DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 21, 2017

Combe Incorporated
Richard Grabarz, M.S., R. A. C.
Sr. Manager Regulatory Affairs
1101 Westchester Avenue
White Plains, NY 10604

Re: K171855
Trade/Device Name: Vaginal Moisturizing Gel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 19, 2017
Received: June 21, 2017

Dear Richard Grabarz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K171855

Device Name
Vaginal Moisturizing Gel

Indications for Use *(Describe)*
The device 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 and polyisoprene condoms. 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**

**Submitter:** Combe Incorporated
1101Westchester Avenue
White Plains, NY 10604
Phone: 800-873-7400
Electronic: www.combe.com/contact

**Official Correspondent:** Richard S. Grabarz, M.S., RAC
Sr. Manager Regulatory Affairs
Email: rgrabarz@combe.com
Phone: (914) 461-4467
Fax: (914) 697-7717

**Date Prepared:** July 20, 2017

**Device Proprietary Names:** Vaginal Moisturizing Gel
**Device Common Name:** Personal Lubricant
**Classification:** 21 CFR 884.5300 (Condom )
**Regulatory Class:** II

**Product Code:** NUC (lubricant, personal)
**Predicate Device:** Internal Hydrating Gel (K141718) and Vaginal Moisturizing Gel (K150615)

The predicate devices have not been subject to a design-related recall.

**Device Description:**

Vaginal Moisturizing Gel is a non-sterile, water based, colorless, transparent viscous gel. It is identical to the predicate devices except that it is packaged for use in tube sizes of either 5 or 50 grams (0.18oz. /1.8 oz.). Tubes are comprised of a laminate structure. The larger 50 gram size will utilize a flip-top cap while the smaller 5 gram size will utilize a screw on cap.

This device is compatible with natural rubber latex and polyisoprene condoms. This device is not compatible with polyurethane condoms. The following parameters are included as part of the device specification:

- Appearance
- Color
- Odor
- pH
- Viscosity
- Osmolality

- Antimicrobial effectiveness
- Total Aerobic Microbial Count (TAMC)
- Total Yeast and Mold Count (TYMC)
- Absence of Pathogenic Organisms (at minimum *Pseudomonas aeruginosa, Staphylococcus aureus, and Candida albicans)*

**Comparison of Indication for Use and Technological Characteristics:**

| **Device & Predicate Device(s):** | K171855 | K150615 | K141718 |
|---|---|---|---|
| General Device Characteristics | | | |
| Sponsor | Combe | Combe | Combe |
| Indication for Use | The device 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. Not compatible with polyurethane condoms. | The device 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. | The device 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 polyisoprene condoms only. |
| Formulation | Same (see Device Description) | Identical | Identical |
| Condom Compatibility | Natural rubber latex and polyisoprene condoms | Natural rubber latex and polyisoprene condoms | Polyisoprene condoms only |
| Base Type | Water | Water | Water |
| Packaging | Laminate tube | Single use pre-filled applicator with twist off cap | Laminate tube with screw-on plastic syringe |
| Amount of lubricant in package (g) | 5 and 50 | 5.9 | 28 |

| | | | |
|---|---|---|---|
| Applicator Length (mm) | | | |
| Barrel | N/A | N/A | 118.49 ± 1.02 |
| Plunger | N/A | N/A | 124.90 ± 1.01 |
| Applicator Width/ Diameter (mm) | | | |
| Barrel | N/A | N/A | 11.18 ± 0.75 |
| Plunger | N/A | N/A | 14.22 ± 0.75 |
| Tube Length(mm) | | | |
| Tube | 58.8/127.0 | 66.68 ± 1 | 104.775 |
| Neck | 3.86/5.89 | 63.00 ± 1 | 5.56 |
| Tube Width (mm) | | | |
| Tube | 15.875/28.178 | 19.00 ± 0.2 | 22.225 |
| Neck | 3.937/6.350 | 14.00 ± 0.2 | 6.350 |
| Neck base | N/A | 6.42 ± 0.2 | N/A |
| Package color | N/A | Aqua exterior | Natural |
| Material Syringe | N/A | N/A | LDPE |
| Tube Material | | | |
| Tube | LDPE | LDPE | LDPE |
| Tube Body | Foil Laminate | Foil Laminate | Foil Laminate |
| | | | |
| Physical/Chemical | Acceptance range | Acceptance range | Acceptance range |
| Appearance | Clear translucent | Clear translucent | Clear translucent |
| pH | 4.0 – 5.0 | 4.0 – 5.0 | 4.0 – 5.0 |
| Viscosity | 55,000 – 100,000 cps | 55,000 – 100,000 cps | 55,000 – 100,000 cps |
| Osmolality (mOsm/kg) | 1273 ± 9 | 1273 ± 9 | 1273 ± 9 |
| Micro | | | |
| Total plate count | <100 cfu/g | <100 cfu/g | <100 cfu/g |
| Yeast and mold | < 10 cfu/g | < 10 cfu/g | < 10 cfu/g |
| Pseudomonas aeruginosa | Negative | Negative | Negative |
| Staphylococcus aureus (coagulase positive) | Negative | Negative | Negative |
| Candida albicans | Negative | Negative | Negative |
| Performance: Coefficient of Friction | 0.186 | 0.186 | 0.186 |
| Storage conditions | Room temp | Room temp | Room temp |

The subject device indication for use statement is similar to the primary predicate device (K141718), except that the subject device claims to be compatible with natural rubber latex condoms.

The subject device differs from the K141718 predicate device in the following ways:

1. The subject device is provided in two sizes, a 5 & 50 gram laminate tube, while the predicate device, Internal Hydrating Gel (K141718) is provided in a laminate tube (28 g) with a screw off cap of similar construction.
2. The subject device does not utilize any applicators/syringes. The previous predicate

device Internal Hydrating Gel (K141718) included 8 applicators/syringes for internal application.

The different technological characteristics described above do not raise different types of safety and effectiveness questions, as they are commonly encountered in 510(k) reviews for personal lubricants. These differences in packaging can be addressed through shelf-life testing.

**Performance Testing:**

| | |
|---|---|
| Shelf Life | Vaginal Moisturizing Gel has a shelf life of 36 months for the larger, 50 gram tube and a shelf life of 18 months for the smaller, 5 gram tube. The results of accelerated aging and real time studies demonstrate that the subject device in the new packaging meets its specifications over the duration of the proposed shelf life. |
| Biocompatibility | Biocompatibility of the proposed device, External Moisturizing Gel is identical to that of the predicate devices, Internal Hydrating Gel (K141718) and Vaginal Moisturizing Gel (K150615). The formulation of the subject device remains unchanged from that of the predicate devices. |
| Performance Testing Non-Clinical | Performance of the proposed device is identical to the predicate devices, Internal Hydrating Gel (K141718) and Vaginal Moisturizing Gel (K150615). |

**Conclusion:**

The proposed device, Vaginal Moisturizing Gel, is substantially equivalent to the predicate devices.