November 21, 2019

Good Clean Love, Inc.
% Steven Chernoff
Vice President
Drug & Device Development Co., Inc.
P.O. Box 3515
Redmont, WA 98073

Re: K150094
Trade/Device Name: Good Clean Love Personal Lubricants Almost Naked and Natural Cinnamon Vanilla
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: September 30, 2015
Received: October 2, 2015

Dear Steven Chernoff:

This letter corrects our substantially equivalent letter of November 19, 2015.

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)*
K150094

Device Name
Good Clean Love Personal Lubricants Almost Naked and Natural Cinnamon Vanilla

Indications for Use *(Describe)*
Good Clean Love Personal Lubricant Almost Naked and Natural Cinnamon Vanilla are personal lubricants 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, 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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Section 5. 510(k) Summary (21 CFR 807.92)

Date prepared: Nov. 19, 2015

Submitter:
Good Clean Love, Inc.
207 West 5th Avenue
Eugene, OR 97401
Contact Person: Wendy Strgar
Ph: 541-344-4483
Fax: 541-685-1335

Proprietary name:
Good Clean Love Personal Lubricants Almost Naked and Natural Cinnamon Vanilla

Common name:
Personal Lubricant

Classified name:
Condom
CFR 884.5300 Class II Product code NUC

Intended use:
Good Clean Love Personal Lubricant Almost Naked and Natural Cinnamon Vanilla are personal lubricants 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, and polyurethane condoms.

Predicate device:
The Good Clean Love personal lubricants are substantially equivalent to Aloe Cadabra personal lubricants (K124044).

Description of device:
Good Clean Love Personal Lubricants Almost Naked and Natural Cinnamon Vanilla contain water-solvent organic materials. The primary ingredient is aloe vera (95%). The products are provided in tube containers and have a gel consistency. They include aromatics of cinnamon, vanilla, and lemon. The lubricants are not a spermicide or contraceptive. They are compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Summary of technological characteristics compared to predicate devices:
Both the Good Clean Love products and its predicate device, Aloe Cadabra, consist of 95% organic aloe vera. Both products are compatible with natural rubber latex and polyisoprene condoms and are biocompatible.

Non-clinical testing:

Testing has established that lubricants met specifications for appearance, odor, pH, viscosity, osmolality, antimicrobial effectiveness, total microbial count, fungal/yeast/mold limits, and absence of pathogenic organisms. Shelf-life has been established at one-year.

Condom compatibility testing following ASTM D7661-10 concluded that the lubricants are compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Biocompatibility testing for Vaginal Mucosa Irritation (ISO 10993-10:2010), Acute Systemic Toxicity (ISO 10993-11:2006), Maximization Test for Delayed Hypersensitivity (ISO-10993-10:2010), and Cytotoxicity (MatTek EpiVaginal Tissue Model) all had acceptable results.

Conclusion:

The conclusions drawn from the non-clinical tests and predicate comparison demonstrate that the subject device performs as well as the legally marketed device and the Good Clean Love's personal lubricants are substantially equivalent to the cited predicate device for intended use and technological characteristics.