November 19, 2019

Valencia Naturals Inc.
% Louie Goryoka
Sr. Regulatory & Quality Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K192204
Trade/Device Name: Sensuva Unscented Personal Lubricant, Sensuva Strawberry Personal Lubricant, Sensuva Apple Candy Personal Lubricant, Sensuva Butter Rum Personal Lubricant, Sensuva Orange Creamsicle Personal Lubricant, Sensuva Salted Caramel Personal Lubricant, Sensuva Blueberry Muffin Personal Lubricant, Sensuva Watermelon Personal Lubricant, Sensuva Cotton Candy Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 27, 2019
Received: October 29, 2019

Dear Louie Goryoka:

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,

Monica D. Garcia, Ph.D.
Acting 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)*
K192204

Device Name
Sensuva Unscented Personal Lubricant, Sensuva Strawberry Personal Lubricant, Sensuva Apple Candy Personal Lubricant, Sensuva Butter Rum Personal Lubricant, Sensuva Orange Creamsicle Personal Lubricant, Sensuva Salted Caramel Personal Lubricant, Sensuva Blueberry Muffin Personal Lubricant, Sensuva Watermelon Personal Lubricant, Sensuva Cotton Candy Personal Lubricant.

Indications for Use *(Describe)*
The Sensuva Personal Lubricants are personal lubricants, 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. These products are compatible with natural 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.

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510 (k) Summary – K192204

1. Submitter Information

Applicant: Valencia Naturals Inc.
Contact: Louie Goryoka
Sr. Regulatory and Quality Consultant
Address: 9731 Topanga Canyon PL.
Chatsworth, CA 91311
Phone: (877) 470-7578
Email: mdci@m-dci.us

2. Correspondent Information

Contact: Louie Goryoka
Sr. Regulatory and Quality Consultant
Med-Device Consulting, Inc.
Address: 5804 Rainbow Hill Road
Agoura Hills, CA 91301
Phone: (818) 585-7488
Email: mdci@m-dci.us

3. Date prepared: November 18, 2019

4. Device Information

Device Name:	Sensuva Unscented Personal Lubricant, Sensuva Strawberry Personal Lubricant, Sensuva Apple Candy Personal Lubricant, Sensuva Butter Rum Personal Lubricant, Sensuva Orange Creamsicle Personal Lubricant, Sensuva Salted Caramel Personal Lubricant, Sensuva Blueberry Muffin Personal Lubricant, Sensuva Watermelon Personal Lubricant, Sensuva Cotton Candy 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:	JO Gelato Flavored Personal Lubricants
510(k) Number:	K172447
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

The Sensuva Personal Lubricants are available in the following formulations:

- Sensuva Unscented Personal Lubricant
- Sensuva Strawberry Personal Lubricant

- Sensuva Apple Candy Personal Lubricant
- Sensuva Butter Rum Personal Lubricant
- Sensuva Orange Creamsicle Personal Lubricant
- Sensuva Blueberry Muffin Personal Lubricant
- Sensuva Salted Caramel Personal Lubricant
- Sensuva Watermelon Personal Lubricant
- Sensuva Cotton Candy Personal Lubricant

Sensuva Personal Lubricants are water-based, non-sterile personal lubricants for over-the-counter use, formulated to be slightly cloudy and odorless. The device is designed to supplement the body's own natural lubrication and is compatible for use with natural rubber latex, polyurethane, and polyisoprene condoms during intimate sexual activity. Sensuva Personal Lubricants are neither a contraceptive nor a spermicide.

The device specifications for Sensuva Personal Lubricants are listed in the table below:

Table 1: Device Specifications for "The Sensuva Personal Lubricants"

Property	**Specification**
Appearance	Slight hazy, viscous liquid
Color	Particle-Free / slightly cloudy color
Odor for original flavor	Odorless
Viscosity (cps)	4,000 cps – 6,800 cps
pH	4-5
Osmolality	380-550 mOsm/kg
Specific Gravity	0.95 - 1.05
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

The Sensuva Personal Lubricants are water-based 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. These products are compatible with natural rubber latex, polyurethane and polyisoprene 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 – The Sensuva Personal Lubricants and Predicate Device JO Gelato Flavored Personal Lubricants

	Sensuva Personal Lubricants (K192204)	**JO Gelato Flavored Personal Lubricants (K172447)**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	Personal lubricant, for 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. These products are compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	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 compatible with natural rubber latex, Polyisoprene, Polyurethane.
Water soluble	Yes	Yes
Contains water	Yes	Yes
Primary ingredients	Filtered Water, Zemea Propanediol , Geogard Ultra, Stevia Leaf Ext SE 98% Reb A, Potassium Sorbate, Hydroxyethylcellulose (HEC), Citric Acid, Natural Vanilla Masking plus additional flavors	Water (Aqua), Glycerin, Potassium Sorbate, Hydroxyethylcellulose, Flavor (Aroma), Sodium Chloride, Sucralose, Citric Acid
pH	4-5	5-6
Osmolality	380-550 mOsm/kg	1350 – 1550 mOsm/kg
Over the counter use	Yes	Yes
Sterile	No	No
Condom Compatibility	Natural Rubber Latex, Polyisoprene, Polyurethane	Natural Rubber Latex, Polyisoprene, Polyurethane
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Shelf life	19 months	2 years

The subject and predicate device have similar indications for use and have the same intended use. The subject and predicate device have different technological characteristics, including different formulations, specifications, 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, 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)
- Acute Systemic Toxicity (ISO 10993-11:2006)

The results of this testing demonstrated that the Sensuva Personal Lubricants are non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

The subject devices are non-sterile personal lubricants with a 19-month shelf-life in accordance with the results of accelerated aging studies per ASTM F1980-16. All device specifications listed in **Table 1** were evaluated for 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 demonstrate that the Sensuva Personal Lubricants are compatible with natural rubber latex, polyurethane and polyisoprene condoms.

10. Conclusion

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