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 20, 2015

Package Solutions LLC
Jack Scalisi
Director Of Operations
2131 Blount Road
Pompano Beach, Florida 33069

Re: K150153
Trade/Device Name: Swiss Navy Premium Silicone Lubricant; Swiss Navy Premium Water Based Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: September 15, 2015
Received: September 16, 2015

Dear Jack Scalisi:

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)*
K150153

Device Name
SWISS NAVY® Premium Silicone Lubricant

Indications for Use *(Describe)*
This 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 and polyisoprene condoms. This product is not compatible with 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K150153

Device Name
SWISS NAVY® Premium Water-Based Lubricant

Indications for Use *(Describe)*
This 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 and polyisoprene condoms. This product is not compatible with 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:	Package Solutions LLC
	2131 Blount Road
	Pompano Beach, FL 33069
Contact Person:	Jack Scalisi,
	Director of Operations
	Telephone: (954) 725-5502 ext 1312
	Fax: (954) 725-6922
	Email: jscalisi@mdsciencelab.com
Date Prepared:	January 20, 2015
Proprietary Name:	Swiss Navy® Premium Silicone Lubricant
	Swiss Navy® Premium Water-Based Lubricant
Common Name:	Personal Lubricant
Classification Name:	Condom
Regulation:	21 CFR §884.5300
Product Code:	NUC
Device Class:	Class II
Predicate Device: Manufacturer 510(k) Number:	Pjur Original Silicone Lubricant (for Swiss Navy® Premium Silicone Lubricant) Pjur Group, Luxembourg SA K133233
Predicate Device: Manufacturer 510(k) Number:	ID Glide Water-Based Personal Lubricant (for Swiss Navy® Premium Water-Based Lubricant) Westridge Laboratories, Inc K051295

Indications For Use:

The Swiss Navy Premium Lubricants are personal lubricants 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. These products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Device Description:

Swiss Navy® Premium Silicone Lubricant is a non-sterile, silicone-based personal lubricant for use with or without a condom. It is specifically formulated to be a clear, non-irritating, non-greasy and odorless liquid. This device is not a contraceptive, not does it contain any spermicidal components. Swiss Navy Premium Silicone Lubricant comes packaged in the following configurations: 20 ml square PET mini bottle with a screw-on cap fitted with an aluminized Mylar seal, 2-ounce, 4-ounce, 8-ounce, 16-ounce, and 32-ounce PET bottles with a pump. All have the cap or pump shrink-wrapped. The 32-ounce PET size contains a travel cap with an aluminized Mylar induction seal. A pump is included with this size. This product also is packaged in 5-ml foil sachets.

The specifications for this device include color, odor, viscosity, water activity level, total aerobic microbial count, total yeast and mold count, absence of pathogenic organisms, and specific gravity.

Swiss Navy® Premium Water-Based Lubricant is a non-sterile water-based personal lubricant for use with or without a condom. It is clear, non-irritating and non-greasy. It is not a contraceptive, nor does it contain any spermicidal components. Swiss Navy® Premium Water Based Lubricant is packaged into the following configurations: 20 ml square PET mini bottle with ascrew-on cap fitted with an aluminized Mylar seal, 2-ounce, 4-ounce, 8-ounce, 16-ounce, and 32-

ounce PET bottles with a pump. All have the cap or pump shrink-wrapped. The 32-ounce PET size contains a travel cap with an aluminized Mylar induction seal. A pump is included with this size. This product also is packaged in 5-ml foil sachets.

The specifications for this device include pH, osmolality, color, odor, viscosity, water activity level, total aerobic microbial count, total yeast and mold count, absence of pathogenic organisms, and specific gravity.

Technological Characteristics:

The Swiss Navy® Premium Lubricants have similar technological characteristics to their proposed predicate devices.

Biocompatibility:

Biocompatibility testing was performed on each of the lubricants subject of this 510(k) in accordance with FDA recognized ISO 10993-1 by independent third-party laboratories.

Testing Performed	Results
Cytotoxicity	Swiss Navy Premium Lubricants were not considered to have a cytotoxic effect based on grading criteria in ISO 10993-5: 2009
Maximization & Sensitization	Swiss Navy Premium Lubricants do not elicit a sensitization response in guinea pigs according to methods detailed in ISO 10-993-10: 2010
Acute Systemic Toxicity	There is no evidence of systemic toxicity in mice after being injected with the Swiss Navy Premium Lubricants. This test was performed according to ISO 10993-11: 2006 standards.
Vaginal Irritation	Results of the testing show that Swiss Navy Premium Lubricants were non-irritating to the vaginal mucosa in female New Zealand White Rabbits utilizing ISO 10993-10 methods

Condom Compatibility:

Testing was performed in accordance with ATM D7661-10, Standard Test Method for Determining Compatibility of Swiss Navy Premium Lubricants with Natural Rubber Latex Condoms" on three marketed brands of Natural Rubber Latex Condoms and one brand of Polyisoprene condoms.

The results of condom compatibility testing demonstrated the Swiss Navy Premium lubricants are compatible with commercially available male condoms made from natural rubber latex and polyisoprene materials. This product is not compatible with polyurethane materials.

Shelf Life:

Swiss Navy Premium Lubricants have a 1-year shelf life based on the results of an accelerated aging study. A real-time aging study is presently being conducted to confirm results of the accelerated aging study.

Conclusion:

Swiss Navy® Premium Lubricants have the same intended use and technological characteristics as the predicate devices. Swiss Navy® Premium Lubricants are substantially equivalent to its proposed predicate devices and are as safe and effective as the predicate devices.