June 7, 2024

Lucida Scientific and Regulatory Consulting, LLC
Om Singh
Principal Regulatory Consultant
9667 Norfolk Ave.
Laurel, Maryland 20723

Re: K234099
Trade/Device Name: Select Hybrid Personal Lubricant and
Select Pure Silicone Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 9, 2024
Received: May 10, 2024

Dear Om Singh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael T. Bailey -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234099

Device Name
Select Hybrid Personal Lubricant and Select Pure Silicone Personal Lubricant

Indications for Use *(Describe)*
Select Hybrid Personal Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Select Pure Silicone Personal Lubricant 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 not 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
Select Labs, LLC
Select Hybrid Personal Lubricant and Select Pure Silicone Personal Lubricant

Company Name: Select Labs, LLC

Company Address: 4236 Wilkinson Blvd.
Charlotte, NC 28208, USA

Contact Number: Phone: 704-399-4400
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Contact Person: Brent Fox, CEO
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Submission Correspondent: Om V. Singh, Ph.D.
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Summary Preparation Date: June 5, 2024

Device Trade Names: Select Hybrid Personal Lubricant
Select Pure Silicone Personal Lubricant

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

Table 1: Predicate Devices

	Select Hybrid Personal Lubricant	**Select Pure Silicone Lubricant**
Predicate 510(k) Number	K191480	K212260
Predicate Trade Name	Wet® Water Based Personal Lubricant	Sensuva Premium Silicone Personal Lubricant
Predicate Manufacturer	TRIGG Laboratories, Inc.	Valencia Naturals, Inc.

The predicate devices identified above have not been subject to design-related recalls.

Device Description

The Select Hybrid Personal Lubricant and Select Pure Silicone Personal Lubricant are non-sterile, over the counter, personal lubricants. These devices are 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. Both lubricants are not compatible with natural rubber latex, polyisoprene, and polyurethane condoms. These lubricants are neither a contraceptive nor a spermicide.

The Select Hybrid Personal Lubricant formulation consists of distilled water, cyclopentasiloxane, dimethicone, dimethiconol, methylparaben, Cellosize™ hydroxyethyl cellulose PEG-10, and propylene glycol. The Select Pure Silicone Personal Lubricant formulation consists of cyclopentasiloxane, dimethicone, and dimethiconol.

Both subject devices are packaged in high density polyethylene bottles (2oz., 4oz., 8oz., 16oz., 32 oz., 64oz., and 128 oz.) with low density polyethylene caps or polypropylene/polyethylene/stainless steel combination pumps. The bottle closure/pumps are covered with a heat shrink polyethylene terephthalate glycol sleeve film.

Device specifications are provided in Tables 2 and 3.

Table 2. Device Specifications for the Select Hybrid Personal Lubricant

Physical Specification Test	**Specification**
Appearance	White Opaque Liquid
Color	White
Odor	Characteristic
Viscosity per USP <912>	15,000 – 16,500 cP
pH per USP <791>	5.62 – 6.07
Osmolality per USP <785>	744 – 783 mOsm/kg
Antimicrobial effectiveness per USP <51>	Category 2 product: 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.
Total Aerobic Microbial Count (TAMC) per USP <61> and <1111>	<20 CFU/g
Total Yeast and Mold Count (TYMC) per USP <61> and <1111>	<10 CFU/g
Absence of Pathogens per USP <62>	Absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Candida albicans*

Table 3. Device Specifications for the Select Pure Silicone Personal Lubricant

Physical Specification Test	**Specification**
Appearance	Clear Liquid
Color	Colorless
Odor	Characteristic

Viscosity per USP <912>	247 – 305 cP
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
Absence of Pathogens per USP <62>	Absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Candida albicans*

Indication for Use

Select Hybrid Personal Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Select Pure Silicone Personal Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Comparison of Intended Use and Technological Characteristics with the Predicate Device

The tables below compare the intended use and technological characteristics of the subject and predicate devices.

Table 4. Comparison Table for Subject Device Select Hybrid Personal Lubricant and Predicate Device Wet® Water Based Personal Lubricant

Parameter	**Subject Device Select Hybrid Personal Lubricant**	**Predicate device (K191480) Wet® Water Based Personal Lubricant**	**Comparison**
Manufacturer	Select Labs, LLC	TRIGG Laboratories, Inc.	N/A
Indications for Use	Select Hybrid Personal Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	The Wet Water Based Personal Lubricant (additionally, branded as WET Platinum Houston, Elite Water-Based Hybrid) is a personal lubricant for penile, anal 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Not identical

