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, 2015

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, IL 60060

Re: K143322
Trade/Device Name: Medline Natural Lubricating Liquid
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 22, 2015
Received: May 26, 2015

Dear Jennifer Mason:

This letter corrects our substantially equivalent letter of July 2, 2015.

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" (21CFR 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)*

K143322

Device Name
Medline Natural Lubricating Liquid

Indications for Use *(Describe)*

Medline Natural 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, polyisoprene and 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.

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

Summary Preparation Date

July 1, 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
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Device Name / Classification

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

Predicate Device

Astroglide Natural, K141581

Device Description

The Medline Natural Lubricating Liquid is a non-sterile aqueous personal lubricant. Medline Natural Liquid is clear, odorless and colorless. The ingredients are similar to other personal lubricants currently on the market.

The Medline Natural Lubricating Liquid is compatible with natural rubber latex, polyisoprene and polyurethane condoms. The product will be offered in two sizes, a 2.5 fluid ounce and a 5 fluid ounce. The primary packaging consists of a polyethylene terephthalate (PETG) bottle with a screw down, flip top polypropylene closure. Each bottle of product will be packaged into a cardboard carton, which constitutes the product's outer packaging.

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Indications for Use

Medline Natural 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, polyisoprene and polyurethane condoms.

Summary of Technological Characteristics

Information within this Premarket Notification demonstrates that there are no significant differences in technological characteristics between Medline's Natural Lubricating Liquid and the cited predicate device.

Feature	Proposed Device	Predicate Device	Comparison
Product Name	Medline Natural Lubricating Liquid	Astroglide Natural K141581	N/A
Intended Use	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 only compatible with natural rubber latex, polyisoprene and polyurethane condoms.	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 only compatible with natural rubber latex and polyisoprene condoms.	Same
Aqueous Formulation	Yes	Yes	Same
Ingredients	• Water • Hydroxyethylcellulose • Pectin • Aloe Vera Gel • Xylitol • Chlorhexidine Gluconate • Glucono Delta Lactone • Tocopherol Acetate • Chamomile Extract • Sodium Benzoate	• Water • Hydroxyethylcellulose • Pectin • Aloe Barbadensis Leaf Juice • Xylitol • Potassium ascorbyl tocopheryl phosphate • Chamomilla Recutita (Matricaria) Flower Extract • Phenoxyethanol • Lactic Acid	Similar

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Non-sterile	Yes	Yes	Same
Packaging	Primary packaging – bottle Secondary packaging - box	Primary packaging – bottle Secondary packaging - box	Same
Over-the-Counter Use	Yes	Yes	Same
Condom Compatibility	Natural Rubber Latex, Polyisoprene, Polyurethane	Natural Rubber Latex and Polyisoprene	Similar

The proposed Medline Natural Lubricating Liquid is identical in intended use and function to the Astroglide Natural cleared under K141581. Both lubricants are clear, water based lubricants. The ingredients in the Medline Natural Lubricating Liquid are very similar to the Astroglide Natural, with the primary difference being the preservative and pH adjuster used. The results of biocompatibility testing, condom compatibility testing and the in use clinical study support that these differences do not affect the safety and effectiveness of the device when used as labeled.

Summary of Non-Clinical Testing

The safety and effectiveness of Medline's Natural Lubricating Liquid is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Biocompatibility testing of the Medline Natural Lubricating Liquid was conducted in accordance with ANSI/AAMI/ISO 10993:1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process, as recognized by FDA. The following biocompatibility tests were performed:

Cytotoxicity according to ISO 10993-5:2009
Sensitization according to ISO 10993-10:2010
Vaginal Irritation according to ISO 10993-10:2010
Systemic Toxicity according to ISO 10993-11:2006 (2010)

The results of the biocompatibility tests demonstrated that the Medline Natural Lubricating Liquid is biocompatible.

Condom Compatibility

Condom compatibility testing was performed in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms". The testing evaluated the compatibility of the Medline Natural Lubricating Liquid with various types of condoms including natural rubber latex, polyisoprene and polyurethane. The results show the Medline Natural Lubricating Liquid met the acceptance criteria per ASTM D7661 and is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

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Shelf Life

Accelerated and real time shelf life studies were performed on the Medline Lubricating Liquid per ASTM F1980-07:2011. Preservative effectiveness was demonstrated at critical time-points throughout stability testing. These studies demonstrated that the product specifications were maintained throughout the shelf life period.

Summary of Clinical Testing

A ten day in use clinical study was performed on the subject device. The study was conducted over a 10 day period with 27 subjects applying the Natural Lubricating Liquid once per day. The results of the study demonstrated that the Natural Lubricating Liquid is safe when used as intended.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Natural Lubricating Liquid is safe, effective and substantially equivalent to the predicate device, Astroglide Natural K141581, as described herein.