



Food and Drug Administration  
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May 1, 2015

Combe Incorporated  
Pushpa Rao, Ph.D., D.A.B.T., R.A.C.  
Sr. Director Global Regulatory Affairs/Product Safety  
1101 Westchester Avenue  
White Plains, NY 10604

Re: K150615  
Trade/Device Name: Vaginal Moisturizing Gel  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: March 9, 2015  
Received: March 10, 2015

Dear Pushpa Rao,

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 yours,

**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

## Indications for Use

510(k) Number (if known)

K150615

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 latex 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## 510(k) Summary

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|----------------------------------|--|
| <p><b>510(k) Owner:</b></p>      | <p>Combe Incorporated<br/>1101 Westchester Avenue<br/>White Plains, NY 10604</p>   |
| <p><b>Contact Person</b></p>     | <p>Pushpa Rao, Ph.D., D.A.B.T., R.A.C.<br/>Sr. Director Global Regulatory Affairs/Product Safety<br/>Email: <a href="mailto:prao@combe.com">prao@combe.com</a><br/>Phone: (914) 461-4458<br/>Fax: (914) 697-7764</p>   |
| <p><b>Name of Device</b></p>     | <p>Trade name – Vaginal Moisturizing Gel<br/>Classification name - Personal lubricant<br/>Citation: 21 CFR 884.5300<br/>Product Code: NUC Class: II</p>  |
| <p><b>Predicate Device</b></p>   | <p>Internal Hydrating Gel (K141718)</p>  |
| <p><b>Device Description</b></p> | <p>Vaginal Moisturizing Gel is identical to the predicate device except that it is presented in 8 pre-filled applicators for easy use.</p> <p>Vaginal Moisturizing Gel is intended for use as a personal lubricant. This product 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 product specification:</p> <ul style="list-style-type: none"> <li>• Appearance</li> <li>• Color</li> <li>• Odor</li> <li>• pH</li> <li>• Viscosity</li> <li>• Osmolality</li> <li>• Antimicrobial effectiveness</li> <li>• Total Aerobic Microbial Count (TAMC)</li> <li>• Total Yeast and Mold Count (TYMC)</li> <li>• Absence of Pathogenic Organisms (at minimum <i>Pseudomonas aeruginosa</i>, <i>Staphylococcus aureus</i>, and <i>Candida albicans</i>)</li> </ul> <p>Vaginal Moisturizing Gel has a pH of 4.5-5.0 and a shelf life of 18 months.</p> |

## 510(k) Summary

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|---|--|
| <b>Indications for Use</b>                | 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.  |
| <b>Technological Characteristics</b>      | The proposed device, Vaginal Moisturizing Gel has the identical technological characteristics as the predicate device.   |
| <b>Biocompatibility Data</b>              | Biocompatibility of the new applicator was supported with a study of extractable and leachable materials from the applicator. The new applicator was subjected to extractable testing according to USP <661>: Physicochemical Tests for Plastics. Extracts were also analyzed using infrared analysis, gas chromatography coupled with mass spectrometry (GC-MS), and inductively coupled plasma mass spectroscopy. Extracted molecules were only detected after aggressive extraction with ethanol as determined by GC-MS. Risk analysis showed that ethanol extractable materials were in amounts much lower than the tolerable intake of any component. |
| <b>Performance Testing- Non- Clinical</b> | The proposed device was tested for condom compatibility according to ASTM D7661-10 and found to be compatible with natural rubber latex and polyisoprene condoms.  |
| <b>Conclusions</b>                        | Based on the results of non-clinical testing, the proposed device, Vaginal Moisturizing Gel, is substantially equivalent to the predicate device.  |