April 19, 2021

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

Re: K203654
Trade/Device Name: Solevy Co. LLC Water-Based Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 11, 2020
Received: December 15, 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) 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

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)*
K203654

Device Name
Solevy Co. LLC Water-Based Lubricant

Indications for Use *(Describe)*
Solevy Co. LLC Water-Based Lubricant is a water-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, 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 – K203654

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 Water-Based 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 H2O Water Based Personal Lubricant
	510(k) Number:	K150480
	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 Water-Based Lubricant is a clear, colorless, semi-viscous personal lubricant that is 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 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 per USP<912>	1,200 – 1,800 cps
pH	6.0 – 7.0
Osmolality per USP<785>	750 – 950 mOsm/kg
Specific Gravity per USP<841>	1.12 – 1.20
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<100 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Presence of Pathogenic organisms *(Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans* per USP <62>)	Absent

Indications for Use

Solevy Co. LLC Water-Based Lubricant is a water-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, polyurethane, and polyisoprene 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 Water-Based Lubricant (K203654)**	**JO H2O Water-Based Personal Lubricant (K150480)**
Indications for Use	Solevy Co. LLC Water-Based Lubricant is a water-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, polyurethane, and polyisoprene condoms.	JO H20 Personal Lubricant is a water-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, polyurethane, and polyisoprene condoms.
Product Code	NUC	NUC
Ingredients	Glycerin, Water, Cellulose Gum, Methylparaben, Propylparaben	Glycerin, Water, Cellulose Gum, Methylparaben, Propylparaben
Appearance	Clear, colorless, semi-viscous liquid	Clear, colorless, semi-viscous liquid
Water-Based	Yes	Yes
Over-the-Counter Use	Yes	Yes
Condom Compatibility	Natural Rubber Latex, Polyisoprene, Polyurethane	Natural Rubber Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Non-Sterile	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 Non-Clinical Performance Data

Biocompatibility

Solevy Co. LLC Water-Based 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 (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

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

Shelf-Life

The Solevy Co. LLC Water-Based 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 Water-Based 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 Water-Based Lubricant is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Conclusion

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