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

July 31, 2015

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

Re: K143532
Trade/Device Name: Durex Silicone
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 9, 2015
Received: June 17, 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,

Joyce M. Whang -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)*
K143532

Device Name
Durex Silicone

Indications for Use *(Describe)*
Durex Silicone 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, 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

Submitted by: Reckitt Benckiser, LLC
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973-404-2715
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Contact Person: Elizabeth Torre, MPH, Regulatory Operations Lead, Reckitt Benckiser, LLC

Date Prepared: December 8th, 2014

Proprietary Name: Durex Silicone

Trade Name: Durex Silicone

Common Name: Personal Lubricant

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

Predicate Device(s): ONE® SILICONE Personal Lubricant
ONE®
510(k) Document Control Number: K110690

Description of the Device:

Durex Silicone is a Personal Lubricant Device that is a non-sterile, odorless, anhydrous, silicone formulation that provides personal lubrication during intimate sexual activity. It is made up of 100% Dimethicone. The ingredient is clear (same as water) in appearance. The Viscosity at 25°C is 80-110 cps. The device will be made available in a 1.69 FL oz. (50mL) HDPE pump sealed bottle with an outer carton. The final dimensions of the carton are 138mmx74mmx28mm.

Intended Use of the Device: The intended use of this device is an OTC personal lubricant (for vaginal and penile application).

Indications of Use Statement: Durex Silicone 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, polyisoprene, and polyurethane condoms.

Device Characteristics: Durex Silicone is a silicone based clear, odourless and colorless personal lubricant. The lubricant contains 100% Dimethicone. This ingredient is similar to the ingredients found in the predicate device.

Table: Identification of Legally Marketed (Equivalence) Devices

510(k)	Device Name	Intended Use	Indications for Use	Manufacturer
K110690	ONE® SILICONE Personal Lubricant	ONE® SILICONE Personal Lubricant is intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.	ONE® SILICONE 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, polyisoprene, and polyurethane condoms.	ONE®

Stability: Durex Silicone is shown to have a 24 month shelf life based on 12 month accelerated and real-time stability data. The device maintained its specifications during accelerated testing for up to 12 months.

Summary of Performance Data: The functional testing of Durex Silicone was conducted according to ISO 10993-1 for biocompatibility and ASTM D7661-10 for condom compatibility. Like the predicate device, this lubricant was tested per the above-mentioned standards, and was demonstrated to be biocompatible and compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Cytotoxicity: Durex Silicone was demonstrated to be non-cytotoxic per ISO 10993-5:2009.

ISO Vaginal Irritation and Systemic Toxicity: Durex Silicone was shown to be non-irritating to the vaginal area and not systemically toxic in a combined test based upon ISO 10993-10:2010 and ISO 10993-11:2010.

ISO Maximization Sensitization: Durex Silicone was shown to be non-sensitizing per ISO 10993-10:2010

Condom Compatibility: Durex Silicone has been demonstrated to be compatible with natural rubber latex, polyisoprene and polyurethane condoms. Testing was done using ASTM method D7661-10 using condoms on three marketed brands of Natural Rubber Latex condoms, one brand of polyisoprene condom, and one brand of polyurethane condoms.

Conclusion: The results of the testing discussed above demonstrate that the device is as safe, as effective, and performs as well the predicate device. Therefore, Durex Silicone is substantially equivalent to the predicate device.