April 20, 2018

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

Re: K180219
Trade/Device Name: JO H2O Flavored Personal Lubricants
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: January 23, 2018
Received: January 25, 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. 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.

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.

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,

Charles Viviano -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)*

K180219

Device Name
JO H2O Flavored Personal Lubricants

Indications for Use *(Describe)*

JO H2O Flavored Personal Lubricants are water-based personal lubricants 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. These products are compatible with natural rubber latex and polyisoprene condoms. These products are 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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K180219 - JO H2O Flavored Personal Lubricants

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
Summary Preparation Date:	April 19, 2018
Trade Names:	JO H2O Flavored Personal Lubricants JO H2O Strawberry Kisses Flavored Personal Lubricant JO H2O Cherry Burst Flavored Personal Lubricant JO H2O Raspberry Sorbet Flavored Personal Lubricant JO H2O Succulent Watermelon Flavored Personal Lubricant JO H2O Lemon Splash Flavored Personal Lubricant JO H2O Tropical Passion Flavored Personal Lubricant JO H2O Juicy Pineapple Flavored Personal Lubricant JO H2O Banana Lick Flavored Personal Lubricant JO H2O Chocolate Delight Flavored Personal Lubricant JO H2O Sweet Pomegranate Flavored Personal Lubricant JO H2O Peachy Lips Flavored Personal Lubricant JO H2O Tangerine Dream Flavored Personal Lubricant JO H2O Red Licorice Flavored Personal Lubricant JO H2O Black Licorice Flavored Personal Lubricant JO H2O Vanilla Cream Flavored Personal Lubricant JO H2O Green Apple Flavored Personal Lubricant JO H2O Cotton Candy Flavored Personal Lubricant
Common Name:	Personal Lubricant

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Device Classification:		
	Regulation Name:	Condom
	Regulation Number:	21 CFR § 884.5300
	Product Code:	NUC (lubricant, personal)
	Device Class:	Class II
Predicate Device:	Product Name:	Astroglide Sensual Strawberry
	510(k) Number:	K140590
	Manufacturer:	BioFilm, Inc.
	Product Code:	NUC
	Device Class:	Class II

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

Device Description:

JO H2O Flavored Personal Lubricants are clear, semi-viscous personal lubricants that are compatible with condoms made of natural rubber latex and polyisoprene. These products are not compatible with polyurethane condoms. These devices are non-sterile personal lubricants 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.

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

The device specifications are listed in the table below:

Table 1: Device Specifications for JO H2O Flavored Personal Lubricants

Property	Specification
Appearance	Clear, semi-viscous liquid
Color	Colorless to slightly yellow
Odor	Sweet/Characteristic
Viscosity (cps)	1200 cps to 2500 cps
pH	5.9 to 7.1
Specific Gravity	1.020 to 1.200
Osmolality	750 - 900 (1:5 dilution,) 1400 - 1650 (undiluted) mOsm/kg
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

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Total yeast and mold count (TYMC) per USP <61> and <1111>	Less than 10 cfu/g
Presence of Pathogens per USP <62>	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida Albicans	Absent

Indications for Use:

JO H2O Flavored Personal Lubricants are water-based personal lubricants 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. These products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.

Predicate Device Comparison:

The table below lists the comparative indication for use and technological characteristics of the subject and predicate devices.

Table 2: Comparator Table for Subject Device – JO H2O Flavored Personal Lubricants and Predicate Device Astroglide Sensual Strawberry

Feature	JO H2O Flavored Personal Lubricants	Astroglide Sensual Strawberry (K140590)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indication for Use	JO H2O Flavored Personal Lubricants are water-based personal lubricants 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. These products are compatible with natural rubber latex and polyisoprene condoms. These products are not compatible with polyurethane condoms.	The BioFilm, Inc. Astroglide Sensual Strawberry 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, polyisoprene and polyurethane condoms.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Glycerin, Water (Aqua), Flavor (Aroma), Sodium Carboxymethylcellulose, Methylparaben, Propylparaben, Masking Agent	Water (Aqua), Glycerin, Propylene Glycol, Hydroxyethylcellulose, Natural and Artificial Strawberry Flavor, Sodium Gluconate, Sodium Saccharin, Methylparaben, Sodium Benzoate, Citric Acid

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Feature	JO H2O Flavored Personal Lubricants	Astroglide Sensual Strawberry (K140590)
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex, Polyisoprene	Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	3 years	2 years

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

Summary of Performance Data:

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Sensitization testing 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 lubricants are non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life:

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

Condom Compatibility:

The compatibility of the subject devices 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 indicate that JO H2O Flavored Personal Lubricants are compatible with natural rubber latex and polyisoprene condoms. These devices are not compatible with polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that the JO H2O Flavored Personal Lubricants are as safe and effective as the predicate device and supports a determination of substantial equivalence.