April 13, 2022

Valencia Naturals, Inc.
% Stephanie Morris
Principal Consultant, Owner
SLMCO, Inc.
19762 Steinway Street
Canyon Country, CA 91351

Re: K212260
Trade/Device Name: Sensuva Premium Silicone Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 11, 2022
Received: March 14, 2022

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. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212260

Device Name
Sensuva Premium Silicone Personal Lubricant

Indications for Use *(Describe)*

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.

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) Summary – K212260

Sensuva Premium Silicone Personal Lubricant

510(k) Owner/Submitter:	Valencia Naturals, Inc.	
Street Address:	9731 Topanga Canyon Place Chatsworth, CA 91311	
Contact Person(s):	Anthony Santoro President, Valencia Naturals, Inc.	
Contact Number(s):	Phone: (877) 470-7578	
Summary Preparation Date:	April 11, 2022	
Trade Name:	Sensuva Premium Silicone Personal Lubricant	
Common Name:	Personal Lubricant	
Device Classification:	Regulation Name:	Condom
	Regulation Number:	21 CFR 884.5300
	Product Code:	NUC (lubricant, personal)
	Regulatory Class:	Class II
Predicate Device:	Product Name:	Silicone Personal Lubricant
	510(k) Number:	K180083
	Manufacturer:	United Consortium
	Product Code:	NUC (lubricant, personal)
	Regulatory Class:	Class II

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

Device Description:

Sensuva Premium Silicone Personal Lubricant is a non-sterile, clear, colorless, thin liquid, silicone-based personal lubricant. This device is 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. It is compatible with natural rubber latex, polyisoprene and polyurethane condoms. Its formulation consists of dimethicone, dimethiconol, and cyclopentasiloxane.

Sensuva Premium Silicone Personal Lubricant is sold as an over-the-counter (OTC) device and is provided in polyethylene terephthalate bottles. The 1.93 fl. oz./57 mL bottles are fitted with 20/410 smooth black pump sprayers and clear polypropylene caps. The 4.23 fl. oz./125 mL and 8.12 fl. oz./240 mL bottles are capped with 24/410 smooth black lotion pumps.

The device specifications are listed in the table below:

Table 1: Device Specifications for Sensuva Premium Silicone Personal Lubricant

Property	Specification
Appearance	Thin liquid
Color	Clear, colorless
Odor	Characteristic
Viscosity (cps)	300-630 cps
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> (*Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella/Shigella, Escherichia coli, Candida albicans*)	Absent

Indications for Use:

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.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices:

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

Table 2: Comparator Table for Subject Device – Sensuva Premium Silicone Personal Lubricant and Predicate Device Silicone Personal Lubricant

Feature	Sensuva Premium Silicone Personal Lubricant K212260 Subject Device	Silicone Personal Lubricant K180083 Predicate Device	Comparison
Device Classification Name	Lubricant, Personal	Lubricant, Personal	**Same**
Product Code	NUC	NUC	**Same**
Indications for Use	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 ofintimate sexual activity and supplement the body's natural	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 thebody's	The subject and predicate device have the same indications for use and intended use.

	lubrication. This product is compatible with natural rubber latex, polyisoprene and polyurethane condoms.	natural lubrication. This product is compatible with naturalrubber latex, polyurethane and polyisoprene condoms.	
Water Soluble	No	No	**Same**
Contains Water	No	No	**Same**
Primary Ingredients	Dimethicone, Cyclopentasiloxane, Dimethiconol	Dimethicone, Dimethiconol	**Different:** The subject and predicate devices have different formulations. These differences do not raise different questions of safety and effectiveness (S&E).
Appearance/Color	Clear, colorless thin liquid	Clear, semi-viscous liquid	**Similar**
Odor	Characteristic	Odorless	**Different:** The predicate and subject devices have differences in their odors. These differences do not raise different questions of S&E.
Viscosity	300-630 cps	800-1075 cps	**Different:** The predicate device has a higher viscosity than the subject device. Differences in viscosity do not raise different questions of S&E.
TAMC	<100 cfu/g	<10 cfu/g	**Different:** The subject device has a higher TAMC specification. This difference does not raise a different question of S&E.
TYMC	<10 cfu/g	<10 cfu/g	**Same**
Absence of Pathogenic Organisms	Absent	Absent	**Same**
Over the Counter (OTC) Use	Yes	Yes	**Same**
Sterile	No	No	**Same**
Condom Compatibility	Natural Rubber Latex, Polyurethane, Polyisoprene	Natural Rubber Latex, Polyurethane, Polyisoprene	**Same**

Biocompatibility Tested	Yes	Yes	**Same**
Shelf-Life	8.4 months	2 years	**Different:** The subject device has a shorter shelf-life than the predicate device. Differences in shelf-life duration do raise different questions of S&E.

The subject and predicate devices have the same indications for use and intended use. The subject and predicate devices have differences in technological characteristics, including different formulations, odor, viscosity, TAMC, and shelf-life duration. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Data:

Biocompatibility

Biocompatibility studies were performed 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*." The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Acute Systemic Toxicity (ISO 10993-11:2017)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)

The results of testing support the biocompatibility of the device materials.

Shelf-Life:

The subject device has a shelf-life of 8.4 months. Results from an accelerated-aging study demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility:

The compatibility of the subject device with condoms was evaluated in accordance with ASTM D7661-18 *StandardTest Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this testing showed the Sensuva Premium Silicone Personal Lubricant is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

Conclusion:

The results of the performance testing described above demonstrate that the Sensuva Premium Silicone Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.