June 14, 2021

COCONU, LLC.
% Louie Goryoka
Sr. QA/RA Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K210814
Trade/Device Name: Coconu Water Based Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 11, 2021
Received: March 17, 2021

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 -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

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)*
K210814

Device Name
Coconu Water Based Personal Lubricant

Indications for Use *(Describe)*
Coconu Water Based 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K210814
Coconu Water Based Personal Lubricant

I. Submitter Information

Applicant: COCONU, LLC.
Company Address: 1968 E. ASHLEY MESA LANE
SANDY, UT 84092 USA

Company Phone: (801) 550-8611
Company Contact: Taylor Warnick

Contact Person: Louie Goryoka
Sr. Regulatory and Quality Consultant
Med-Device Consulting, Inc.
Email: **mdci@m-dci.us**
(818) 585-7488

II. Date Prepared

June 11, 2021

III. Device Information

Trade Name: Coconu Water Based Personal Lubricant
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC (lubricant, personal)

IV. Predicate Device

Trade Name: Coconut Infused Hybrid Personal Lubricant
510(k) Number: K180712
Manufacturer: United Consortium
Common Name: Personal Lubricant
Device Class: Class II
Product Code: NUC (lubricant, personal)

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

V. Device Description

Coconu Water Based Personal Lubricant is a non-sterile, water-based personal lubricant that is intended for penile and vaginal application 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.

Its formulation consists of water, Cocos Nucifera (Coconut) fruit juice, Microcare SB (water, sodium benzoate, potassium sorbate), Keltrol CG (xanthan gum), Purac FCC 50 (water, lactic acid), Geogard 111S (sodium dehydroacetate), CMC 7H3SF PHARM (sodium carboxymethylcellulose).

Coconu Water Based Personal Lubricant is packaged in a MDPE (medium density polyethylene) 3 oz tube, packaged in an outer box. Coconu Water Based Personal Lubricant is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in the Table below:

Property	Specification
Appearance	Opaque Flowable Gel
Color	Off-White - Light Yellow
Odor	None
Viscosity@25°C Spindle #RVS@20rpm (cps)	2,800 cps – 4,500 cps
Specific Gravity@25°C	0.90-1.11
pH @ 25°	4.0 to 5.0
Osmolality (mOSm/kg) (1:10 dilution) per USP<785>	42.0 mOSm/kg – 46.0 mOSm/kg
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
Antimicrobial effectiveness per 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 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
Presence of Pathogens per USP <62> (*Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella/Shigella, Escherichia coli,* and *Candida albicans* per USP <62>)	Absent

VI. Indications for Use

Coconu Water Based 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

VII. Predicate Device Comparison

A comparison of the intended use and technological characteristics of the subject and predicate device is summarized in the table below:

Characteristic/Feature	Coconu Water Based Personal Lubricant – Subject Device	Coconut Infused Hybrid Personal Lubricant K180712 (Predicate Device)	Comparison

Indications for Use	Coconu Water Based 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Coconut Infused Hybrid Personal Lubricant is a water-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.	Similar
Water-Based Lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Odorless	Yes	Yes	Same
Viscosity (cps)	2,800 – 4,500	20,000 – 31,000	Different
pH	4.0 – 5.0	5.7 – 6.3	Different
Osmolality (mOsm/kg)	42.0 – 46.0 (1:10 dilution)	450 – 900	Different
Condom Compatibility	Natural rubber latex and polyisoprene condoms only.	Natural rubber latex and polyisoprene condoms only.	Same
Primary Ingredients	Water (Aqua), Cocos Nucifera (Coconut) Fruit Juice, Microcare SB (Water, Sodium Benzoate, Potassium Sorbate), Keltrol CG (Xanthan Gum), Purac FCC 50 (Water, Lactic Acid), Geogard 111S (Sodium Dehydroacetate), CMC 7H3SF PHARM (Sodium Carboxymethylcellulose)	Water (Aqua), Propylene Glycol, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Flavor (Aroma), Phenoxyethanol, Polyacrylate 13, Cellulose Gum (Sodium Carboxymethylcellulose), Raphanus Sativus (Radish) Seed Extract, Polyisobutene, Polysorbate 20, PEG-45M	Different
Shelf life	8.5 months	3 years	Different

The subject and predicate device have similar indications for use and have the same intended use, i.e., provides lubrication during intimate sexual activity. The subject and predicate device have different technological characteristics, including different formulations, viscosity, pH, osmolality, and shelf life. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness as compared to the predicate device.

VIII. Summary of Non-Clinical Performance Testing

Biocompatibility

Coconu Water Based Personal Lubricant has undergone biocompatibility testing 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." Testing included:

- Cytotoxicity – Direct Contact Method, ISO 10993-5:2009/(R)2014

- Dermal Sensitization – Guinea Pig Maximization Sensitization, ISO 10993-10:2010/(R)2014
- Vaginal Irritation – Vaginal Mucosa Irritation Test, ISO 10993-10:2010/(R)2014
- Acute Systemic Toxicity – ISO 10993-11:2017

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility

Coconu Water Based Personal Lubricant was tested in accordance with ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Results showed that Coconu Water Based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Shelf Life Testing

Coconu Water Based Personal Lubricant has a shelf-life of 8.5 months, according to the results of an accelerated aging study per ASTM F1980-16. All device specifications listed in **Section V. Device Description** of this summary were evaluated in the shelf-life study. The subject device met the device specifications at all time points.

IX. Conclusion

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