June 1, 2018

Good Clean Love, Inc.
% Abhishek Gurnani
Partner
Amin Talati Upadhye, LLP
100 S. Wacker Drive, Suite 2000
Chicago, Illinois 60606

Re: K180136
Trade/Device Name: BioNude Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 2, 2018
Received: May 4, 2018

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180136

Device Name
BioNude Lubricant

Indications for Use *(Describe)*
BioNude 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. It 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.

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510(k) SUMMARY
BioNude Lubricant – K180136

This summary uses the format provided in 21 CFR 807.92:

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

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Summary Prepared: May 31, 2018

(a)(2) **Trade Name:** BioNude Lubricant

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Regulatory Class: Class II

Product Code: NUC (lubricant, personal)

(a)(3) **Identification of Predicate Device:** Sheffield Laboratories Warming LubriGel Personal Lubricant (K052162)

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

(a)(4) **Device Description:** BioNude is a 100% isotonic water-based formula with ingredients including lactic acid, hydroxyethylcellulose, carrageenan, sodium chloride, potassium sorbate, sodium benzoate, carob gum, xanthan gum, sodium hydroxide, and calcium chloride. The product is provided in a tube container and has a gel consistency. Its specifications include appearance, color, odor, pH, specific gravity, viscosity, antimicrobial effectiveness, total aerobic microbial count, total yeast and mold count, and

absence of pathogenic organisms. The lubricant is not a spermicide or contraceptive. It is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

(a)(5) **Indications for Use Statement:** BioNude 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. It is not compatible with polyurethane condoms.

The subject and predicate device have the same intended use.

(a)(6) **Comparison of Technological Characteristics:** The following table summarizes the key technological characteristics of the subject and predicate device:

	K80136	K052162
	Subject Device	**Predicate Device**
Sponsor	Good Clean Love Inc.	Sheffield Laboratories
Regulation Number Product Code Device Class	884.5300 NUC II	884.5300 NUC II
Base Type	Water	Water
Primary Ingredients	Water Lactic Acid Hydroxyethylcellulose	Propylene glycol Polyethylene glycol Hydroxypropyl cellulose Lactic Acid
Condom Compatibility	Natural Rubber Latex Polyisoprene	Natural Rubber Latex

The subject and predicate device have differences in technological characteristics, including formulation and specifications. However, those differences do not raise new questions on safety or effectiveness.

(b) **Summary of Performance Data:**

Biocompatibility

BioNude has undergone biocompatibility testing including cytotoxicity per ISO 10993-5:2009, human repeat insult patch testing (sensitization and irritation), and acute systemic toxicity testing per ISO 10993-11:2006. The testing found that BioNude is biocompatible.

Condom Compatibility
BioNude was tested for condom compatibility per ASTM D7661-10 and was found to be compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms.

Shelf Life

The results of shelf life testing demonstrate that BioNude maintains its specifications over the duration of their proposed shelf life.

Conclusion:
The results of performance testing demonstrate that the subject and predicate device are substantially equivalent.