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

August 21, 2015

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundlelein, Illinois 60060

Re: K143529
Trade/Device Name: Ultrasmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: July 21, 2015
Received: July 22, 2015

Dear Jennifer Mason:

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,

Herbert P. Lerner -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)*
K143529

Device Name
Ultrasmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer

Indications for Use *(Describe)*
Ultrasmooth Lubricating Liquid 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.

Medline Lubricating Liquid and Vaginal Moisturizer 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)

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."

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060-4486

510(k) Summary (as required per 21 CFR 807.92)

Summary Preparation Date

August 20, 2015

Submitter / 510(k) Sponsor

Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060

Contact Person

Jennifer Mason
Sr. Regulatory Affairs Specialist
Phone: 847-643-3652
Fax: 847-643-4482

Device Name / Classification

Device Name: UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer
Proprietary Name: UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer
Common Name: Personal Lubricants
Classification Name: Condom (21 CRF 884.5300, product code – NUC)

Predicate Device

K-Y UltraGel, K020827

Device Description

The UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer are non-sterile aqueous personal lubricants. Both lubricants are clear, odorless and colorless. The ingredients for the UltraSmooth Lubricating Liquid are similar to other personal lubricants currently on the market. The specifications for UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer include color, odor, pH, viscosity, lubricity, osmolarity, antimicrobial effectiveness, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms.
Both the UltraSmooth, and Medline Lubricating Liquid and Vaginal Moisturizer are compatible with natural rubber latex and polyisoprene condoms.

The UltraSmooth Lubricating Liquid product will be offered in two sizes, a 2 fluid ounce and a 6 fluid ounce. The primary packaging consists of a high density polyethylene (HDPE) bottle with

a polypropylene closure. Each bottle of product will be packaged into a cardboard carton, which constitutes the product's outer packaging.

The Medline Lubricating Liquid and Vaginal Moisturizer will be offered in two sizes, 2.5 fluid ounces and 4 fluid ounces. The primary packaging consists of a high density polyethylene (HDPE) bottle with a polypropylene closure. Each bottle of product will be packaged into a cardboard carton, which constitutes the product's outer packaging.

Indications for Use

Ultrasmooth Lubricating Liquid 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.

Medline Lubricating Liquid and Vaginal Moisturizer 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.

Summary of Technological Characteristics

The UltraSmooth Lubricating Liquid and Medline Lubricating Liquid and Vaginal Moisturizer and the cited predicate device have similar technological characteristics per the table below.

General Device Characteristics			
	Subject Device (K143529)	Subject Device (K143529)	Predicate Device
Device & Predicate Device(s):	UltraSmooth Lubricating Liquid	Medline Lubricating Liquid and Vaginal Moisturizer	K-Y UltraGel
Sponsor	Medline Industries, INC.	Medline Industries, INC.	Personal Products CO.
510(k) Number	K143529	K143529	K020827
Regulation Number	884.5300	884.5300	884.5300
Product Code	NUC	NUC	NUC
Device Class	II	II	II
Clearance Date	N/A	N/A	06/12/2002

Condom Compatibility	Yes (Natural Rubber Latex, Polyisoprene)	Yes (Natural Rubber Latex, Polyisoprene)	Yes (Natural Rubber Latex only)
Base Type	Water-based	Water-based	Water-based
OTC Use	Yes	Yes	Yes
Biocompatible	Yes	Yes	Yes
Non-Sterile	Yes	Yes	Yes

Summary of Non-Clinical Testing

UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer are biocompatible based on the results of the following biocompatibility studies:

- Cytotoxicity per ISO 10993-5:2009 using a direct contact method
- Guinea Pig Maximization Sensitization per ISO 10993-10:2010
- Vaginal Irritation per ISO 10993-10:2010
- Systemic Toxicity according to ISO 10993-11:2006 (2010)

The results of accelerated aging studies demonstrate that UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer maintain its specifications over the duration of its one-year shelf life.

The UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer were tested for compatibility with natural rubber latex, polyisoprene, and polyurethane condoms in accordance with ASTM D7661, Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Results showed that the UltraSmooth, and Medline Lubricating Liquid and Vaginal Moisturizer are compatible with natural rubber latex and polyisoprene condoms. These devices are not compatible with polyurethane condoms.

Non-staining testing was performed per AATCC Test Method 130 Soil Release: Oily Stain Release. Lubricant was applied to 9 different fabric types and allowed to age on each fabric for 24 hours prior to the fabric being run through a machine wash cycle. Each fabric type and the lubricant's staining ability were rated according to the test standard. The UltraSmooth Lubricating Liquid was concluded to be non-staining to the fabrics that were tested.

Summary of Clinical Testing

A ten day in use clinical study was performed on the subject devices. The study was conducted over a 10-day period with 30 subjects applying the Medline's Lubricating Liquid and Vaginal Moisturizer and 29 subjects applying UltraSmooth Lubricating Liquid once per day. The results of the study demonstrated that Medline's Lubricating Liquid and Vaginal Moisturizer

and UltraSmooth Lubricating Liquid are safe when used as intended.

Conclusion

The UltraSmooth Lubricating Liquid, and Medline Lubricating Liquid and Vaginal Moisturizer are substantially equivalent to their predicate device.