September 19, 2024

Good Clean Love, Inc.
% Abhishek Gurnani
Regulatory Counsel
Amin Wasserman Gurnani LLP
549 W. Randolph Street
Suite 400
Chicago, Illinois 60661

Re: K242162
Trade/Device Name: Coconut Hybrid
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 22, 2024
Received: July 24, 2024

Dear Abhishek Gurnani:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, PhD
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)*

K242162

Device Name
Coconut Hybrid

Indications for Use *(Describe)*

Coconut Hybrid 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.

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
PRAStaff@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
K242162
Coconut Hybrid

(a)(1) **Submitter/Owner:**

Good Clean Love, Inc.
207 West 5th Avenue
Eugene, OR 97401
Contact: Wendy Strgar
Phone: 541 344 4483
Email: Wendy@GoodCleanLove.com

Preparer/Contact:

Abhishek K. Gurnani
Amin Wasserman Gurnani LLP
230 W Monroe Street
Suite 1405
Chicago IL 60606

Phone: 312 327 3325
Fax: 312 884 7352
Email: agurnani@awglaw.com

Summary Prepared: September 18, 2024

(a)(2) **Subject Device Information**

Trade Name:	Coconut Hybrid
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Device Classification:	Class II
Product Code:	NUC (Lubricant, Personal)

(a)(3) **Predicate Device Information**

Trade Name:	Coconut Infused Hybrid Personal Lubricant
501(k) Number:	K180712
Manufacturer	United Consortium
Regulation Number:	21 CFR 884.5300
Device Classification:	Class II
Product Code:	NUC (Lubricant, Personal)

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

(a)(4) **Device Description**: Coconut Hybrid is a water-based personal lubricant that is non- sterile, contains coconut oil, and provides lubrication during intimate sexual activity. This device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists of water, hydroxyethylcellulose, fractionated coconut oil, tremella fuciformis extract, hyaluronic acid, propanediol, DL lactic acid, xanthan gum, sodium benzoate, potassium sorbate, and natural coconut flavor. Coconut Hybrid is packaged in a 50 mL polyethylene tubes and is a personal lubricant for

over the counter (OTC) use.

Device specifications are listed in Table 1 below.

Table 1: Subject Device Specifications

Parameter	Specification	Method
Appearance	Gel	Visual Inspection
Color	Opaque	Visual Inspection
Odor	Characteristic (coconut)	Olfactory Inspection
pH	3.5 – 4.2	USP <791>
Viscosity	8,000 – 59,000 cPs	USP <912>
Osmolality	200 – 400 mOsm/kg	USP <785>
Antimicrobial Effectiveness	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.	USP <51>
Total Aerobic Microbial Count	<100 cfu/g	USP <61>
Total Yeast and Mold Count	<10 cfu/g	USP <61>
Absence of Pathogenic Organisms (*Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Escherichia coli, Salmonella, Clostridium Species*)	Absent	USP <62>

(a)(5) **Indications for Use Statement:** Coconut Hybrid 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.

(a)(6) **Comparison of Technological Characteristics**

Table 2. Technological Characteristics of Coconut Hybrid as Compared to the Predicate

	K242162	**K180712**
	Subject Device	**Predicate**
Sponsor	Coconut Hybrid	Coconut Infused Hybrid Personal Lubricant
Regulation Number Product Code Device Class	844.5300 NUC II	844.5300 NUC II
Indications for Use	Coconut Hybrid 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.
Physical Features	Opaque Gel	White to off-white liquid
Water-based	Yes	Yes
Primary Ingredients	Water, hydroxyethylcellulose, fractionated coconut oil, tremella fuciformis extract, hyaluronic acid, propanediol, DL lactic acid, xanthan gum, sodium benzoate, potassium sorbate, and natural coconut flavor	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
pH	3.5 – 4.2	5.7 – 6.3
Osmolality	200 – 400 mOsm/Kg	450 – 900 mOsm/kg
Viscosity	8,000 – 59,000 cps	20,000 – 31,000 cps
Sterile	No	No
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex and Polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested (USP <51>, USP <61>, USP <62>)	Yes	Yes

The subject and predicate devices do not have identical indications for use statements, as the predicate is also intended for anal use. This difference does not represent a different intended use, but rather a more limited use for the subject device, as both devices are intended for providing additional lubrication during intimate sexual activity. As noted in the table above, the subject and predicate device have differences in technological characteristics (e.g., formulations, specifications, etc.). These differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

(b) Summary of Performance Data

Biocompatibility: Coconut Hybrid has undergone biocompatibility testing including Cytotoxicity based on alternate testing comparable to ISO 10993-5: 2009, Human Repeat Insult Patch Testing (sensitization and irritation), and Acute Systemic Toxicity Testing per ISO 10993: 2017. The testing found that Coconut Hybrid is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility: The compatibility of the subject device with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-18 "*Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*" and was determined to be compatible with natural rubber latex and polyisoprene condoms. The subject device was determined not to be compatible with polyurethane condoms.

Shelf Life: Coconut Hybrid has a 1-year shelf life in accordance with the results of an accelerated aging stability study. Results from testing demonstrated that the device could maintain its specifications (as shown in Table 1) over the duration of its shelf life.

Conclusion: The results of the performance testing described above demonstrate that the Coconut Hybrid Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.