



April 19, 2021

Solevy Co. LLC  
Joe Mendoza  
Quality/Regulatory Manager  
29017 Avenue Penn  
Santa Clarita, CA 91355

Re: K203644  
Trade/Device Name: Solevy Co. LLC Silicone Based Personal Lubricant  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: December 12, 2020  
Received: December 14, 2020

Dear Joe Mendoza:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For  
Monica D. Garcia, Ph.D.  
Assistant 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

## Indications for Use

510(k) Number (if known)  
K203644

Device Name  
Solevy Co. LLC Silicone Based Personal Lubricant

### Indications for Use (Describe)

Solevy Co. LLC Silicone Based 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.

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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## 510(k) Summary – K203644

510(k) Owner: Solevy Co. LLC

Street Address: 29017 Avenue Penn  
Santa Clarita, CA 91355

Contact Person: Joe Mendoza  
Quality/Regulatory Manager

Contact Number: Phone: (661) 622-4880

Summary Preparation Date: April 16, 2021

Trade Name: Solevy Co. LLC Silicone Based 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: JO Premium Personal Lubricant  
510(k) Number: K132954  
Manufacturer: United Consortium, Inc.  
Product Code: NUC  
Device Class: Class II

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

### Device Description:

Solevy Co. LLC Silicone-Based Personal Lubricant is a clear, colorless, semi-viscous personal lubricant that is compatible with condoms made of natural rubber latex and polyisoprene. The device is not compatible for use with polyurethane condoms. The device is a non-sterile lubricant, for penile and/or vaginal application, to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is provided in volumes of 1, 2.5, 4.5, 8, and 16 fl. oz in polyethylene bottles. The 1-8 fl. oz. bottles are closed with polypropylene (PP) caps, while the 16 fl. oz. bottle includes a polypropylene lotion pump. The 16 fl. oz. bottle is sealed using tamper-resistant shrink wrap band. The 1-8 fl. oz. bottles are sealed using an induction seal constructed of aluminized mylar.

The device specifications are listed in Table 1 below:

Table 1: Device Specifications

Property	Specification
Appearance	Clear, semi-viscous liquid
Color	Colorless
Odor	Odorless
Viscosity (cps) – USP<912>	750 to 950
Total aerobic microbial count (TAMC) – USP<61>/USP<1111>	Less than 100 cfu/g
Total yeast and mold count (TYMC) – USP<61>/USP<1111>	Less than 10 cfu/g
Presence of Pathogens	Specification
<i>Pseudomonas aeruginosa</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Candida albicans</i>	Absent

Indications for Use:

Solevy Co. LLC Silicone Based 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.

Predicate Device Comparison:

A comparison of the indications for use and technological characteristics of the subject and predicate device is summarized in Table 2 below:

Table 2: Predicate Device Comparison

Feature	Solevy Co. LLC Silicone Based Personal Lubricant (K203644)	JO Premium Personal Lubricant (K132954)
Indications for Use:	Solevy Co. LLC Silicone Based 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.	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.
Product Code	NUC	NUC
Primary Ingredients	Dimethicone Cyclopentasiloxane Cyclotetrasiloxane Dimethiconol	Dimethicone Cyclopentasiloxane Cyclotetrasiloxane Dimethiconol
Silicone-Based	Yes	Yes
Over-the-Counter	Yes	Yes
Condom Compatibility	Natural Rubber Latex, Polyisoprene	Natural Rubber Latex, Polyisoprene
Sterile	No	No
Biocompatibility Tested	Yes	Yes
Shelf Life	3 years	3 years

The indications for use for the subject and predicate devices are the same; therefore, they have the same intended use.

The subject and predicate devices have the same technological characteristics. As the technological characteristics of the subject and predicate device are the same, there are no differences raising different questions of safety and effectiveness.

Summary of Performance Data:

Solevy Co. LLC Silicone Based Personal Lubricant has undergone biocompatibility testing in accordance with the 2020 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.” Testing included:

- Cytotoxicity
- Sensitization
- Vaginal Irritation
- Acute Systemic Toxicity

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Shelf-Life:

TheSolevy Co. LLC Silicone Based Personal Lubricant has a three-year shelf-life based on the results of a real-time aging study. The shelf-life study evaluated all device specifications listed above in Table 1, Device Specifications. The subject device met all device specifications over the stated shelf-life duration.

Condom Compatibility:

The compatibility of the Solevy Co. LLC Silicone Based Personal Lubricant was evaluated with natural rubber latex, polyisoprene, and polyurethane condoms per ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of testing demonstrated that the Solevy Co. LLC Silicone Based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms but is not compatible with polyurethane condoms.

Conclusion:

The results of performance testing demonstrate that the Solevy Silicone Based Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.