DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 4, 2014

Reckitt Benckiser, LLC
Sapana Amin
Regulatory Operations Lead
399 Interpace Parkway
Parsippany, NJ 07030

Re: K140193
Trade/Device Name: Durex Embrace Pleasure Gels (Warming Sensation Gel and Tingling Experience Gel)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: October 3, 2014
Received: October 8, 2014

Dear Sapana Amin,

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 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)*
K140193

Device Name
Durex Embrace Pleasure Gels (Warming Sensation Gel and Tingling Experience Gel)

Indications for Use *(Describe)*
Durex Embrace Pleasure Gels, which includes the Warming Sensation Gel and Tingling Experience Gel, are 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. Both lubricants are compatible with natural rubber latex, synthetic 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.

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510(k) Summary K140193

Submitted by: Reckitt Benckiser LLC
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Contact Person: Sapana Amin, Regulatory Affairs Operations Lead, Reckitt Benckiser LLC

Date Prepared: October 23rd, 2014

Proprietary Name: Durex Personal Lubricant

Trade Name: Durex Embrace Pleasure Gels:

Warming Sensation Gel

Tingling Experience Gel

Common Name: Personal Lubricant

Classification Name: Condom (21 CFR §884.5300)

Product Code: NUC (lubricant, personal)

Predicate Device(s):

KY Yours + Mine
J&J Healthcare Products, Division of McNeil-PPC Inc.
510(k) Document Control Number: K072421

Indication for Use:

Durex Embrace Pleasure Gels, which includes the Warming Sensation Gel and Tingling Experience Gel, are 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. Both lubricants are compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.

Description of the Device:

Durex Embrace Pleasure Gels are clear odorless slightly viscous liquids that are packaged together and consist of two different formulations. The male formulation is water-based with multisensate (Tingling Experience Gel) and the female formulation (Warming Sensation Gel) is Vanillyl Butyl Ether in Glycerine base. The female lubricant (Pink Bottle) offers a warming experience, and one for the male partner (Purple bottle) offers a tingling experience.

Devices are supplied in 60 ml PETG pump bottles. Both lubricant bottles are covered with a shrink sleeve including graphics that also provides tamper evident protection. Bottles are then placed in clear trays, which are then shrink-wrapped and placed in printed cartons.

The table below lists parameters for which acceptance specifications for the devices have been developed:

Specifications
Appearance
Odor
pH@ 25 degree C
Total Aerobic Microbial Count
Total Yeast and Mold Count
Lack of Pathogenic Organisms (Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans)
Preservative Effectiveness
Viscosity-RV4, 10rpm at 25 degree C
Osmolality

Comparison of Technological Characteristics with the Predicate Device

Intended Use Comparison

The table below shows the indication statements for the Durex Embrace Pleasure Gels and the KY Yours + Mine (K072421) predicate device:

	Durex Embrace Pleasure Gels	KY Yours + Mine
510(k) Number	K140193	K072421
Indication for Use	Durex Embrace Lubricants which are packaged together are 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. Both lubricants are compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.	KY Yours + Mine is intended as a personal lubricant for penile and vaginal application compatible with latex condoms

The indications of use statement for the KY Yours + Mine is cleared for use for application to the vaginal or penile area or a condom in order to enhance comfort ease and pleasure of intimate activity. The only difference in the intended use of KY Yours + Mine in comparison to Durex Embrace Pleasure Gels is condom compatibility. KY Yours + Mine is compatible only with natural rubber latex condoms, while the Durex Embrace Pleasure Gels are compatibile with natural rubber latex, synthetic polyisoprene and polyurethane condoms. This difference does not represent a new intended use. Therefore, both devices can be considered to have the same Intended Use.

Technological Characteristics:

Durex Embrace Pleasure Gels are substantially equivalent to the predicate device KY Yours + Mine in terms of technological characteristics such as being non-sterile, color/appearance/odor, pH and for over the counter use. Durex Embrace Pleasure Gels contain similar formulation components.

