November 21, 2018

Trigg Laboratories DBA Wet International
% Louie Goryoka
Regulatory & Quality Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K182027
Trade/Device Name: Wet Organics Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 23, 2018
Received: October 25, 2018

Dear Louie Goryoka:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Sharon M. Andrews -S

for
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)*
K182027

Device Name
Wet Organics Personal Lubricant

Indications for Use *(Describe)*
The Wet Organics Personal 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. The 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.

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510(K) SUMMARY
K182027
Wet Organics Personal Lubricant

Company Name: Trigg Laboratories DBA Wet International

Company Address: 4220 W Windmill Lane, Suite 140
Las Vegas, NV 89139

Contact Number: Phone: (702) 957-4400
Email: mdci@m-dci.us

Contact Person: Louie Goryoka – Regulatory & Quality Consultant
Med-Device Consulting, Inc.
Phone: (818) 735-0488
Email: mdci@m-dci.us

Summary Preparation Date: November 21, 2018

Device Trade Name:	Wet Organics Personal Lubricant
Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR §884.5300
Product Code:	NUC (lubricant, personal)
Device Class:	Class II

Predicate Devices:	Aloe Cadabra Personal Lubricant
510(k) Number:	K124044
Manufacturer:	Seven Oaks Ranch, Inc.
Product Code:	NUC
Device Class:	Class II

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

Device Description

The Wet Organics Personal Lubricant is a non-sterile, water-based, over-the-counter personal lubricant. The proposed device contains a blend of organic aloe and other ingredients similar to ingredients found in the predicate device.

The device is designed to supplement the body's own natural lubrication fluids during intimate sexual activity. The device is also compatible for use with natural rubber latex and polyisoprene condoms. The device is neither a contraceptive nor a spermicide.

The Wet Organics Personal Lubricant is packaged in 3 oz. polyethylene terephthalate bottle with a dispensing bottle cap with a disc top.

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K182027
Wet Organics Personal Lubricant

The device specifications are listed in the table below:

Table 1: Device Specifications for Wet Organics Personal Lubricant

Property	Specification
Appearance	Clear to slightly cloudy, semi-viscous, particle-free liquid
Color	brown
Odor	Odorless (Characteristic)
Viscosity@25°C Spindle LV#3hu@10rpm (cps)	1,000 cps – 2,300 cps
Specific Gravity@25°C	0.95 - 1.05
pH	4.0 to 5.0
Osmolality	<1,800 mOSm
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Absence of Pathogens per USP <62>	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
E. Coli	Absent
Salmonella	Absent
Candida albicans	Absent

Indications for Use

The Wet Organics Personal 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. The product is compatible with natural rubber latex and Polyisoprene condoms. This product is not compatible with Polyurethane condoms.

Predicate Device Comparison

The table below lists the comparative intended use and technological characteristics of the subject and predicate device.

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K182027
Wet Organics Personal Lubricant

Table 2: Comparator Table for Subject Device –Wet Organics Personal Lubricant and Predicate Device Aloe Cadabra Personal Lubricant.

Characteristic/Feature	Wet Organics Personal Lubricant	Aloe Cadabra Personal Lubricant (k) number K124044
Indications for Use	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. The product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms	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.
Primary Ingredients	Purified Water Organic aloe barbadensis leaf juice Zemea Select Propanediol Vegeluron Gel Cellosize QP-30000-H Xanthan Gum Sodium Hyaluronate Microcare SB Citric Acid Co Extract Blend	Organic aloe vera Xanthan Gum Citric Acid Potassium Sorbate Sodium Benzoate
Over-the-Counter Use	Yes	Yes
Condom compatibility	Natural rubber latex and polyisoprene	Natural rubber latex and polyisoprene
Sterile	No	No
Shelf life	12 months	3 years

510(K) SUMMARY
K182027
Wet Organics Personal Lubricant

The subject and predicate device have the same intended use - for penile 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.

The Wet Organics Personal Lubricant contains similar ingredients to other cleared lubricants, including the predicate device. However, the subject and predicate device have slightly different formulations, different specifications and different shelf life. These differences do not raise different types of safety and effectiveness questions.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies were performed 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" and ISO 10993-1:2009 as follows:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Vaginal Irritation per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2006

The results of testing demonstrated the subject device is not cytotoxic, not sensitizing, not irritating and is not acutely systemically toxic.

Condom Compatibility
Condom compatibility testing was performed per ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" on three marketed brands of natural rubber latex condoms, one brand of polyisoprene condoms, and one brand of polyurethane condoms. The results demonstrated that the Wet Organics Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. The results also demonstrated that the product is not compatible with polyurethane condoms.

Shelf Life Testing
The results of real time studies demonstrated that the Wet Organics Personal Lubricant is shown to have a 12 months shelf-life and met the device specifications as listed in Table 1 of this 510(k) Summary.

Conclusion

The Wet Organics Personal Lubricant has the same intended use as the predicate device. In addition, the Wet Organics Personal Lubricant has similar technological characteristics as compared to the predicate device. Differences in technological characteristics between the subject and predicate device did not raise different questions of safety and effectiveness. Performance testing conducted on the Wet Organics Personal Lubricant demonstrated that it was as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.