



December 1, 2023

Woo Essentials, Inc.  
Mackie Swan  
CEO  
1801 Brackenridge St. A  
Austin, TX 78704

Re: K232093  
Trade/Device Name: Woo More Play Coconut Love Oil  
Regulation Number: 21 CFR§ 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: November 1, 2023  
Received: November 1, 2023

Dear Mackie Swan:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Monica D. Garcia -S**

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

## Indications for Use

510(k) Number (if known)

K232093

Device Name

Woo More Play Coconut Love Oil

Indications for Use (Describe)

Woo More Play Coconut Love Oil is a personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(K) Summary – K232093**  
**Woo More Play Coconut Love Oil**

**I. General Information on Submitter**

**Applicant:** Woo Essentials, Inc.  
**Address:** 1801 Brackenridge St. A  
Austin, TX  
78704  
**Telephone:** 858-634-0994  
**Contact Person:** Mackie Swan  
**Contact Title:** CEO  
Woo Essentials, Inc.  
**Email:** [mackie@woomoreplay.com](mailto:mackie@woomoreplay.com)  
**Date Prepared:** November 29, 2023

**II. General Information on Device**

**Proprietary Name:** Woo More Play Coconut Love Oil  
**Common Name:** Personal Lubricant  
**Regulation Name:** Condom  
**Regulation Number:** 21 CFR 884.5300  
**Regulatory Class:** II  
**Product Code:** NUC (Lubricant, Personal)

**III. Predicate Device**

| Predicate Device                            | 510(k) Number |
|---------------------------------------------|---------------|
| Bloomi Delight Oil-Based Personal Lubricant | K222175       |

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

**IV. Description of Device**

Woo More Play Coconut Love Oil is a non-sterile, flavored, oil-based personal lubricant that provides lubrication during intimate sexual activity. The subject device is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms. Its formulation consists of Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Beeswax, Deionized Water, Stevia Rebaudiana Leaf Extract, Jojoba Esters, Helianthus Annuus (Sunflower) Seed Wax, Acacia Decurrens Flower Wax, Polyglycerin-3, and Natural Flavor.

Woo More Play Coconut Love Oil is for over-the-counter (OTC) use and is packaged in 3.3 oz. non-sterile bottles.

The specifications for the Woo More Play Coconut Love Oil are described in **Table 1**.

**Table 1.** Device Specifications

| Parameter                                                                                                                     | Test Method         | Specification                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance                                                                                                                    | Visual              | Opaque; thin liquid to semi-solid                                                                                                                                                                                                                                                              |
| Color                                                                                                                         | Visual              | White to off-white                                                                                                                                                                                                                                                                             |
| Odor                                                                                                                          | Olfactory           | Characteristic                                                                                                                                                                                                                                                                                 |
| pH                                                                                                                            | USP <791>           | 4.0-5.5                                                                                                                                                                                                                                                                                        |
| Viscosity                                                                                                                     | USP <912>           | 500-2,000 cPs                                                                                                                                                                                                                                                                                  |
| Osmolality                                                                                                                    | N/A                 | N/A                                                                                                                                                                                                                                                                                            |
| Water Activity                                                                                                                | USP <1112>          | <0.7aw                                                                                                                                                                                                                                                                                         |
| Antimicrobial Effectiveness                                                                                                   | 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 the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days |
| Total Microbial Count                                                                                                         | USP <61> and <1111> | <100 cfu/g                                                                                                                                                                                                                                                                                     |
| Fungal/Yeast/Mold Limits                                                                                                      | USP <61> and <1111> | <10 cfu/g                                                                                                                                                                                                                                                                                      |
| Absence of Pathogenic Organisms<br>( <i>Staphylococcus Aureus</i> , <i>Pseudomonas Aeruginosa</i> , <i>Candida Albicans</i> ) | USP <62>            | Absent                                                                                                                                                                                                                                                                                         |
| Specific gravity                                                                                                              | USP <841>           | 0.86-0.96                                                                                                                                                                                                                                                                                      |

## V. Indications for Use

Woo More Play Coconut Love Oil is a personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and 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.