The subject device Durex Embrace Pleasure Gels are substantially equivalent to the predicate device. The concept of using two lubricants together or separately is similar to the predicate KY Yours + Mine. The predicate device and Durex Embrace Pleasure Gels are couples lubricants including two different intimate lubricants; the first lubricant designed to offer a tingling experience, and the second lubricant is designed to offer a warming sensation. In addition, when the two lubricants are mixed together, they are designed to create extra sensation. Provided below is a table of similiarities of Durex Embrace Pleasure Gels and KY Yours & Mine:

	Durex Embrace Pleasure Gels	KY Yours + Mine
Number of Lubricants	Two- (Tingling Experience Gel & Warming Sensation Gel)	Two- (Tingling sensation for her & Warming sensation for him)
Formulation of lubricants	Tingling/cooling sensation from Multisensate (water-based) Warming sensation from glycerine based lubricant (glycerin-based)	Tingling/cooling sensation from Methyl salicylate and Menthyl lactate (water-based) Warming sensation from glycerine based lubricant (glycerine-based)
Condom Compatibility	Condom Compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms	Condom compatible with Latex condoms
Over the Counter Use	Yes	Yes
Biocompatible	Yes	Yes
Provided Sterile	No	No

There is no difference in the fundamental technological characteristics of Durex Embrace Pleasure Gels and the predicate KY Yours + Mine. The proposed lubricants are substantially equivalent to the predicate KY Yours + Mine cleared under 510(k) K072421.

Performance Data:

Biocompatibility:

Studies of vaginal and penile irritation in rabbits were conducted and the results showed that the product is non-irritating to genital tissue. Three additional biocompatibility studies were conducted on the subject device. The endpoints evaluated included cytotoxicity, systemic toxicity in mice, and maximization sensitization in guinea pigs. Each study was conducted in accordance with GLP requirements and the applicable ISO 10993 Standard. The results of testing demonstrated device materials to be biocompatible.

The following tests were conducted to evaluate the safety of Durex Embrace Pleasure Gels:

Acute Systemic Toxicity: The test evaluated the systemic response in mice after injection of the subject lubricants, Tingling Experience Gel and Warming Sensation Gel at a dose rate equivalent to 100 ml in a 70 kg human. The test was conducted in accordance with ISO 10993-11:2010. Testing was conducted separately for each of the lubricants as well as in a 1:1 mixture. All test group animals survived the test period and none of the test group animals exhibited any biological reactivity at any of the tested time points.

Vaginal Irritation Testing: The potential of the subject lubricant, Warming Sensation Gel, to produce irritation of the vaginal mucosal tissue was assessed. The testing was conducted on neat (undiluted lubricant and in accordance with ISO 10993-10:2010. The vaginal irritation test was only conducted on the Warming Sensation Gel based on its intended use. Results of the testing indicate that Durex Embrace Pleasure Gel, Warming Sensation Gel, is considered non-irritating.

Penile Irritation Study: The potential of the subject lubricant, Tingling Experience Gel, to produce irritation of the penile mucosal tissue was assessed. The testing was conducted on rabbits in which the test material was applied neat and in accordance with ISO 10993-10:2010. The Penile Irritation test was only conducted on the Tingling Experience Gel based on its intended use. Results of the testing indicate that Durex Embrace Pleasure Gel, Tingling Experience Gel, is considered non-irritating.

Cytotoxicity: The cytotoxicity potential of the Durex Embrace Pleasure Gels was tested using a tissue culture agar diffusion test in accordance with ISO 10993-5:2009. The cytotoxicity results for Warming Sensation Gel both alone and in combination with Tingling Experience Gel may have the potential to produce a biological response. The results of other *in vivo* biocompatibility testing results were shown to be non-irritant and the overall profile of the lubricant does not indicate a significant risk to the safety of consumers.

Sensitization: The ISO Guinea Pig Maximization test was performed on neat (undiluted) Tingling Experience Gel and Warming Sensation Gel to determine to what extent the subject lubricant has the potential to act as a contact sensitizer. Testing was conducted separately for each of the lubricants as well as in a 1:1 mixture. The test was conducted in accordance with ISO 10993-10: 2010. The results of this study indicate that the Durex Embrace Pleasure Gels did not elicit sensitization reactions in study animals.

Condom Compatibility:

Condom compatibility testing was conducted in accordance with ASTM D7661-10. Both formulations of Durex Embrace Pleasure Gels demonstrated they do not affect the mechanical and physical integrity of natural rubber latex, synthetic polyisoprene and polyurethane condoms. Therefore, Durex Embrace Pleasure Gels are compatible with natural rubber latex, synthetic polyisoprene and polyurethane condoms.

Stability:

Shelf life testing was conducted on final devices to support the targeted two-year shelf-life. Testing assessed the parameters outlined in the table included in the Device Description section of this summary. Testing on samples collected up to 12 months of aging (real-time and accelerated at 40˚C-75%RH) showed that devices met their acceptance criteria.

Conclusion

Durex Embrace Pleasure Gels have the same intended use and basic technological characteristics as the predicate device. In addition, results from performance testing shows that Durex Embrace Pleasure Gels performance is substantially equivalent to the predicate device.