August 1, 2019

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

Re: K191214
Trade/Device Name: JO Premium Jelly Original Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 3, 2019
Received: May 6, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Sharon M. Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*

K191214

Device Name

JO Premium Jelly Original Personal Lubricant

Indications for Use *(Describe)*

JO Premium Jelly Original 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, 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 – K191214

1. Submitter Information

Applicant: United Consortium
Contact: Stephanie Morris
Global Regulatory Specialist

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2. Correspondent Information

Contact: Stephanie Morris
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Phone: (661) 295-1700, ext. 232
Fax: (661) 295-1800
Email: smorris@systemjo.com

3. Date prepared: July 30, 2019

4. Device Information

Device Name:	JO Premium Jelly Original Personal Lubricant
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

5. Predicate Device Information

Device Name:	Astroglide Diamond Silicone Gel Personal Lubricant
510(k) Number:	K163395
Manufacturer:	BioFilm, Inc.
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

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

6. Device Description

JO Premium Jelly Original Personal Lubricant is a clear/water white, viscous gel-type personal lubricant that is compatible with condoms made of natural rubber latex, polyurethane and polyisoprene. 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. This product is provided in clear, polyethylene (PE)

tubes. These 4 oz. size tubes are capped with silver, glossy, polypropylene (PP) flip tops. The individual tubes are hermetically sealed during the production process.
The device specifications are listed in the table below:

Table 1: Device Specifications for JO Premium Jelly Original Personal Lubricant

Property	**Specification**
Appearance	Viscous gel
Color	Clear, water white
Odor	Odorless
Viscosity (cps)	1375 cps to 1700 cps
Specific Gravity	0.870 to 1.025
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>	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella/Shigella	Absent
Escherichia coli	Absent
Candida albicans	Absent

7. Indications for Use

JO Premium Jelly Original 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, polyurethane and polyisoprene condoms.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Table 2: Comparator Table for Subject Device – JO Premium Jelly Original Personal Lubricant and Predicate Device Astroglide Diamond Silicone Gel Personal Lubricant

Feature	**JO Premium Jelly Original Personal Lubricant**	**Astroglide Diamond Silicone Gel Personal Lubricant (K163395)**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC

Feature	**JO Premium Jelly Original Personal Lubricant**	**Astroglide Diamond Silicone Gel Personal Lubricant (K163395)**
Indications for Use	JO Premium Jelly Original 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, polyurethane and polyisoprene condoms.	Astroglide® Diamond Silicone Gel 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.
Water soluble	No	No
Contains water	No	No
Primary ingredients	Dimethicone, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone / Vinyl Dimethicone Crosspolymer, Dimethiconol	Dimethicone, Cyclomethicone Dimethicone / Vinyl Dimethicone Crosspolymer, Cocos Nucifera (Coconut) Oil
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyurethane, Polyisoprene	Natural Rubber Latex, Polyurethane, Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	2 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 similar technological characteristics, including similar formulation. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

9. Summary of Non-Clinical Performance Testing

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 lubricant is biocompatible.

Shelf-Life

The subject device is a non-sterile personal lubricant with a two-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 and 2 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 Premium Jelly Original Personal Lubricant is compatible with natural rubber latex, polyurethane and polyisoprene condoms.

10. Conclusion

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