510(k) Summary

510(k) Owner:		United Consortium
Street Address:		29000 Hancock Parkway Valencia, CA 91355
Contact Person:		Joe Mendoza Quality Assurance Manager
Contact Numbers:		Phone: (661) 295-1700 ext. 209 FAX: (661) 295-1800
Summary Preparation Date:		May 1, 2014
Trade Name:		JO Premium Personal Lubricant
Common Name:		Personal Lubricant
Device Classification:	Classification Name:	Condom
	Product Code:	NUC (lubricant, personal)
	Regulation:	21 CFR § 884.5300
	Device Class:	Class II
Predicate Device:	Product Name:	LifeStyles Luxe Premium Personal Lubricant
	510(k) Number:	K122477
	Manufacturer:	Ansell Healthcare Products, LLC
	Product Code:	NUC
	Regulation:	21 CFR § 884.5300
	Device Class:	Class II

Device Description:

JO Premium Personal Lubricant is a clear, colorless, semi-viscous silicone-based lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. The device is not compatible for use with polyurethane condoms. The device is a non-sterile lubricant designed to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is provided in Polyethylene (PET) bottles fitted with Polypropylene caps. The bottles are sealed using an induction seal constructed of aluminized mylar. There is a 16 fl. Oz./480 mL bottle with a different configuration. This consists of a clear Polyethylene (PET) bottle with a Polypropylene lotion

pump. This bottle is also fitted with a shrink band. The device specifications are listed in the table below:

Property
Appearance
Color
Odor
Viscosity (cps)
Specific Gravity
Total aerobic microbial count (TAMC)
Total yeast and mold count (TYMC)
Absence of Pathogens
Pseudomonas aeruginosa
Staphylococcus aureus.
Candida albicans

Indications for Use:

JO Premium 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Summary of Technological Characteristics:

JO Premium Personal Lubricant contains ingredients that are similar to those used in the manufacture of the predicate device. The table below compares the technological characteristics of JO Premium Lubricant to the predicate device LifeStyles Luxe Premium Personal Lubricant.

Feature	JO Premium Personal Lubricant	LifeStyles Luxe Premium Personal Lubricant
Contains Dimethicone	Yes	Yes - Cyclomethicone is a mixture of Dimethicones, and various chain length cyclic siloxanes such as Cyclopentasiloxane and Cyclotetrasiloxane
Contains Cyclopentasiloxane	Yes	
Contains Cyclotetrasiloxane	Yes	
Contains Dimethiconol	Yes	Yes
Over-the counter use	Yes	Yes
Condom Compatible	Yes	Yes
Sterile	No	No

Summary of Performance Data

Independent third-party laboratories conducted the Biocompatibility studies including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity, and Sensitization were performed according to FDA recognized ASTM and ISO 10993 standards.

Acute Systemic Toxicity: This test evaluated the systemic response in mice after injection of the subject lubricant JO Premium Personal Lubricant. This test was conducted according to ISO 10993-11: 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity. All test group animals survived the test period and none of the test group animals exhibited any biological reactivity at any of the tested time points.

Vaginal Irritation Testing: The potential of the subject lubricant JO Premium Personal Lubricant to produce irritation of the vaginal mucosal tissue was assessed according to ISO 10993-10: 2010 Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization. Results of the testing indicate that the JO Premium Personal Lubricant was considered a minimal irritant.

Cytotoxicity: The cytotoxicity potential of the JO Premium Personal Lubricant was determined according ASTM F895-11 Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity. Results of the test show that the subject lubricant JO Premium Personal Lubricant was not considered to have a cytotoxic effect.

Sensitization: The ISO Guinea Pig Maximization Test was performed on the subject device JO Premium Personal Lubricant to determine to what extent the subject lubricant has the potential to act as a contact sensitizer. This test was conducted according to ISO 10993-10: 2010 Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Skin Sensitization. The results of this study indicate that the JO Premium Personal Lubricant did not elicit sensitization reactions in the animals involved in the study.

Shelf Life: The subject device JO Premium Personal Lubricant has a three-year shelf life based on the results of a real time aging study.

Condom Compatibility: The compatibility of the subject device JO Premium Personal Lubricant was evaluated with natural rubber latex, polyisoprene, and polyurethane condoms per ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test indicate that the JO Premium Personal Lubricant is compatible with natural rubber latex and polyisoprene but not compatible with polyurethane.

Preservative Effectiveness Testing: Preservative Effectiveness testing according to the protocols outlined in USP 36-2013 Antimicrobial Effectiveness Testing <51> was conducted on samples of JO Premium Personal Lubricant samples that have been aged for 1-year, 2-years, and 3-years. All samples were aged in real time. Results from this study indicate that the

preservative is effective in exerting its antimicrobial effectiveness through the proposed three-year shelf life of the product.

Conclusion:

JO Premium Personal Lubricant has the same intended use and basic technological characteristics as the predicate device. The JO Premium Personal Lubricant is substantially equivalent to its proposed predicate device.

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

June 11, 2014

United Consortium
Craig May
General Manager
29000 Hancock Parkway
Valencia, CA 91355

Re: K132954
Trade/Device Name: JO Premium Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 9, 2014
Received: May 12, 2014

Dear Craig May:

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 (21CFR 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21CFR 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

Indications for Use

510(k) Number: K132954

Device Name: JO Premium Personal Lubricant

Indications for Use:

JO Premium Personal Lubricant is a silicone based 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. This product is not compatible with polyurethane condoms.

Prescription Use _____ AND/OR Over-the-Counter Use __X__
(Part 21 CFR 801 Subpart D) (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)

Herbert P. Lerner -S
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