August 27, 2018

United Consortium
Stephanie Morris
Regulatory Specialist
29000 N. Hancock Pkwy.
Valencia, CA 91355

Re: K181408
Trade/Device Name: JO Classic Hybrid Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 25, 2018
Received: May 30, 2018

Dear Stephanie Morris:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Sharon M. Andrews -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181408

Device Name

JO Classic Hybrid Personal Lubricant

Indications for Use *(Describe)*

JO Classic Hybrid Personal Lubricant is a personal lubricant for penile, anal 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.

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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K181408 - JO Classic Hybrid Personal Lubricant

K181408 - 510(k) Summary

510(k) Owner:	United Consortium
Street Address:	29000 N. Hancock Parkway Valencia, CA 91355
Contact Person:	Stephanie Morris Regulatory Specialist Bruce Albert Head of Technical Services
Contact Numbers:	Phone: (661) 295-1700, ext. 232 Phone: (661) 295-1700, ext. 231 FAX: (661) 295-1800
Preparation Date:	August 9, 2018
Trade Name:	JO Classic Hybrid Personal Lubricant
Common Name:	Personal Lubricant

Device Classification:	Regulation Name:	Condom
	Regulation Number:	21 CFR § 884.5300
	Product Code:	NUC (lubricant, personal)
	Device Class:	Class II
Predicate Device:	Product Name:	TROJAN™ LUBRICANTS Continuous Silkiness Personal Lubricant
	510(k) Number:	K120751
	Manufacturer:	Church & Dwight Co., Inc.
	Product Code:	NUC
	Device Class:	Class II

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

Device Description:

JO Classic Hybrid Personal Lubricant is an off-white, semi-viscous, translucent gel type personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. This product is not compatible with polyurethane condoms. This device is a non-sterile personal lubricant for penile, anal and/or vaginal application, to lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

K181408 - JO Classic Hybrid Personal Lubricant

This product is provided in clear, Polyethylene Terephthalate (PET) cylinder bottles. The 1 oz. size bottles are capped with natural polypropylene disc top dispenser caps. The 2 oz., 4 oz. and 8 oz. size bottles are capped with silver polypropylene disc top dispenser caps. The individual bottles are hermetically sealed during the production process. This product is also available in polyester-faced laminated pouches.

The device specifications are listed in the table below:

Table 1: Device Specifications for JO Classic Hybrid Personal Lubricant

Property	Specification
Appearance	Opaque thick liquid
Color	Off-white
Odor	Odorless
Viscosity (cps)	15,000 cps to 34,000 cps
pH	6.20 to 7.20
Specific Gravity	0.950 to 1.075
Osmolality	350 - 599 mOsm/kg (diluted 1:10 with purified water) and 600 - 990 mOsm/kg (undiluted)
Antimicrobial effectiveness per USP <51>	Meets US <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	Less than 10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	Less than 10 cfu/g
Presence of Pathogens per USP <62>	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida albicans	Absent

Indications for Use:

JO Classic Hybrid Personal Lubricant is a personal lubricant for penile, anal 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.

Predicate Device Comparison:

The table below lists the comparative indications for use and technological characteristics of the subject and predicate device.

K181408 - JO Classic Hybrid Personal Lubricant

Table 2: Comparator Table for Subject Device – JO Classic Hybrid Personal Lubricant and Predicate Device TROJAN™ LUBRICANTS Continuous Silkiness Personal Lubricant

Feature	JO Classic Hybrid Personal Lubricant	TROJAN™ LUBRICANTS Continuous Silkiness Personal Lubricant (K120751)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	JO Classic Hybrid Personal Lubricant is a personal lubricant for penile, anal 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.	TROJAN™ LUBRICANTS Continuous Silkiness 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 natural rubber latex and polyisoprene condoms. Not compatible with polyurethane or other condoms.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Propylene Glycol, Water (Aqua), Phenoxyethanol, Dimethicone, Cellulose Gum, Cyclopentasiloxane, Sodium Polyacrylate, Trideceth-6, PEG/PPG- 18/18 Dimethicone	Propylene Glycol, Water, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Hydroxyethyl Acrylate, Sodium Acryloyl Dimethyl Taurate Copolymer, Methylparaben, Propylparaben
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene	Natural Rubber Latex, Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	2 years

The subject and predicate device have similar indications for use. The indication for the subject device has been expanded to also include anal use. This change does not represent a new intended use as the intended use of this device is the same as the predicate device, i.e., lubrication of an orifice during intimate sexual activity. The subject and predicate device have different technological characteristics, including differences in formulation and a different shelf life. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

Summary of Performance Data:

K181408 - JO Classic Hybrid Personal Lubricant

Biocompatibility

Biocompatibility studies were performed in accordance with the 2016 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Penile Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

The results of this testing demonstrated that the subject lubricant is biocompatible.

Shelf-Life:

The subject device is a non-sterile personal lubricant with a three-year shelf-life in accordance with the results of a real time and accelerated aging study. All device specifications listed in **Table 1** were tested at 0, 1, 2 and 3 years. The subject device met the device specifications at all time points.

Condom Compatibility:

The compatibility of the subject device with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test indicated that JO Classic Hybrid Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This device is not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that the JO Classic Hybrid Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.