DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 11, 2016

Reckitt Benckiser LLC
Elizabeth Torre
Regulatory Operations Lead
399 Interpace Parkway
Parsippany, NJ 07054

Re: K151884
Trade/Device Name: K-Y® Marilyn Pleasure Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: December 2, 2015
Received: December 3, 2015

Dear Elizabeth Torre,

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)*
K151884

Device Name
K-Y® Marilyn Pleasure Gel

Indications for Use *(Describe)*

Intended 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. This product is not compatible with 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.

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510(k) Summary

Submitted by: Reckitt Benckiser, LLC

399 Interpace Parkway
Parsippany, NJ 07054-0224
973-404-2715
973-404-5702

Contact Person: Elizabeth Torre, Regulatory Operations Lead, Reckitt Benckiser, LLC.

Date Prepared: January 4, 2016

Proprietary Name: K-Y ® Marilyn Pleasure Gel

Trade Name: K-Y ® Marilyn Pleasure Gel

Common Name: Personal Lubricant

Classification Name: Lubricant (21 CFR §884.5300, Product Code NUC)

Predicate Device(s):

KY® Brand Liquid Reckitt Benckiser LLC
Product Code: NUC
510(k) No.: K955648

Durex® Embrace Warming Sensation Gel
Reckitt Benckiser LLC
Product Code: NUC
510(k) No.: K140193

Durex® Embrace Tingling Experience Gel
Reckitt Benckiser LLC
Product Code: NUC
510(k) No.: K140193

Description of the Device:

KY Marilyn is personal lubricant that is a non-sterile, water-based formulation that provides personal lubrication and stimulation during intimate sexual activity. It is made up of Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Flavor, Benzoic Acid and Sodium Hydroxide. The subject device is clear in appearance. The specifications for KY Marilyn include appearance, odor, pH, viscosity, benzoic acid, total aerobic microbial count, total yeast and mold count, and absence of pathogenic organisms (Pseudomonas aeruginosa, Staphylococcus aureus, and Candida albicans) and Antimicrobial Effectiveness.

The subject device will be packaged as follows:

- 12 mL Polyethylene terephthalate (PET) bottle
- Polypropylene (PP) pump
- Polypropylene (PP) snap-on cap
- Outer carton

The device, KY Marilyn, will be marketed as a non-prescription medical device for over-the- counter (OTC) use.

Indications for Use Statement: KY Marilyn is indicated 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. This product is not compatible with polyurethane condoms.

Summary of Technological Characteristics of New Device in Comparison to Predicate:
Predicate comparison can be seen in Table 1 below.

Table 1: Technological Characteristics of Subject Device Compared to Predicate

510(k)	Device Name	Intended Use	Indications for Use	Physical Features	Manufacturer
K151884	KY Marilyn	The intended use of this device is 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 device is compatible with natural rubber latex and synthetic Polyisoprene condoms. This device is not compatible with polyurethane condoms.	Intended 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. This product is not compatible with polyurethane condoms.	Homogeneous Clear Gel/Odorless	Reckitt Benckiser LLC

K955648	KY Liquid	The intended use of this device is a personal lubricant (for vaginal and penile application) compatible with latex condoms ONLY.	Intended as a personal lubricant for penile and vaginal application. It is compatible with latex condoms ONLY.	Homogeneous Clear Gel/Odorless	Reckitt Benckiser LLC
K140193	Durex Embrace Warming Sensation Gel	The intended use of this device is 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 device is compatible with natural rubber latex, synthetic Polyisoprene and polyurethane condoms.	Intended 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. Lubricant is compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.	Homogeneous Clear Gel/Odorless	Reckitt Benckiser LLC
K140193	Durex Embrace Tingling Experience Gel	The intended use of this device is 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 device is compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.	Intended 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. Lubricant is compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.	Homogeneous Clear Gel/Odorless	Reckitt Benckiser LLC

Stability: KY Marilyn is shown to have a 9 month shelf life based on 9 month accelerated stability data provided for the formulation. The formulation has met the specification criteria at all temperature conditions.

Summary of Performance Data:

Table 2: Summary of Performance Data

Standard Used	Name of Standard	Result	Conclusion
ISO 10993-10:2009	Biological Evaluation and Biocompatibility Testing of Medical Devices	The test article was considered a non-irritant to vaginal tissue of the rabbit.	Device shown to be non-irritating
ISO 10993-10:2009	Biological Evaluation and Biocompatibility Testing of Medical Devices	The test article solution showed no evidence of causing delayed dermal contact sensitization in the guinea	Device shown to be non-sensitizing in guinea pig maximization study.

ISO 10993-11:2009	Biological Evaluation and Biocompatibility Testing of Medical Devices	The test article was not considered a sensitizer in the guinea pig maximization test.	Device did not cause any mortality or systemic toxicity
USP <87> :2015	Biological Reactivity Tests, *in vitro*	There was evidence of slight cytotoxicity to the cells exposed to the test item of the subject device.	Device shown to be non-cytotoxic
ASTM D7661-10: 2010	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber latex Condoms	The test results indicate that KY Marilyn (TDS8125708), have passed the condom compatibility test for 510(k) condom for 3NRL and PI condoms– with no tests having % difference values > 20% and the majority of results < 10%.	The Device is shown to be compatible with NRL and PI condoms and not compatible with PU condoms.

Conclusion: Substantial Equivalence of proposed devices can be achieved when the proposed device and the predicate device(s) share the same intended use and the same technological characteristics or when the proposed device and the predicate device(s) share the same intended use with different technological characteristics but when the information submitted to the FDA: 1) does not raise different questions of safety and efficacy of the proposed device and 2) demonstrates that the proposed device is at least as safe and effective as the legally marketed device.

In this case, the predicate devices K140193 and K955648 as well as the proposed device (K151884) share the same intended use for penile and vaginal application for personal lubrication. Based on this information the proposed device and the predicates fall under the FDA Classification NUC for personal lubricant. Both predicates (K140193 and K955648) as well as the proposed device (K151884) are compatible with NRL condoms as per ASTM D7661-10.

Both the proposed device (K151884) and predicate devices K140193 and K955648 are transparent, odorless liquids. They have similar formulation profiles and all contain a thickener, humectant, pH modifier and preservatives. The proposed and predicate devices also share similar technological characteristics including pH and microbial profiles (Specified Organisms Testing). In addition to the technological characteristics, the safety profiles of the proposed and predicate devices are similar. All are non-sensitizing, non-irritating and none are shown to result in mortality or systemic toxicity. All cleared devices have the same fundamental and scientific technology, and based on presented data are considered safe and effective for use. Based on this information, it can be stated that the proposed device is substantially equivalent to the predicate devices.