December 15, 2017

SXWELL USA LLC
Robert Mahler
Director, Regulatory Affairs for the Americas
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K172473
Trade/Device Name: LifeStyles® SKYN® Intimate Moments Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: November 28, 2017
Received: November 30, 2017

Dear Robert Mahler:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*
K172473

Device Name
LifeStyles® SKYN® Intimate Moments Personal Lubricant

Indications for Use *(Describe)*
LifeStyles® SKYN® Intimate Moments 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 polyisoprene condoms. This product is not compatible with natural rubber latex or 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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510k Summary

K172473

Submitter:
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Rob.mahler@ansell.com

Contact Person:
Robert S. Mahler
Director Regulatory Affairs for the Americas
Phone: 732-345-2174
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Date Prepared:
December 15, 2017

Device Name:	LifeStyles® SKYN® Intimate Moments Personal Lubricant
Common Name:	Personal Lubricant
Regulation:	21 CFR 884.5300, Condom
Device Class:	Class II
Product Code:	NUC (lubricant, personal)
Classification Panel:	Obstetrics/Gynecology

Primary Predicate Device:

510(K) Number:	K120751
Device Name:	TROJAN™ LUBRICANTS Continuous Silkiness Personal Lubricant
Manufacturer:	Church & Dwight Co., Inc.

The predicate device has not been subject to a design-related recall.

Device Description:
LifeStyles® SKYN® Intimate Moments Personal Lubricant is a non-sterile, propylene glycol/water/silicone-based personal lubricant designed to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. It is made of propylene glycol, water, cyclopentasiloxane, dimethicone/ vinyl dimethicone crosspolymer, hydroxyethyl acrylate/sodium acryloyl dimethyl taurate copolymer, cyclohexasiloxane, 1,2-hexanediol, caprylyl glycol and fragrance (aroma). The personal lubricant is packaged in a 100 mL tube or a 5 mL sample sachet.

The device specifications for the LifeStyles® SKYN® Intimate Moments Personal Lubricant include appearance, color, odor, viscosity, specific gravity, osmolality, pH, total aerobic microbial count per USP<61>, total yeast and mold count per USP<61>, absence of specific microorganisms per USP<62>, and antimicrobial effectiveness per USP <51>.

The device is not a contraceptive or spermicide, nor does it contain any such component. It is compatible with polyisoprene condoms but not compatible with natural rubber latex or polyurethane condoms.

Indications for Use:
LifeStyles® SKYN® Intimate Moments Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex or polyurethane condoms.

Predicate Comparison:
The following table compares the LifeStyles® SKYN® Intimate Moments Personal Lubricant to the predicate device with respect to the indications for use and technological characteristics:

	Subject Device	**Predicate Device**
Trade Name	LifeStyles® SKYN® Intimate Moments Personal Lubricant	TROJAN™ LUBRICANTS Continuous Silkiness Personal Lubricant
510(k) Number	K172473	K120751
Submitter	SXWELL USA LLC	Church & Dwight Co., Inc
Product Code	NUC	NUC
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Personal Lubricant	Personal Lubricant
Indications for Use	LifeStyles® SKYN® Intimate Moments Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex or polyurethane condoms.	[Continuous Silkiness – Warm & Tingling] [Continuous Silkiness] is a personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.
Prescription or Over-The-Counter Use	Over-The-Counter Use	Over-the-Counter Use

	Subject Device	**Predicate Device**
Ingredients	Propylene glycol, water, cyclopentasiloxane, dimethicone/ vinyl dimethicone crosspolymer, hydroxyethyl acrylate/sodium acryloyl dimethyl taurate copolymer, cyclohexasiloxane, 1,2-hexanediol, caprylyl glycol and fragrance (aroma).	Propylene glycol, water, dimethicone, dimethicone/ vinyl dimethicone crosspolymer, hydroxyethyl acrylate, sodium acryloyl dimethyl taurate copolymer, methylparaben and propylparaben.
Condom Compatibility	Compatible with commercially available polyisoprene condoms. Not compatible with natural rubber latex and polyurethane condoms	Compatible with commercially available natural rubber latex and polyisoprene condoms
Sterilization	Non-sterile	Non-Sterile
Shelf Life	3 years	2 years

The LifeStyles® SKYN® Intimate Moments Personal Lubricant has the same intended use but different technological characteristics compared to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Performance Testing:

Biocompatibility

Biocompatibility testing was conducted in accordance with ISO-10993-1:2009, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2010), vaginal irritation (ISO 10993-10:2010), and acute systemic toxicity (ISO 10993-11:2006). The testing demonstrated that the LifeStyles® SKYN® Intimate Moments Personal Lubricant is biocompatible.

Condom Compatibility

The results of condom compatibility testing per ASTM D7661-10 demonstrated that the LifeStyles® SKYN® Intimate Moments Personal Lubricant is compatible with Polyisoprene condoms only.

Shelf Life

The results of accelerated stability testing demonstrate that the LifeStyles® SKYN® Intimate Moments Personal Lubricant maintains its specifications for the declared shelf life of three years.

Clinical Performance Data:

Not Applicable

Conclusion:

Based on the comparison and analysis above, the LifeStyles® SKYN® Intimate Moments Personal Lubricant is substantially equivalent to the predicate device.