



June 3, 2020

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

Re: K200602  
Trade/Device Name: Premium Cooling Personal Lubricant, Premium Anal Cooling Lubricant  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: March 5, 2020  
Received: March 9, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For  
Jason R. Roberts, 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)

K200602

Device Name

Premium Cooling Personal Lubricant  
Premium Anal Cooling Lubricant

Indications for Use (Describe)

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.

Premium Anal Cooling 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.

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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Premium Cooling Personal Lubricant and Premium Anal  
Cooling 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: May 29, 2020

Trade Name: Premium Cooling Personal Lubricant  
Premium Anal Cooling Lubricant

Common Name: Personal Lubricant

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

Predicate Device: Product Name: Trojan Chain Reaction Personal  
Lubricant

510(k) Number: K161544  
Sponsor: Church & Dwight Co.,  
Inc  
Product Code: Inc  
Device Class: NUC (lubricant,  
personal) Class II

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

**Device Description:**

Premium Cooling Personal Lubricant and Premium Anal Cooling Lubricant are clear, semi-viscous personal lubricants that are compatible with natural rubber latex, polyisoprene and 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.

**Premium Cooling Personal Lubricant and Premium Anal  
Cooling Lubricant**

Premium Cooling 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 Cooling Lubricant is sold as an over-the-counter (OTC) product in 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 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.

These devices are composed of Dimethicone, Dimethiconol and Menthol.

The device specifications are listed in the table below:

**Table 1: Device Specifications for Premium Cooling Personal Lubricant and Premium Anal Cooling Lubricant**

Property	Specification
Appearance	Semi-viscous liquid
Color	Colorless
Odor	Odorless
Viscosity (cps) per USP <911>	800 to 1,075
Specific Gravity per USP <841>	0.875 to 1.020
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
<b>Presence of Pathogens per USP &lt;62&gt;</b>	<b>Specification</b>
<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:**

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.

Premium Anal Cooling 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.



Premium Cooling Personal Lubricant and Premium Anal  
Cooling Lubricant

**Predicate Device Comparison:**

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

**Table 2: Comparator Table for Subject Device – Premium Cooling Personal Lubricant and Premium Anal Cooling Lubricant and Predicate Device – Trojan Chain Reaction Personal Lubricant**

Feature	Premium Cooling Personal Lubricant Premium Anal Cooling Lubricant	Trojan Chain Reaction Personal Lubricant (K161544)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	<p>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.</p> <p>Premium Anal 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.</p>	<p>Trojan Chain Reaction 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. Not compatible with polyurethane condoms.</p>
Water soluble	No	No
Ingredients	Dimethicone Dimethiconol Menthol	Dimethicone Dimethiconol Sensate
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene and Polyurethane	Natural Rubber Latex and Polyisoprene



Premium Cooling Personal Lubricant and Premium Anal  
Cooling Lubricant

Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	2 years

The subject and predicate devices 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 questions of safety and effectiveness questions.

**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 10993-1:20019 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 lubricants are only slightly cytotoxic with a passing reactivity score, non-irritating, non-sensitizing and non-systemically toxic.

**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 devices with natural rubber latex, polyisoprene and polyurethane condoms were 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 Cooling Personal Lubricant and Premium Anal Cooling Lubricant are compatible with natural rubber latex, polyisoprene and polyurethane condoms.

**Conclusion:**

The results of the performance testing described above demonstrate that Premium Cooling Personal Lubricant and Premium Anal Cooling Lubricant are as safe and effective as the predicate device and supports a determination of substantial equivalence.