November 21, 2017

WSM Investment LLC, dba Topco Sales
Julie Casagrande
Quality Control Manager
3990 Suite B Heritage Oak Court
Simi Valley, CA 93063

Re: K171044
Trade/Device Name: Climax Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 23, 2017
Received: October 23, 2017

Dear Julie Casagrande:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*

K171044

Device Name

Climax Personal Lubricant

Indications for Use *(Describe)*

Climax 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 natural lubrication. This product is compatible with natural rubber latex, polyurethane, 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)

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.

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510(k) Summary
K171044

General Information

510(k) Owner: WSM Investments dba Topco Sales
3990-B Heritage Oak Court
Simi Valley, CA, 93063
Telephone: 805-842-9197

Contact Person(s): Julie Casagrande
QC/Regulatory Manager
3390-B Heritage Oak Court
Simi Valley, CA 93063
Phone: 805-842-9197

Summary Preparation Date: November 20, 2017

Device Information

Device Trade Name: Climax Personal Lubricant

Common Name: Personal Lubricant

Classification Name: Condom
(21 CFR 884.5300, Class II, Product Code: NUC (lubricant, personal))

Predicate Device

Device Name: Astroglide Sensual Strawberry
510(k) Clearance Number: K140590

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

Device Description
Climax Personal Lubricant is a non-sterile, water soluble, viscous liquid which is intended to be used as a personal lubricant. The ingredients are Purified Water (Aqua), Glycerin, Propylene Glycol, Hydroxyethylcellulose, Diazolidinyl Urea, Methylparaben, Propylparaben. The product specifications include appearance, color, odor, pH, viscosity, specific gravity, osmolality, total aerobic microbial count per USP <61>, total yeast and mold count per USP <61>, absence of pathogenic organisms per USP <62>, and antimicrobial effectiveness per USP <51>. Climax Personal Lubricant is packaged in 5 fl. oz, and 6.5 fl. oz. bottles.

Indications for Use
Climax 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 natural lubrication. This product is compatible with natural rubber latex, polyurethane and polyisoprene condoms.

The subject and predicate device have the same intended use.

Technological Characteristics

	K171044	**K140590**	**Comments**
General Device Characteristics	**Subject**	**Predicate**	
Trade Name	Climax Personal Lubricant	Astroglide Sensual Strawberry	N/A
Submitter	WSM Investment LLC, dba Topco Sales	BioFilm Inc.	N/A
Regulation Number Product Code Device Class	884.5300 NUC Class II	884.5300 NUC Class II	Same
Condom Compatibility	Natural Rubber Latex (NRL), Polyurethane, and Polyisoprene	Natural Rubber Latex (NRL), Polyurethane, and Polyisoprene	Same
Base Type	Water	Water	Same
Primary Ingredients	Water Glycerin Propylene Glycol Hydroxyethylcellulose	Water Glycerin Propylene Glycol Hydroxyethylcellulose	Same
Packaging	polyethylene terephthalate (PET) bottle with pump	polyethylene terephthalate (PET) bottle with flip top	Same

The subject and predicate device have differences in technological characteristics, including formulation and specifications. However, those differences do not raise new questions on safety or effectiveness.

Performance Testing

Biocompatibility
Climax Personal Lubricant has undergone biocompatibility testing including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity testing per ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006. The testing found that Climax Personal Lubricant is biocompatible.

Condom Compatibility
Climax Personal Lubricant was tested for condom compatibility per ASTM D7661-10 and was found to be compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Shelf Life
The results of shelf life testing demonstrate that the subject device maintains its specifications over the duration of their proposed shelf life.

Conclusion
The results of performance testing demonstrate that the subject and predicate device are substantially equivalent.