## VI. Substantial Equivalence Discussion

A comparison of the intended use and technological features of the subject and predicate devices is provided in **Table 2** below:

**Table 2.** Intended Use and Technological Characteristics of Subject Device Compared to Predicate Device

| Characteristic / Feature          | Woo More Play Coconut Love Oil (subject device)                                                                                                                                                                                                                                                                                                | Bloomi Delight Oil-Based Personal Lubricant (predicate device) – K222175                                                                                                                                                                                                                                                                                        | Comparison                                                                                                                                                  |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indication for use                | Woo More Play Coconut Love Oil is a personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and 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 Bloomi Delight Oil-Based Personal Lubricant is a personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and 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. | Same                                                                                                                                                        |
| Appearance                        | Opaque, thin liquid to semi-solid                                                                                                                                                                                                                                                                                                              | Semi-fluid                                                                                                                                                                                                                                                                                                                                                      | <b>Different</b>                                                                                                                                            |
| Color                             | White to Off-White                                                                                                                                                                                                                                                                                                                             | Yellow                                                                                                                                                                                                                                                                                                                                                          | <b>Different</b>                                                                                                                                            |
| Odor                              | Characteristic                                                                                                                                                                                                                                                                                                                                 | Odorless                                                                                                                                                                                                                                                                                                                                                        | <b>Different</b>                                                                                                                                            |
| Viscosity                         | 500-2,000 cPs                                                                                                                                                                                                                                                                                                                                  | 2,300-20,000 cPs                                                                                                                                                                                                                                                                                                                                                | <b>Different</b>                                                                                                                                            |
| Over the Counter                  | Yes                                                                                                                                                                                                                                                                                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                             | Same                                                                                                                                                        |
| Water Activity                    | <0.7aw                                                                                                                                                                                                                                                                                                                                         | Not available                                                                                                                                                                                                                                                                                                                                                   | <b>Different</b>                                                                                                                                            |
| Not a contraceptive or Spermicide | Yes                                                                                                                                                                                                                                                                                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                             | Same                                                                                                                                                        |
| Non-sterile                       | Yes                                                                                                                                                                                                                                                                                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                             | Same                                                                                                                                                        |
| Primary Ingredients               | Cocos Nucifera (Coconut) Oil, Caprylic/Capric Triglyceride, Beeswax, Deionized Water, Stevia Rebaudiana Leaf Extract, Jojoba Esters, Helianthus Annuus (Sunflower) Seed Wax, Acacia Decurrens Flower Wax, Polyglycerin-3, and Natural Flavor                                                                                                   | Extra Virgin Coconut Oil, Organic Sunflower Seed Oil, Organic Cocoa Butter, Shea Butter, Sunflower Wax, and Sea Buckthorn Fruit Oil                                                                                                                                                                                                                             | <b>Different:</b> The ingredients of the predicate device are different; the ingredients do not raise different questions of Safety & Effectiveness (S & E) |

|                      |                                                                                                                                                                                                            |                                                                                                                                                                                                            |      |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Microbial Limits     | Total mold/yeast count <10 cfu/mL<br>Total aerobic microbial count <100 cfu/mL<br>Absence of pathogens<br>( <i>Candida albicans</i> ,<br><i>Pseudomonas aeruginosa</i> ,<br><i>Staphylococcus aureus</i> ) | Total mold/yeast count <100 cfu/mL<br>Total aerobic microbial count <10 cfu/mL<br>Absence of pathogens<br>( <i>Candida albicans</i> ,<br><i>Pseudomonas aeruginosa</i> ,<br><i>Staphylococcus aureus</i> ) | Same |
| Condom Compatibility | Not compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms                                                                                                                   | Not compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms                                                                                                                   | Same |

The subject and predicate devices have identical indications for use statements and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations and device specifications. The different technological characteristics do not raise different types of safety and effectiveness questions.

## VII. Summary of Non-Clinical Performance Testing

### **Biocompatibility**

Biocompatibility testing on the subject lubricant was 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”* and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

### **Shelf Life**

The subject device is a non-sterile personal lubricant packaged in 3.3 oz. non-sterile bottles with a 3-month shelf-life in accordance with the results of a real-time aging study. The device specifications listed in **Table 1** were tested across the device shelf-life and the subject device met the specifications at all time points.

### **Condom Compatibility**

Condom compatibility testing was not conducted for the subject device. Therefore, Woo More Play Coconut Love Oil is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

## **VIII. Conclusion**

The results of the testing described above demonstrate that Woo More Play Coconut Love Oil is as safe and effective as the predicate device and supports a determination of substantial equivalence.