December 21, 2018

Cewal, Inc. dba Premiere Enterprises
% Abhishek K. Gurnani
Partner
Amin Talati Upadhye, LLP
100 S. Wacker Drive, Suite 2000
Chicago, IL 60606

Re: K180014
Trade/Device Name: Créme de la Femme Feminine Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 28, 2018
Received: December 3, 2018

Dear Abhishek K. Gurnani:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180014

Device Name
Crème de la Femme Feminine Lubricant

Indications for Use *(Describe)*
Crème de la Femme 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 not compatible with rubber latex, polyurethane, and polyisoprene 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

K180014

Crème de la Femme Feminine Lubricant

Submitter/Owner: Cewal, Inc.
2806 Oakhurst Avenue
Los Angeles, CA
92127
Phone: 310-839-5000
Contact: Jerome Vozoff

Preparer/Contact: Abhishek K. Gurnani
Amin Talati Upadhye, LLP100 South Wacker Drive, Suite 2000Chicago, IL 60606Phone: 312-327-325Fax: 312-884-7352Email: Abhishek@AminTalati.com

Summary Prepared: December 21, 2018

Device Trade Name: Crème de la Femme Feminine Lubricant

Device Common Name: Personal Lubricant

Regulation Name/Number: Condom (21 CFR 884.5300)

Device Product Code: NUC (Lubricant, Personal)

Device Class: II

Predicate Device: K171985: Astroglide® O Oil Personal Lubricant and Massage Oil.

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

Device Description:

Crème de la Femme Feminine Lubricant is a non-sterile, mineral oil based personal lubricant designed to supplement the body's own natural lubrication fluids, and to enhance the ease and comfort of intimate sexual activity. The product is provided in a low-density polyethylene tube with a white polypropylene screw on the cap. The device will be supplied with an applicator. Its specifications include appearance, color, odor, pH, viscosity, antimicrobial effectiveness (USP<51>), total aerobic microbial count (USP<61>), total yeast and mold count (USP<62>, and absence of pathogenic organisms (USP<62>). The lubricant is not a spermicide or contraceptive. The device is not compatible with natural rubber latex, polyisoprene or polyurethane condoms.

Indications for Use:

Crème de la Femme Feminine Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Predicate Device Comparison:

	K1810014 Crème de la Femme Feminine Lubricant Subject Device	K171985 Astroglide® O Oil Personal Lubricant and Massage Oil Predicate Device
Product Feature		
Indication for Use	Crème de la Femme Feminine Lubricant 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 not compatible with natural rubber latex, polyurethane and polyisoprene condoms.	Astroglide O Oil Personal Lubricant & Massage Oil 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 not compatible with condoms.
Over-the-counter Use	Yes	Yes
Base Type	Oil	Oil
Sterile	No	No
Primary Ingredients	Mineral Oil Petrolatum-Ozokerite Paraffin	Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Cocos Nucifera (Coconut) Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinesis (Jojoba) Seed Oil, Argania Spinosa Kernel (Argan Tree Nut) Oil, Tocopherol, Cananga Odorata (Ylang Ylang) Flower Oil

The subject and predicate devices do not have identical indications for use statements; however, their intended uses are the same, i.e., lubrication during intimate sexual activity and not compatible with condoms.

The subject device and predicate devices also have different technological characteristics, including their color, formulation and specifications. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Performance Testing:

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- 1:2009 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 biocompatible.

Condom Compatibility:

Condom Compatibility testing was performed in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." Testing demonstrated that the subject device is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf- Life:

Accelerated shelf-life testing was conducted on the subject device to support its labeled shelf-life period. Results from testing demonstrated that the device can maintain its specifications over the duration of its shelf- life.

Conclusions:

The results of the performance testing described above demonstrate that the Crème de la Femme Feminine Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.