March 12, 2020

Good Clean Love, Inc.
% Abhishek Gurnani
Partner
Amin Talati Wasserman, LLP
100 South Wacker Drive, Suite 2000
Chicago, IL 60606

Re: K193448
Trade/Device Name: BioNourish Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 11, 2019
Received: December 13, 2019

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 control's 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,

For
Sharon M. Andrews
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)*
K193448

Device Name
BioNourish Lubricant

Indications for Use *(Describe)*
BioNourish 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.

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510(k) Summary – K193448

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Summary Prepared: March 10, 2020

Trade Name: BioNourish Lubricant

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulatory Name: Condom

Regulatory Class: Class II

Product Code: NUC (lubricant, personal)

Identification of Predicate Device: Hyalo Gyn Personal Lubricant (K094039)

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

Device Description: BioNourish Lubricant is a personal lubricant that is non-sterile, contains hyaluronic acid, 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, hyaluronic acid, carrageenan, sodium chloride, xanthan gum, lactic acid, potassium sorbate, sodium benzoate, ceratonia siliqua (carob) gum, and calcium

chloride. BioNourish is packaged in 2 fl. oz plastic tubes. The device is packaged with a low-density polyethylene (LDPE) applicator. BioNourish lubricant is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in Table 1 below.

Table 1: Subject Device Specifications

Property	**Specification**
Appearance	Clear and transparent
Odor	Characteristic
Viscosity	5,000 – 28,000 cps
Osmolality	250 – 400 mOsm/kg
pH at 25 °C	3.8-4.2
Total Aerobic Microbial Count (USP <61>)	<100 cfu/g
Total Yeast & Mold Count (USP <61>)	<10 cfu/g
Absence of Pathogenic Organisms (USP <62>)	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli, Salmonella, Clostridium Species	Absent
Antimicrobial Effectiveness (USP<51>)	Not less than a >2.0 log reduction from initial count at 14 days and no increase from the 14-day count at 28 days for bacteria and no increase from the initial calculated count at 14 and 28 days for yeasts/molds.

Indications for Use Statement: BioNourish 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.

Predicate Device Comparison

Table 2. Technological Characteristics of BioNourish as Compared to the Predicate

	K193448	**K094039**	**Comparison**
	Subject Device	**Predicate**	
Sponsor	BioNourish Lubricant	Hyalo Gyn Personal Lubricant	-
Regulation Number Product Code Device Class	844.5300 NUC II	844.5300 NUC II	-
Indications for Use	BioNourish 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.	Hyalo gyn is a personal lubricant for penile and /or vaginal application intended to moisture and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubricant. This product is compatible with condoms; lubricated/nonlubricated latex, lubricated polyurethane, lubricated natural skin.	Similar
Physical	Clear liquid	Clear liquid	Same
Water-based	Yes	Yes	Same
Primary Ingredients	Water, Hydroxyethylcellulose, Hyaluronic Acid, Carrageenan, Sodium Chloride, Lactic Acid, Potassium Sorbate, Sodium Benzoate, Ceratonia Siliqua (Carob) Gum, Xanthan Gum, and Calcium Chloride	Water, Hydeal-D, Propylene Glycol, Carbomer, Methyl p-hydroxybenzoate, Propyl p-hydroxybenzoate, Sodium Hydroxide	Different: The subject and predicate devices have differences in ingredients. These differences do not raise different questions of safety and effectiveness (S&E).

pH	3.8-4.2	5.5-6.5	Different: The subject device has a lower pH than the predicate. This difference does not raise different questions of S&E.
Osmolality	250-400 mOsm/kg	Not known	Different: The osmolality of the predicate device is not known. This difference does not raise different questions of S&E. Additionally, the osmolality of the subject device is comparable to other cleared personal lubricant products.
Viscosity	5,000-28,000 cps	Not known	Different: The viscosity of the predicate device is not known. This difference does not raise different questions of S&E.
Sterile	No	No	Same
Condom Compatibility	Natural Rubber Latex and Polyisoprene	Natural Rubber Latex, Polyurethane, and Natural Skin Condoms	Different: The subject and predicate devices have differences in condom compatibility. This difference does not raise different questions of S&E.
Biocompatibility Tested	Yes	Yes	Same
Antimicrobial Tested	Yes	Yes	Same
Shelf-Life	One year	Three years	Different: This difference does not raise different questions of S&E.

The subject and predicate devices have similar indications for use statements and the same intended use (i.e., lubrication during intimate sexual activity). As noted in the table above, the subject and predicate device have different technological characteristics, including differences in formulations, specifications, condom compatibility and shelf-life. The differences in technological characteristics between the subject and predicate device do not

raise different questions of safety and effectiveness.

Summary of Performance Data

Biocompatibility: BioNourish Lubricant has undergone biocompatibility testing in accordance with the 2016 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 per ISO 10993-5: 2009
- Sensitization and Irritation testing using the human repeat insult patch testing, an alternative test method to ISO 10993-10:2010
- Acute systemic toxicity testing per ISO 10993-11:2017.

The testing demonstrate that BioNourish Lubricant is non-cytotoxic, non-sensitizing, non-irritating, and not acutely-systemically toxic.

Condom Compatibility: The compatibility of the subject device with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-10 "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: BioNourish Lubricant has a 1-year shelf life in accordance with the results of an accelerated aging stability study. Results from testing demonstrated that the device can 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 BioNourish Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence