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

January 16, 2015

Combe Incorporated
Pushpa Rao
Senior Director, Global Regulatory Affairs & Product Safety
1101 Westchester Avenue
White Plains, NY 10604

Re: K141718
Trade/Device Name: Internal Hydrating Gel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: October 14, 2014
Received: October 15, 2014

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,

Benjamin R. Fisher -A

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 on last page.

510(k) Number *(if known)*
K141718

Device Name
Internal Hydrating 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 polyisoprene condoms. This device is not compatible with natural rubber latex or 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)

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)*

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

510(k) Owner:	Combe Incorporated 1101Westchester Avenue White Plains, NY 10604
Contact Person	Pushpa Rao, Ph.D., D.A.B.T., R.A.C. Sr. Director Global Regulatory Affairs/Product Safety Email: prao@combe.com Phone: (914) 461-4458 Fax: (914) 697-7764
Name of Device	Trade name – Internal Hydrating Gel Classification name - Personal lubricant Citation: 21 CFR 884.5300 Product Code: NUC Class: II
Predicate Device	HYALO GYN® Vaginal Hydrating Gel(K094039)
Device Description	Internal Hydrating Gel is a colorless, transparent, aqueous, hydrating gel in tube with 8 syringes for easy application. Internal Hydrating Gel is intended for use as a personal lubricant. This product is compatible with polyisoprene condoms. This device is not compatible with natural rubber latex or polyurethane condoms. Accordingly, the following parameters are included as part of the product 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*)

510(k) Summary

	Internal Hydrating Gel has a pH of 4.5-5.0 and a shelf life of 21 months.
Indications 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 polyisoprene condoms. This device is not compatible with natural rubber latex or polyurethane condoms.
Technological Characteristics	The proposed device, Internal Hydrating Gel has the same technological characteristics as the predicate device.
Biocompatibility Data	The following biocompatibility testing was conducted in support of safety of the proposed device: <u>Pre-Clinical Testing</u> Cytotoxicity Zone of Inhibition Systemic Toxicity Vaginal Irritation Guinea Pig Maximization <u>Clinical Testing</u> HRIPT
Performance Testing Non-Clinical	An assessment of non-clinical performance data was conducted and the proposed device performs the same as the predicate devices.
Conclusions	Based the results of the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as the predicate device. The device is substantially equivalent to the predicate device.