November 9, 2021

Dreambrands, Inc.
℅ Cheryl Wagoner
Consultant
Wagoner Consulting LLG
P.O. Box 15729
Wilmington NC 28408

Re: K211967
Trade/Device Name: Sensual Massage/Ultra Pure
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 5, 2021
Received: October 7, 2021

Dear Cheryl Wagoner:

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 and Part 809); 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211967

Device Name
Sensual Massage/Ultra Pure

Indications for Use *(Describe)*

Sensual Massage/Ultra Pure 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 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.

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510(k) Summary – K211967

Submitter	Dreambrands, Inc. 11645 N Cave Creek Rd Ste 5 Phoenix, AZ, 85020-1300 United States
Contact Person	Cecile Kehoe R&D/Regulatory/QA, Dreambrands, Inc. 11645 N. Cave Creek Road Phoenix, AZ 85020 (602)354-7640 (602)354-7641 fax
Date Prepared	November 5, 2021

Trade Name	Sensual Massage/UltraPure
Common Name	Personal Lubricant
Regulation Name	Condom
Regulation Number	21 CFR 884.5300
Product Code	NUC (Lubricant, Personal)
Regulatory Class	Class II

Predicate Device

SILICONE Personal Lubricant	Bath Concept Cosmetics (Dongguan) Co., Ltd	K191654

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

Device Description

Sensual Massage/Ultra Pure is a non-sterile, silicone-based personal lubricant comprised on dimethoconol, dimethicone, and cyclopentasiloxane. This over-the-counter product is formulated to be clear, non-greasy, and odorless. The Sensual Massage/Ultra Pure lubricant is neither a contraceptive nor a spermicide.

Sensual Massage is available in 2 oz. And 50 ml bottles. The device specifications are listed in the table below.

Parameter	Specification
Appearance	Clear
Color	Colorless
Odor	Odorless
Viscosity	200 cps – 400 cps
Water Activity	<0.3 Aw
Total aerobic microbial count (TAMC) per USP <61>	TAMC <100 cfu/g
Total yeast and mold count (TYMC) per USP <61>	TYMC <10 cfu/g
Absence of Pathogenic Organisms per USP <62>	Absence of pathogenic organisms (specifically absence of Candida

	albicans, Pseudomonas aeruginosa, Salmonella, Staphylococcus aureus, E.Coli, Clostridium sporogenes, Bile-tolerant gram-negative bacteria)

Indications for Use
Sensual Massage/Ultra Pure 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of the Intended Use and Technological Characteristics of the Subject and Predicate Device

The table below details a comparison the intended use and technological characteristics of the subject device and the predicate device.

Device & Predicate Device(s):	K211967	K191654	Comments
Device Name	Sensual Massage /UltraPure	SILICONE Personal Lubricant	
Intended Use	Sensual Massage/UltraPure is an over-the-counter personal lubricant.	SILICONE Personal Lubricant is an over-the-counter personal lubricant.	Same
Indications for Use	Sensual Massage/Ultra Pure 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 compatible with	SILICONE Personal 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	Same

	natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms	natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	
Environment of Use	OTC	OTC	Same
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same
Base Type	Silicone Based	Silicone Based	Same
Primary Ingredients	Dow 1503 Fluid (Dimethicone/Dimethiconol blend) Dow ST-Cyclomethicone 5-NF Dow Silicone Fluid 1,000 cst (Dimethicone)	Dimethicone Dimethiconol	Different
Odor	Odorless	Odorless	Same
Appearance	Clear	Clear	Same
Sterility	Non-sterile	Non-sterile	Same
Viscosity	200 – 400 cps	300 – 700 cps	Different
Water Activity	<0.3 Aw	30 – 33%	Different
Microbial Examination USP <61>	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <10 cfu/mL Absence of pathogens (Candida albicans, Pseudomonas aeruginosa, Salmonella, Staphylococcus aureus, E.Coli, Clostridium sporogenes, Bile-tolerant	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <10 cfu/mL Absence of pathogens (E. Coli, Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella Entrica	Same

	gram-negative bacteria)	subsp, Candida Albicans, Clostridium sporogenes, Bile-tolerant gram-negative bacteria)	
Absence of Pathogenic Organisms USP <62>	Absence Confirmed	Absence Confirmed	Same
Shelf Life	3 years	3 years	Same

The subject and predicate device have similar indications for use statements and have the same intended use (i.e., to provide lubrication during intimate sexual activity). The subject and predicate device have different technological characteristics including different formulations and device specifications. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

Summary of Performance Data

Biocompatibility

Biocompatibility testing was performed in accordance with ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing” including:

- ISO 10993-5:2009 Cytotoxicity (Direct contact)
- ISO 10993-10:2010 Guinea Pig Maximization Sensitization test
- ISO 10993-10:2010 Vaginal Irritation
- ISO 10993-11:2017 Acute Systemic Toxicity

The results of this testing demonstrated that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systematically toxic.

Shelf life

Sensual Massage/UltraPure has a 3 year (36 months) shelf life based on the results of an accelerated (per ASTM F1980-16) and real-time aging study. The results of the shelf life study demonstrated that the subject device meet all device specifications at baseline and throughout the proposed shelf life.

Condom Compatibility

Condom compatibility testing was performed using the methods outlined in ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms”. Testing results demonstrate that the subject device is compatible with natural latex and polyisoprene condoms. The subject device is not compatible with polyurethane condoms.

Conclusion

The results of the performance testing described above demonstrate that Sensual Massage/Ultra Pure is as safe and effective as the predicate device and supports a determination of substantial equivalence.