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

October 7, 2014

Simply Solutions, LLC
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K140304
Trade/Device Name: Simply Slick™ Personal Lubricating Lotion
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 30, 2014
Received: October 1, 2014

Dear Mark Job,

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

Indications for Use Statement

510(k) Number (if known): K140304

Device Name: Simply Slick™ Personal Lubricating Lotion

Indications for Use:

Simply Slick™ Personal Lubricating Lotion 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, polyurethane, and synthetic polyisoprene condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

004 **510(k) Summary**

510(k) Summary
Simply Solutions, LLC Simply Slick™ Personal Lubricating Lotion

510(k) Summary	This 510(k) summary is being submitted in accordance with the requirements of 21 C.F.R § 807.92.
Applicant	Simply Solutions LLC
Submitter	Simply Solutions LLC 2949 Venture Dr., Suite 170 Janesville, WI 53546-8501 Tel: 608-563-5555 Fax: none
Contact Person	John Goepfert, CEO
Date Prepared	September 23, 2014
Device Trade Name	Simply Slick™ Personal Lubricating Lotion
Device Common Name	Personal Lubricant
Classification Name	21 CFR 884.5300, Condom, NUC
Classification Panel	Obstetrics and Gynecology
Predicate Devices	K062682, CVS Personal Lubricant and Moisturizer, Lake Consumer Products, Inc.
Indications for Use	Simply Slick™ Personal Lubricating Lotion 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, polyurethane, and synthetic polyisoprene condoms.
Device Description	Device specifications include pH, viscosity, preservation effectiveness, appearance, odor, and testing for bioburden, aerobes, fungi, spore, and obligate anaerobe. It is a biocompatible, water soluble, white, viscous liquid and is non-sterile. It is neither a contraceptive nor a spermicide and is sold over-the-counter in a 2 oz / 59 ml polyethylene squeeze bottle with a screw-on, disc press-flip up cap. A cap liner is placed over the opening of the bottle before the lid is screwed on the bottle. One bottle is placed into a plastic display carton which constitutes the device outer packaging. Simply Slick™ Personal Lubricating Lotion is a non-greasy and fragrance-free formulation and is to be stored at room temperature.
Performance data	Simply Slick™ Personal Lubricating Lotion was tested to and meets the performance specifications for ISO 10993-1 Biological evaluation of medical devices – Part 1: general requirements

	(cytotoxicity, sensitization, irritation), antimicrobial preservative effectiveness test (USP 34, <51>), ISTA P2A (2011), ASTM D4169-09, ASTM D7661-10 Standard Test method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms and water solubility per USP 35. Testing for pH, viscosity, color, feel, scent, aerobic, fungi, spores and obligate anaerobes confirmed a shelf life of 36 months. USP <61> and <1111> and USP <62> microbial limits testing on real-time aged samples indicated microbial quality. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
Summary of Substantial Equivalence	The Simply Slick™ Personal Lubricating Lotion has the same technological characteristics as the predicate device. It shares the following similarities to the predicate device: major ingredients; highly lubricious; liquid form; biocompatible; does not contain fragrance; non-sterile; over-the-counter; water soluble; compatible with natural rubber latex, synthetic polyisoprene, and polyurethane condoms; and packaging material.
Conclusion	Based on the similar indications for use, technological characteristics and performance testing, Simply Solutions LLC believes the proposed device, Simply Slick™ Personal Lubricating Lotion, is substantially equivalent to the CVS Personal Lubricant and Moisturizer (K062682).