Base Type	Hybrid	Hybrid	Same
Ingredients	Water, Cyclopentasiloxane, Dimethicone, Dimethiconol, Methylparaben, Cellosize™ Hydroxyethyl Cellulose PEG-10, Propylene Glycol	Water, Dimethicone, Cyclopentasiloxane, PEG/PPG 18/18 Dimethicone, Propylene Glycol, Caprylhydroxamic Acid, 1,2-Hexanediol, Propanediol, Sodium Polyacrylate, Trideceth-6, Hydroxyethylcellulose, Sodium Acetate, Cellulose	Different
Rx/OTC	OTC	OTC	Same
Sterile	No	No	Same
Appearance	While Opaque liquid	Hazy	Similar
Color	White	Slightly Cloudy (Hazy)	Similar
Odor	Characteristic	Characteristic	Same
Viscosity	15,000 – 16,500 cp	5,000 – 13,000 cp	Different
pH	5.62 – 6.07	6.0 – 7.5	Different
Osmolality	744 – 786 mOsm/kg	3,691 – 6,140 mOsm/kg	Different
Total yeast and mold (TYMC)	<10 CFU/g	<10 CFU/g	Same
Total aerobic microbial count (TAMC)	<20 CFU/g	<10 CFU/g	Different
Absence of Pathogenic Organisms	Absent	Absent	Same
Antimicrobial Effectiveness Tested per USP <51>	Meets USP <51> acceptance criteria for Category 2 products	Meets USP <51> acceptance criteria for Category 2 products	Same
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Different
Biocompatibility	Yes	Yes	Same
Shelf-Life	2 years	1.5 Years	Different

The subject and predicate device indications are not the same in that the predicate device is also indicated for anal use and compatibility with natural rubber latex and polyisoprene condoms. These differences do not represent a new intended use, which is the same for both the predicate and subject devices (i.e., intended to provide lubrication during intimate sexual activity), but rather a more limited indications for use for the subject device. The subject and predicate devices also have differences in technological characteristics, including different formulations, specifications, compatibility with condoms, and shelf-life duration. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

Table 5. Comparison Table for Subject Device Select Pure Silicone Personal Lubricant and Predicate Device Sensuva Premium Silicone Personal Lubricant

Parameter	**Subject Device:** Select Pure Silicone Personal Lubricant	**Predicate device (K212260)** Sensuva Premium Silicone Personal Lubricant	**Comparison**
Manufacturer	Select Labs, LLC	Valencia Naturals, Inc.	N/A
Indications for Use	Select Pure Silicone Personal Lubricant 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Sensuva Premium Silicone Personal Lubricant is a silicone-based personal lubricant for penile, anal 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.	Not identical
Base Type	Silicone	Silicone	Same
Ingredients	Cyclopentasiloxane, Dimethicone, Dimethiconol	Cyclopentasiloxane, Dimethicone, Dimethiconol	Same
Rx/OTC	OTC	OTC	Same
Sterile	No	No	Same
Appearance	Clear liquid	Clear liquid	Same
Color	Colorless	Colorless	Similar
Odor	Characteristic	Characteristic	Same
Viscosity (USP <912>)	247 – 305 cp	300 – 630 cps	Different
Total yeast and mold (TYMC, 10CFU/g per USP <61> and <1111>)	<10 CFU/g	<10 CFU/g	Same
Total aerobic microbial count (TAMC < 100 CFU/g per USP <61> and <1111>)	<100 CFU/g	<100 CFU/g	Same
Absence of Pathogenic Organisms per USP <62>	Absent	Absent	Same

Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Different
Biocompatibility	Yes	Yes	Same
Shelf-Life	2 years	8.4 Months	Different

The subject and predicate device indications are not the same in that the predicate device is also indicated for anal use and compatibility with natural rubber latex, polyisoprene, and polyurethane condoms. These differences do not represent a new intended use, which is the same for both the predicate and subject devices (i.e., intended to provide lubrication during intimate sexual activity), but rather a more limited indications for use for the subject device. The subject and predicate devices also have differences in technological characteristics, including different viscosity specifications, compatibility with condoms, and shelf-life durations. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Data

Biocompatibility

Biocompatibility studies were performed on both subject lubricants in accordance with the 2023 FDA guidance *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)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that the subject lubricants are non-cytotoxic, non-irritating, non-sensitizing, and not acutely systemically toxic.

Condom Compatibility

The condom compatibility of the subject device was not tested against any condom type. Therefore, the subject device is not claimed to be condom compatible.

Shelf-Life Testing

The subject devices have a shelf-life of 2 years based on the results of accelerated aging studies. The shelf-life studies evaluated all device specifications listed in Tables 2 and 3 of the Device Specifications. The subject devices met all device specifications over the stated shelf-life duration.

Conclusion

The results of performance testing described above demonstrate the Select Hybrid Personal

Lubricant and Select Pure Silicone Personal Lubricant are as safe and effective as the predicate devices and support a determination of substantial equivalence.