January 14, 2021

Trophikos, LLC
% Paul E. Dryden
President
Trophikos, LLC c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K201922
Trade/Device Name: Trophikos Vaginal Moisturizer
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 11, 2020
Received: December 15, 2020

Dear Paul E. Dryden:

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,

For
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201922

Device Name
Trophikos Vaginal Moisturizer

Indications for Use *(Describe)*
Trophikos Vaginal Moisturizer is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms and 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

Date Prepared: January 12, 2021

Submission Sponsor:
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Terri Jackson Wade - CEO

Submission Correspondent:
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USA
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Trade Name: Trophikos Vaginal Moisturizer
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: NUC (lubricant, personal)
Regulatory Class: II

Predicate Device: Satisfaite
Manufacturer: FemmePharma Consumer Healthcare, LLC
510(k) Number: K190752

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

Device Description:
Trophikos Vaginal Moisturizer is a water-based, non-sterile personal lubricant, 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, glycerin, Simmondsia Chinensis (Jojoba) seed oil, cetyl alcohol, dimethicone, tetrahexyldecyl ascorbate, Leuconostoc/radish root ferment filtrate, sodium hyaluronate, palmitoyl tripeptide-5, acetyl tetrapeptide-2, hydrogenated lecithin, ubiquinone, tocopheryl acetate, caprylyl glycol, tocopherol, citric acid, potassium sorbate, squalane, glyceryl stearate, polyacrylate crosspolymer-6, and t-butyl alcohol. Trophikos Vaginal Moisturizer is packaged in 30 mL airless bottles made of styrene-acrylonitrile, with a piston made of polyethylene, and an aluminum base. Trophikos Vaginal Moisturizer is a personal lubricant with over-the-counter (OTC) use.

The device specifications are listed in **Table 1** below:

Table 1: Specifications for Trophikos Vaginal Moisturizer (Subject Device)

Parameter	**Specifications**	
Appearance	Gel Cream	
Odor	Characteristic	
Color	Off-White	
pH per USP<912>	3.8 – 4.6	
Viscosity per USP <912>	25,000 – 75,000 cP	
Osmolality per USP <785>	750 – 840 mOsm/kg	
Total Yeast and Mold Count (TYMC) per USP <61> and <1111>	≤ 10 cfu/g	
Total Aerobic Microbial Count (TAMC) per USP <61> and <1111>	≤ 100 cfu/g	
Absence of Pathogenic Organism per USP <62>	*E. coli*	Absent
	Salmonella	Absent
	C.albicans	Absent
	S. aureus	Absent
	P. aeruginosa	Absent
Antimicrobial Effectiveness per USP<51>	Bacteria: No less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count Yeast/Mold: No increase from the initial calculated count at 14 and 28 days.	

Indications for Use:
Trophikos Vaginal Moisturizer is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

Summary of Technological Characteristics of Subject Device in Comparison to Predicate:

Comparison of the technological features of the subject and predicate devices is provided in **Table 2** below:

Table 2: Technological Characteristics of Subject Device Compared to Predicate Device

	K190752 **Predicate Device**	**K201922** **Subject Device**
Device Name	**Satisfaite**	**Trophikos Vaginal Moisturizer**

Indication for Use	Satisfaite™ is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to supplement the body's natural lubrication, and to enhance the ease and comfort of intimate sexual activity. This product is compatible with natural rubber latex, and polyisoprene condoms; and is not compatible with polyurethane condoms.	Trophikos Vaginal Moisturizer is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and to supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.
Water-based	Yes	Yes
Primary Ingredients	Purified water, glycerin, propylene glycol, hydroxyethylcellulose, sodium hyaluronate, hydrochloric acid, methylparaben, vitamin E	Water (aqua), glycerin, Simmondsia Chinensis (Jojoba) seed oil, cetyl alcohol, dimethicone, tetrahexyldecyl ascorbate, sodium hyaluronate, palmitoyl tripeptide-5, acetyl tetrapeptide-2, hydrogenated lecithin, ubiquinone, tocopheryl acetate, caprylyl glycol, tocopherol, citric acid, potassium sorbate, squalane, glyceryl stearate, Leuconostoc/radish root ferment filtrate, polyacrylate crosspolymer-6, t-butyl alcohol
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.
Sterile	No	No
Antimicrobial Tested	Yes	Yes
Biocompatibility Tested	Yes	Yes
OTC use	Yes	Yes

The subject and predicate device have different technological characteristics including their formulation. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

Summary of Performance Testing:

Shelf Life: All device parameters listed in **Table 1** were tested and met the specifications across the shelf life duration.

Biocompatibility: The biocompatibility evaluations were conducted 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"*. The following biocompatibility testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Guinea Pig Maximization Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The above biocompatibility testing was performed, and the results provided are adequate to support the conclusion that the subject device is biocompatible.

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". The results of the testing indicate that the subject device is compatible with natural rubber latex and polyisoprene condoms. The subject device is not compatible with polyurethane condoms.

Substantial Equivalence Conclusion: The results of the performance testing described above demonstrate that Trophikos Vaginal Moisturizer is as safe and effective as the predicate device and supports a determination of substantial equivalence.