



July 2, 2020

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

Re: K200894
Trade/Device Name: Agape Cooling Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 2, 2020
Received: April 3, 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

Indications for Use

510(k) Number (if known)

K200894

Device Name

Agape Cooling Personal Lubricant

Indications for Use (Describe)

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.

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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510(k) Summary – K200894
Agape Cooling Personal Lubricant

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: June 29, 2020

Trade Name: Agape Cooling Personal Lubricant

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: Premium Cooling Personal Lubricant
510(k) Number: K200602
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.

Device Description:

Agape Cooling Personal 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.

This product is sold as an over-the-counter (OTC) product in 1 fl. oz./30 mL and 2 fl.



oz./60 mL sizes provided in clear polyethylene terephthalate (PET) cylinder bottles. 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.

This device is composed of Water, Propanediol, Gluconolactone, Hydroxyethylcellulose, Sodium Benzoate, Polysorbate 20, Citric Acid and Mentha Piperita (Peppermint) Leaf Extract.

The device specifications are listed in the table below:

Table 1: Device Specifications for Agape Cooling Personal Lubricant

Property	Specification
Appearance	Semi-viscous liquid
Color	Colorless
Odor	Peppermint
Viscosity (cps) per USP <911>	2150 to 4000
pH per USP <971>	3.50 to 4.50
Specific Gravity per USP <841>	1.010 to 1.030
Osmolality per USP <785> (1:2 dilution)	500 to 750 mOsm/kg
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:

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.

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 – Agape Cooling Personal Lubricant and Predicate Device – Premium Cooling Personal Lubricant

Feature	Agape Cooling Personal Lubricant	Premium Cooling Personal Lubricant (K200602)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	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.	Premium 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, polyisoprene and polyurethane condoms.
Water soluble	Yes	No
Contains water	Yes	No
Ingredients	Water, Propanediol, Gluconolactone, Hydroxyethylcellulose, Sodium Benzoate, Polysorbate 20, Citric Acid and Mentha Piperita (Peppermint) Leaf Extract	Dimethicone, Dimethiconol and Menthol
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex, Polyisoprene and Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	3 years

The subject and predicate device indications for use are not identical as the predicate device indications for use also states that it is compatible with polyurethane condoms. This difference does not represent a new intended use as the intended use of the subject device is the same as the predicate device, i.e., provides lubrication during intimate sexual activity. In addition, the subject and predicate devices have different technological characteristics; for example, different formulations, water solubility, condom compatibility, etc. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies 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 10993-1:2018 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 non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Shelf-Life:

The subject device is a non-sterile personal lubricant 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 Time 0 and at the end of the three-year shelf-life. The subject device met the device specifications at all time points assessed.

Condom Compatibility:

The compatibility of the subject device with natural rubber latex, polyisoprene and polyurethane 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 indicated that Agape 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 Agape Cooling Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.