubricant/
JO 2 To Tango for Me/ JO 2 To Tango Couples Pleasure Kit/ #LubeLife
Sensations Cooling/ #LubeLife Sensations Pleasure Kit for Two**

Device Description:

H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two are clear, semi-viscous personal lubricants that are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms. These devices are non-sterile personal lubricants 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.

H2O Cooling Personal Lubricant is sold as an over-the-counter (OTC) product in 1 fl. oz./30 mL, 2 fl. oz./60 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 2 fl. oz./60 mL and 4 fl. oz./120 mL size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

H2O Anal Cooling Personal Lubricant is sold as an over-the-counter (OTC) product in 2 fl. oz./60 mL and 4 fl. oz./120 mL. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 2 fl. oz./60 mL and 4 fl. oz./120 mL size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

JO 2 To Tango for Me is sold as an over the counter (OTC) product in 2 fl. oz./60 mL. 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.

JO 2 To Tango Couples Pleasure Kit is sold as an over the counter (OTC) product in 2 fl. oz./60 mL. 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.

#LubeLife Sensations Cooling is sold as an over the counter (OTC) product in 4 fl. oz./120 mL. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 4 fl. oz./120 mL size bottles are capped with natural disc tops. The individual bottles are hermetically sealed during the production process.

#LubeLife Sensations Pleasure Kit for Two is sold as an over the counter (OTC) product in 4 fl. oz./120 mL. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The 4 fl. oz./120 mL size bottles are capped with natural disc tops.



**H2O Cooling Personal Lubricant/ H2O Anal Cooling Personal Lubricant/
JO 2 To Tango for Me/ JO 2 To Tango Couples Pleasure Kit/ #LubeLife
Sensations Cooling/ #LubeLife Sensations Pleasure Kit for Two**

The individual bottles are hermetically sealed during the production process.

These devices are composed of Water (Aqua), Glycerin, Polysorbate 20, Propylene Glycol, Hydroxyethylcellulose, Chlorphenesin, Mentha Piperita (Peppermint) Leaf Extract and Sodium Hydroxide.

The devices specifications are listed in the table below:

Table 1: Device Specifications for H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling, #LubeLife Sensations Pleasure Kit for Two

Property	Specification
Appearance	Semi-viscous liquid
Color	Colorless
Odor	Peppermint
Viscosity (cps) per USP <911>	2150 - 4000
pH per USP <971>	3.50 – 4.50
Specific Gravity per USP <841>	1.010 – 1.030
Osmolality per USP <785>	1000 – 1100 (1:1 dilution with purified water)
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:

H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two 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 and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics to the Predicate Device:

The table below lists a comparison of the intended use and technological characteristics of the subject and predicate devices.



**H2O Cooling Personal Lubricant/ H2O Anal Cooling Personal Lubricant/
JO 2 To Tango for Me/ JO 2 To Tango Couples Pleasure Kit/ #LubeLife
Sensations Cooling/ #LubeLife Sensations Pleasure Kit for Two**

Table 2: Comparator Table for Subject and Predicate Device

Feature	H2O Cooling Personal Lubricant H2O Anal Cooling Personal Lubricant JO 2 To Tango for Me JO 2 To Tango Couples Pleasure Kit #LubeLife Sensations Cooling #LubeLife Sensations Pleasure Kit for Two	Agape Cooling Personal Lubricant (K200894)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two 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 and polyisoprene condoms. These products are not compatible with polyurethane condoms.	Agape 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.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Aqua, Glycerin, Polysorbate 20, Propylene Glycol, Hydroxyethylcellulose, Chlorphenesin, Mentha Piperita (Peppermint) Leaf Extract and Sodium Hydroxide	Aqua, Propanediol, Gluconolactone, Hydroxyethylcellulose, Sodium Benzoate, Polysorbate 20, Citric Acid and Mentha Piperita (Peppermint) Leaf Extract
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex and Polyisoprene	Latex and Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	3 years

The subject and predicate devices have similar indications for use statements and have the same intended use – to provide lubrication 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



**H2O Cooling Personal Lubricant/ H2O Anal Cooling Personal Lubricant/
JO 2 To Tango for Me/ JO 2 To Tango Couples Pleasure Kit/ #LubeLife
Sensations Cooling/ #LubeLife Sensations Pleasure Kit for Two**

Biocompatibility studies, including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity 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 10993-1:2019 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 lubricants are 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 the devices 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 D7661-10 (Reapproved 2017) *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this test indicated that H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that H2O Cooling Personal Lubricant, H2O Anal Cooling Personal Lubricant, JO 2 To Tango for Me, JO 2 To Tango Couples Pleasure Kit, #LubeLife Sensations Cooling and #LubeLife Sensations Pleasure Kit for Two are safe and effective as the predicate device and supports a determination of substantial equivalence.