February 11, 2022

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

Re: K212885
Trade/Device Name: Actively Trying Personal Lubricant Rose Scented
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: January 7, 2022
Received: January 12, 2022

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

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)*
K212885

Device Name
Actively Trying Personal Lubricant Rose Scented

Indications for Use *(Describe)*
Actively Trying Personal Lubricant Rose Scented is a personal lubricant for penile, and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of sexual activity and supplement the body's natural lubrication. This product is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive.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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary – K212885

1. Submitter Information

Applicant: CC Wellness LLC
Contact: Marlent Perez
Regulatory Affairs Specialist
Bruce Albert
Chief Scientific Officer
Address: 29000 N. Hancock Parkway Valencia, CA 91355
Phone: (661) 481-6390
Phone: (661) 295-1700, ext. 231

2. Correspondent Information

Contact: Marlent Perez
Address: 29000 N. Hancock Parkway Valencia, CA 91355
Phone: (661) 481-6390
Email: mperez@ccwellness.com

3. Date prepared: February 7, 2022

4. Device Information

Device Name: Actively Trying Personal Lubricant Rose Scented
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB

5. Predicate Device Information

Device Name: Actively Trying Personal Lubricant
510(k) Number: K182585
Manufacturer: CC Wellness LLC
Regulatory Class: Class II
Product Code: PEB (lubricant, personal, gamete, fertilization, and embryo compatible)

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

6. Device Description

Actively Trying Personal Lubricant Rose Scented is a clear, semi-viscous personal lubricant that is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. This product is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive.

Actively Trying Personal Lubricant Rose Scented is sold as an over-the-counter (OTC) product in 4 fl. oz./120 mL size. This product is provided in a clear polyethylene terephthalate (PET) cylinder bottle. The individual bottles are hermetically sealed during the production process.

This device is composed of Water (Aqua), Hydroxyethylcellulose, Sodium Chloride, Sodium Phosphate, Potassium Phosphate, Propylene Glycol, Chlorphenisen, Fructose, Arabinogalactan, and Rose water (Damascena).

The devices specifications are listed in the table below:

Table 1: Device Specifications for Actively Trying Personal Lubricant Rose Scented

Property	**Specification**
Appearance	Semi-viscous liquid
Color	Clear
Odor	Rose Scented
Viscosity (cps) per USP <911>	8,500 – 13,000
pH per USP <971>	7.25 – 7.80
Specific Gravity per USP <841>	0.900 – 1.100
Osmolality per USP <785>	300 – 410 mOsm/kg
Human Sperm Survival Assay (HSSA)	≥ 80% of control motility at 24 hours after 30 minutes exposure to 10% of subject lubricant
Limulus Amebocyte Lysate (LAL) Gel-Clot Method USP<85> and/or AAMI/ANSI ST72:2011/(R) 2016	<0.5 EU/mL
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**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida albicans	Absent

7. Indications for Use:
Actively Trying Personal Lubricant Rose Scented is a personal lubricant for penile, and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of sexual activity and supplement the body's natural lubrication. This product is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device
The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject Device – Actively Trying Personal Lubricant Rose Scented and Predicate Device – Actively Trying Personal Lubricant

Feature	Actively Trying Personal Lubricant Rose Scented	Actively Trying Personal Lubricant (K182585)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	PEB	PEB
Indications for Use	Actively Trying Personal Lubricant Rose Scented is a personal lubricant for penile, and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of sexual activity and supplement the body's natural lubrication. This product is compatible with sperm, oocytes and embryos and can be used by couples trying to conceive. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Actively Trying 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 condoms and polyurethane condoms.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Aqua, Propylene Glycol, Hydroxyethylcellulose, Sodium Chloride, Sodium Phosphate, Potassium Phosphate, Propylene Glycol, Chlorphenisen, Fructose, Arabinogalactan, Rose Water	Water (Aqua), Propylene Glycol, Hydroxyethylcellulose, Fructose, Arabinogalactan, Sodium Phosphate, Salta, Potassium Phosphate, Methylparaben, Propylparaben
pH	7.25 – 7.80	7.25 – 7.80
Osmolarity	300 – 410 mOsm/kg	800 – 1000 mOsm/kg
Human Sperm Survival Assay (HSSA)	≥ 80% of control motility at 24 hours after 30 minutes exposure to 10% of subject lubricant	After exposure to 10% JO Actively Trying for 30 minutes, ≥ 80% of the control
Limulus Amebocyte Lysate (LAL) Gel-Clot Method	<0.5 EU/mL	<0.7 EU/mL
Lubricant Barrier Assay	Pass	Pass
Over the counter use	Yes	Yes

Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	2 years	2 years

The subject and predicate device have similar indications for use statements and have the same intended use. The subject and predicate device have different technological characteristics, including different formulations and specifications. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization 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- 1:2009 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 lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Non-clinical Performance Testing

The following additional biocompatibility testing was performed on the proposed device, Actively Trying Personal Lubricant Rose Scented:

- Human Sperm Survival Assay
- Endotoxin Testing per USP <85> and/or AAMI/ANSI ST72:2011/(R) 2016 (Limulus Amebocyte Lysate (LAL) Gel-Clot Method)
- Lubricant Barrier Assay

The results indicate that the subject device is compatible with sperm and does not inhibit sperm motility.

Shelf Life

The subject device is a non-sterile personal lubricant with a two-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 and 2 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 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test indicate that Actively Trying Personal Lubricant Rose Scented is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that the Actively Trying Personal Lubricant Rose Scented is as safe and effective as the predicate device and supports a determination of substantial equivalence.