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

March 10, 2016

Toro Management LLC DBA Sylk
% Jeff Morgan
Senior Consultant
Qpc Services
P O Box 818
Ocean Shores, WA 98569

Re: K152646
Trade/Device Name: Sylk Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: February 1, 2016
Received: February 8, 2016

Dear Jeff Morgan,

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)*
K152646

Device Name
Sylk Personal Lubricant

Indications for Use *(Describe)*
Sylk Personal Lubricant is 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

March 10, 2016

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 5 10(k) Summary for the Sylk Personal Lubricant is provided below.

Device Common Name:	Personal Lubricant
Device Proprietary Name:	Sylk Personal Lubricant
Submitter:	Toro Management, LLC 7272 East Indian School Road, Suite 540, Scottsdale, Arizona 85251
Contact:	Jeff Morgan, Senior Consultant QPC Services Phone: 253.208.3430 Email: jmorgan@qpcservices.com
Classification Regulation:	884.5300
Class	Class 2
Classification Name:	Condom
Panel:	Obstetrics and Gynecology
Product Code:	NUC
Predicate Device:	K124044 - Aloe Cadabra® Personal Lubricant - Natural Aloe (Seven Oaks Ranch, Inc. 2658 Channel Drive, Ventura, CA 93003)

Indication for Use:
Sylk Personal Lubricant is 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, polyurethane and polyisoprene condoms.

Device Description:
Sylk Personal Lubricant is formulated to be a non-sterile, non-greasy, non-sticky, non-staining, viscous liquid. The device is not a contraceptive and does not contain a spermicide. This device is packaged in 3 ounce tubes. The specifications for the Sylk Personal Lubricant include appearance, odor, pH, viscosity, osmolality, antimicrobial effectiveness, total microbial count, total yeast and mold count, and absence of pathogenic organisms.

Performance Data:
Biocompatibility studies including Acute System Toxicity, Vaginal Irritation Testing, Cytotoxicity, and Guinea Pig Maximization Test (GPMT) were performed according to ISO 10993 standards. The test procedures described below were followed without deviation.

Cytotoxicity: ISO 10993-5: 2009

The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met. All results passed from full strength to 1:16 dilution. The product did not demonstrate cytotoxicity.

Vaginal Irritation Testing: ISO 10993-10: 2010

None of the control animals had a total score higher than 4, indicating a valid test. The Irritant Rank Score was 0. In conclusion, based on the requirements of this study, the test article was classified as a non-irritant.

Acute Systemic Toxicity: ISO 10993-11: 2010

The polar extracts of the tested material did not induce any toxic reaction in the investigated mice within an observation period of 72 hours.

The apolar extracts of the tested material did not induce any toxic reaction in the investigated mice within an observation period of 72 hours.

Guinea Pig Maximization Test (GPMT): ISO 1099310: 2010

None of the control animals had a total score higher than 4, indicating a valid test. The Irritant Rank Score was 0. In conclusion, based on the requirements of this study, the test article was classified as a non-irritant.

Shelf Life:

The shelf life of Sylk Personal Lubricant is 11 months. This is based on the results of real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life.

Condom Compatibility:

Condom Compatibility was performed using the FDA Recognized Consensus Standard ASTM D7661-10 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.* RESULTS: Sylk Personal Lubricant was found to be compatible with Natural Rubber Latex, Polyisoprene and Polyurethane condoms.

Conclusions drawn from Testing Performed:

The device is substantially equivalent to the predicate device, Aloe Cadabra® Personal Lubricant - Natural Aloe and is as safe and effective as the predicate device.