



April 9, 2018

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

Re: K180083  
Trade/Device Name: Silicone Personal Lubricant, ALL-IN-ONE  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: January 9, 2018  
Received: January 11, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Benjamin R. Fisher -S**

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 (if known)

K180083

Device Name

Silicone Personal Lubricant

ALL-IN-ONE

Indications for Use (Describe)

Silicone Personal Lubricant is a silicone-based 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.

ALL-IN-ONE is a silicone-based 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.

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## K180083 - Silicone Personal Lubricant, ALL-IN-ONE Traditional Submission

### 510(k) Summary

510(k) Owner: United Consortium

Street Address: 29000 N. Hancock Parkway  
Valencia, CA 91355

Establishment Registration Number: 3005691625

Contact Person: Stephanie Morris  
Regulatory Specialist

Bruce Albert  
Head of Technical Services

Contact Numbers: Phone: (661) 295-1700, ext. 232  
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Summary Preparation Date: April 6, 2017

Trade Names: Silicone Personal Lubricant  
ALL-IN-ONE

Common Name: Personal Lubricant

Device Classification:

Common Name:	Personal Lubricant
Classification Name:	Condom
Classification Number:	21 CFR § 884.5300
Product Code:	NUC (lubricant, personal)
Device Class:	Class II

Predicate Device:

Product Name:	JO Premium Personal Lubricant
510(k) Number:	K132954
Manufacturer:	United Consortium
Product Code:	NUC
Device Class:	Class II

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



## K180083 - Silicone Personal Lubricant, ALL-IN-ONE Traditional Submission

### **Device Description:**

Silicone Personal Lubricant and ALL-IN-ONE are clear, semi-viscous personal lubricants that are compatible with condoms made of natural rubber latex, polyurethane and polyisoprene. The 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 Polyethylene Terephthalate (PET) bottles capped with natural polypropylene disc top dispenser caps. The individual bottles are hermetically sealed during the production process. There is also 16 fl. oz./480 mL bottle with a different configuration for the Silicone Personal Lubricant. This consists of a clear Polyethylene Terephthalate (PET) bottle with a polypropylene lotion pump instead of the disc top dispenser used in all other sizes. This bottle is configured with a shrink wrap seal. These products are also available in polyester-faced laminated pouches.

The device specifications are listed in the table below:

**Table 1: Device Specifications for Silicone Personal Lubricant and ALL-IN-ONE**

Property	Specification
Appearance	Clear, semi-viscous liquid
Color	Clear
Odor	Odorless
Viscosity (cps)	800 cps to 1075 cps
Specific Gravity	0.850 to 1.020
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
<i>Pseudomonas aeruginosa</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Salmonella</i>	Absent
<i>Escherichia coli</i>	Absent
<i>Candida albicans</i>	Absent

### **Indications for Use:**

Silicone Personal Lubricant is a silicone-based 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.



## K180083 - Silicone Personal Lubricant, ALL-IN-ONE Traditional Submission

ALL-IN-ONE is a silicone-based 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.

**Predicate Device Comparison:**

The table below lists the comparative intended use and technological characteristics of the subjects and predicate device.

**Table 2: Comparator Table for Subject Devices – Silicone Personal Lubricant and ALL-IN-ONE and Predicate Device JO Premium Personal Lubricant**

Feature	Silicone Personal Lubricant and ALL-IN-ONE	JO Premium Personal Lubricant (K132954)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Intended Use	<p>Silicone Personal Lubricant is a silicone-based 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.</p> <p>ALL-IN-ONE is a silicone-based 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.</p>	<p>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.</p>
Water soluble	No	No
Contains water	No	No
Primary ingredients	Dimethicone, Dimethiconol	Dimethicone, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethiconol



## K180083 - Silicone Personal Lubricant, ALL-IN-ONE Traditional Submission

Feature	Silicone Personal Lubricant and ALL-IN-ONE	JO Premium Personal Lubricant (K132954)
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene, Polyurethane	Natural Rubber Latex, Polyurethane
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 devices have similar technological characteristics including similar formulation. 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 testing, Vaginal Irritation testing, Penile Irritation testing, Cytotoxicity and Sensitization testing were performed in accordance with the 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, and non-sensitizing.

#### **Shelf-Life:**

The subject devices are non-sterile personal lubricants 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 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 indicated that the Silicone Personal



## **K180083 - Silicone Personal Lubricant, ALL-IN-ONE Traditional Submission**

Lubricant and ALL-IN-ONE are compatible with natural rubber latex, polyurethane and polyisoprene condoms.

### **Conclusion:**

The results of the performance testing described above demonstrate that the Silicone Personal Lubricant and ALL-IN-ONE are as safe and effective as the predicate device and supports a determination of substantial equivalence.