September 18, 2019

United Consortium
Marlent Perez
Quality Specialist
29000 N. Hancock Pkwy.
Valencia, CA 91355

Re: K190858
Trade/Device Name: Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 15, 2019
Received: August 19, 2019

Dear Marlent Perez:

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 Andrews
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 HUMANSERVICES
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)*
K190858

Device Name
Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant

Indications for Use *(Describe)*

Bucked Stride Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Thin Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

JO XTRA SILKY Ultra-Thin 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 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.

510 (k) Summary – K190858

1. Submitter Information

Applicant: United Consortium
Contact: Marlent Perez
Quality Specialist

Bruce Albert
Head of Technical Services
Address: 29000 N. Hancock Parkway
Valencia, CA 91355
Phone: (661) 295-1700, ext. 1007

FAX: (661) 295-1800

2. Correspondent Information

Contact: Marlent Perez
Address: 29000 N. Hancock Parkway
Valencia, CA 91355
Phone: (661) 295-1700, ext. 1007
Fax: (661) 295-1800
Email: mperez@systemjo.com

3. Date prepared:

September 16, 2019

4. Device Information

Device Name:	Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone 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:	Silicone Personal Lubricant, ALL-IN-ONE
510(k) Number:	K180083
Manufacturer:	United Consortium
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

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

6. Device Description

Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant are clear, thin, liquid personal lubricants that are compatible with condoms made of natural rubber latex and polyisoprene. These products are not compatible with polyurethane condoms. These devices are non-sterile personal lubricants 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.

The Bucked Stride Silicone Lubricant product is to be sold as an over-the-counter (OTC) product in 2 fl. oz./60 mL and 4 fl. oz./120 mL sizes. This product is provided in clear polyethylene terephthalate (PET) cylinder bottles. The bottles are capped with matte black pumps covered with a metallic coated polypropylene (PP) overcap and shrink wrapped to ensure product integrity.

#LubeLife Thin Silicone Lubricant is to be sold as an over-the-counter (OTC) product in 8 fl. oz./240 mL size bottles. This product is provided in clear, polyethylene terephthalate (PET) cylinder bottles and capped with natural disc tops. The individual bottles are hermetically sealed during the production process.

JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant is to be sold as an over-the-counter (OTC) product in 1 fl. oz./30 mL, 2 fl. oz./60 mL and 4 fl. oz./120 mL sizes. This product is provided in clear, polyethylene terephthalate (PET) cylinder bottles. The 1 fl. oz./30 mL size bottles are capped with natural disc tops. The 2 fl. oz./60 mL and 4 fl. oz./120 mL size bottles are capped with silver disc tops. The individual bottles are hermetically sealed during the production process.

The device specifications are listed in the table below:

Table 1: Device Specifications for Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant

Property	**Specification**
Appearance	Clear, thin liquid
Color	Clear, colorless
Odor	Odorless
Viscosity (cps)	200 to 325 cps
Specific Gravity	0.850 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 100 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

Bucked Stride Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

#LubeLife Thin Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

JO XTRA SILKY Ultra-Thin 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.

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

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

Table 2: Comparator Table for Subject Device – Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant and Predicate Device Silicone Personal Lubricant, ALL-IN-ONE

	Bucked Stride Silicone Lubricant #LubeLife Thin Silicone Lubricant JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant	**Silicone Personal Lubricant, ALL-IN-ONE (K180083)**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	Bucked Stride Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms. #LubeLife Thin Silicone 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.	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.

Feature	Bucked Stride Silicone Lubricant #LubeLife Thin Silicone Lubricant JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant	Silicone Personal Lubricant, ALL-IN-ONE (K180083)
	JO XTRA SILKY Ultra-Thin 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms	
Water soluble	No	No
Contains water	No	No
Primary ingredients	Dimethicone, Dimethiconol, Tocopheryl (Vitamin E) Acetate	Dimethicone, Dimethiconol
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene	Natural Rubber Latex, Polyisoprene, 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 and have the same intended use. The subject and predicate device have similar technological characteristics, including similar formulation and shelf-life. 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 isnon-cytotoxic, non-irritating, and non-sensitizing, and non-systemically toxic..

Shelf-Life

The subject device is a non-sterile personal lubricant with a two-year shelf-life in accordance with the results of real time and accelerated aging studies on the various packaging types available for the lubricants, i.e., bottles with cap and bottles with pump closure. All device specifications listed in **Table 1** were evaluated for the largest volumes associated with each packaging type which were considered worst case for evaluating shelf-life. 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 Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant are compatible with natural rubber latex and polyisoprene condoms. This device is not compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that the Bucked Stride Silicone Lubricant, #LubeLife Thin Silicone Lubricant and JO XTRA SILKY Ultra-Thin Silicone Personal Lubricant are as safe and effective as the predicate device and supports a determination of substantial equivalence.