DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 8, 2015

United Consortium, Inc.
Joe Mendoza
Quality Assurance Manager
29000 Hancock Parkway
Valencia, CA 91355

Re: K150480
Trade/Device Name: JO H2O Water Based Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 3, 2015
Received: June 5, 2015

Dear Joe Mendoza,

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)*
K150480

Device Name
JO H2O Water Based Personal Lubricant

Indications for Use *(Describe)*

JO H2O Personal Lubricant is a water-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, polyurethane, and polyisoprene 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.

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510(k) Summary

510(k) Owner:	United Consortium
Street Address:	29000 Hancock Parkway Valencia, CA 91355
Establishment Registration Number:	3005691625
Contact Person:	Joe Mendoza Quality Assurance Manager
Contact Numbers:	Phone: (661) 295-1700 ext. 209 FAX: (661) 295-1800
Summary Preparation Date:	July 6, 2015
Trade Name:	JO H2O Water Based 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:	I-D Glide Personal Lubricant
	510(k) Number:	K051295
	Manufacturer:	Westridge Laboratories, Inc.
	Product Code:	NUC
	Device Class:	Class II

Device Description:

JO H2O Water Based Personal Lubricant is a clear, colorless, semi-viscous personal lubricant that is compatible with condoms made of natural rubber latex, polyurethane, and polyisoprene. The device is a non-sterile lubricant, for penile and/or vaginal application, 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 with Polypropylene caps. The individual bottles are sealed using an induction seal constructed of aluminized mylar. There is a 16 fl. Oz./480 mL bottle with a different configuration consisting of a clear Polyethylene (PET) bottle with a Polypropylene lotion pump. This bottle is fitted with a shrink band. The device specifications are listed in the table below:

Indications for Use:
JO H2O Water Based 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, polyurethane, and polyisoprene condoms.

Summary of Technological Characteristics:
JO H2O Water Based Personal Lubricant contains water and water-soluble ingredients similar to ingredients found in the predicate device.

Summary of Performance Data
Independent third-party laboratories conducted the biocompatibility studies including acute systemic toxicity, vaginal irritation, cyctotoxicity and guinea pig maximization sensitization testing according to FDA recognized ISO 10993 standards. The results of these tests demonstrate that JO H2O Water Based Personal Lubricant is safe.

Shelf Life: The subject device, JO H2O Water Based Personal Lubricant, has a three-year shelf life based on the results of a real time aging study. The shelf life study evaluated the following parameters of this product: appearance, color, odor, pH, osmolality, viscosity, specific gravity, total aerobic microbial count, total yeast and mold count, absence of pathogens, and antimicrobial effectiveness.

Condom Compatibility: The compatibility of the subject device, JO H2O Water Based 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 H2O Water Based Personal Lubricant is compatible with natural rubber latex, polyurethane, and polyisoprene.

Predicate Device Comparison

Feature	JO H2O Water Based Personal Lubricant	I-D Glide Water Based Lubricant
Intended Use	Same as the predicate	Personal lubricant for penile and vaginal use (enhance the comfort and ease of intimate)
Appearance		Clear, colorless
Formulation	Comparable with the predicate	Water-based; ingredients include glycerin, propylene glycol, cellulose polymer, etc.
Condom Compatibility	Latex, Polyurethane, Polyisoprene	Latex, Polyurethane

Conclusion:

JO H2O Water Based Personal Lubricant has the same intended use and comparable technological characteristics as the predicate device. therefore, the JO H2O Water Based Personal Lubricant is substantially equivalent to the predicate device.