



October 31, 2017

United Consortium  
Stephanie Morris  
RA/QA Specialist  
29000 N. Hancock Pkwy.  
Valencia, CA 91355

Re: K172447  
Trade/Device Name: JO Gelato Flavored Personal Lubricants  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: August 10, 2017  
Received: August 14, 2017

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.

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 (DICE) 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 (DICE) 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,

  
**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)

K172447

Device Name

JO Gelato Flavored Personal Lubricants

Indications for Use (Describe)

JO Gelato Flavored Personal Lubricants are water-based personal lubricants 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) JO Gelato Flavored Personal Lubricants Traditional Submission

### K172447 - 510(k) Summary

510(k) Owner: United Consortium

Street Address: 29000 Hancock Parkway  
Valencia, CA 91355

Establishment Registration Number: 3005691625

Contact Person: Stephanie Morris  
RA/QA 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: October 27, 2017

Trade Name: JO Gelato Flavored Personal Lubricants  
JO Gelato Salted Caramel Personal Lubricant  
JO Gelato Crème Brulee Personal Lubricant  
JO Gelato Hazelnut Espresso Personal Lubricant  
JO Gelato Mint Chocolate Personal Lubricant  
JO Gelato Tiramisu Personal Lubricant

Common Name: Personal Lubricant

Device Classification: Classification Name: Condom  
Product Code: NUC (lubricant, personal)  
Regulation: 21 CFR § 884.5300 (Condom)  
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.



## 510(k) JO Gelato Flavored Personal Lubricants Traditional Submission

### **Device Description:**

JO Gelato Flavored Personal Lubricants are clear, semi-viscous personal lubricants that are 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 lubricate and moisturize, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is provided in Polyethylene Terephthalate (PET) bottles fitted with Polypropylene caps or foil sachets. The individual bottles are sealed using an induction seal constructed of aluminized mylar.

The device specifications are listed in the table below:

**Table 1: Device Specifications for JO Gelato Flavored Personal Lubricants**

<b>Property</b>	<b>Specification</b>
Appearance	Clear, semi-viscous liquid
Color	Clear
Odor	Sweet/Characteristic
Viscosity (cps)	2000 cps to 3700 cps
Specific Gravity	0.900 to 1.050
pH	5.0 to 6.0
Osmolality	1350 to 1550 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
Total yeast and mold count (TYMC) per USP <61> and <1111>	Less than 10 cfu/g
<b>Presence of Pathogens per USP &lt;62&gt;</b>	<b>Specification</b>
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Salmonella	Absent
Escherichia coli	Absent
Candida albicans	Absent

### **Indications for Use:**

JO Gelato Flavored Personal Lubricants are water-based personal lubricants 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.

### **Predicate Device Comparison:**

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



## 510(k) JO Gelato Flavored Personal Lubricants Traditional Submission

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

Feature	JO Gelato Flavored Personal Lubricants	Astroglide Sensual Strawberry (K140590)
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Intended Use	JO Gelato Flavored Personal Lubricants are water-based personal lubricants 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.	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	Water (Aqua), Glycerin, Potassium Sorbate, Hydroxyethylcellulose, Flavor (Aroma), Sodium Chloride, Sucralose, Citric Acid	Water (Aqua), Glycerin, Propylene Glycol, Hydroxyethylcellulose, Natural and Artificial Strawberry Flavor, Sodium Gluconate, Sodium Saccharin, Methylparaben, Sodium Benzoate, Citric Acid
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Latex, Polyisoprene, Polyurethane	Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	2 years	2 years

The subject and predicate device have the same intended use - 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. The subject and predicate device have different technological characteristics, including different formulation. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions. All personal lubricants must independently demonstrate they are biocompatible, compatible with condoms, and can maintain their specifications for their expected shelf life.



## 510(k) JO Gelato Flavored Personal Lubricants Traditional Submission

### Summary of Performance Data:

#### Biocompatibility

Independent third-party laboratories conducted the biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Penile Irritation Testing, Cytotoxicity and Sensitization testing; each were performed in accordance with 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 Agarose Overlay Method, ISO 10993-5:2009)
- Sensitization (ISO Guinea Pig Maximization Sensitization, ISO 10993-10:2010)
- Vaginal Irritation (ISO Vaginal Irritation Study in Rabbits, ISO 10993-10:2010)
- Penile Irritation (ISO Penile Irritation Study in Rabbits, ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO Tests for Systemic Toxicity, ISO 10993-11:2006)

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

#### Shelf-Life:

The proposed device, JO Gelato Flavored Personal Lubricant, 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. In addition, both versions of the device packaging were evaluated. The subject device in both versions of its packaging met the device specifications at all time points.

#### Condom Compatibility:

The compatibility of the subject device, JO Gelato Personal Lubricant, was evaluated with natural rubber latex, polyisoprene and polyurethane condoms 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 the JO Gelato Flavored Personal Lubricants are compatible with natural rubber latex, polyurethane and polyisoprene condoms.

#### Conclusion:

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