June 23, 2023

MD Labs, LLC
% Louie Goryoka
Sr. RA/QA Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K230518
Trade/Device Name: HydraDose Vaginal Suppositories
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 19, 2023
Received: May 22, 2023

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/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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230518

Device Name
HydraDose Vaginal Suppositories

Indications for Use *(Describe)*
HydraDose Vaginal Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene 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 – K230518
HydraDose Vaginal Suppositories

I. General Information on Submitter

Applicant:	MD Labs LLC
Address:	780 Lakefield Road, Suite H Westlake Village, California, 91361-2628
Telephone:	818-585-7488
Contact Person:	Louie Goryoka
Contact Title:	Sr. Regulatory and Quality Consultant Med-Device Consulting, Inc
Email:	mdci@m-dci.us
Date Prepared:	June 21, 2023

II. General Information on Device

Proprietary Name:	HydraDose Vaginal Suppositories
Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Regulatory Class:	II
Product Code:	NUC (Lubricant, Personal)

III. Predicate Device

Predicate Device	510(k) Number
Revaree Plus Vaginal Suppositories	K213220

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

IV. Description of Device

HydraDose Vaginal Suppositories is a glyceride-based personal lubricant for over-the-counter use. The subject device is a non-sterile solid preparation containing hyaluronic acid, cocoa butter, triglycerides, and cera alba.

The subject device is packaged in sets of five a polyvinyl chloride (PVC)/polyethylene (PE) blister pack. The lubricant is not compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms.

The specifications for HydraDose Vaginal Suppositories are described in **Table 1.**

Table 1. Device Specifications

Parameter	Test Method	Specification
Appearance	Visual	Solid; yellowish to white color
Odor	Olfactory	None
pH	N/A	N/A
Viscosity	N/A	N/A
Osmolality	N/A	N/A
Antimicrobial Effectiveness	USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Total Microbial Count	USP <61> and <1111>	<100 cfu/g
Fungal/Yeast/Mold Limits	USP <61> and <1111>	<10 cfu/g
Absence of Pathogenic Organisms (*Staphylococcus Aureus, Pseudomonas Aeruginosa, Candida Albicans*)	USP <62>	Absent
Content of hyaluronic acid	Spectrophotometric	0.25 - 2%
Disintegration time	USP <701> and <2040>	12 minutes 21 seconds; 37.5°C
Average weight	Analytical balance	2g

V. Indications for Use

HydraDose Vaginal Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

VI. Substantial Equivalence Discussion

A comparison of the intended use and technological features of the subject and predicate devices is provided in Table 2 below:

Table 2. Intended Use and Technological Characteristics of Subject Device Compared to Predicate Device

Characteristic / Feature	HydraDose Vaginal Suppositories (subject device)	Revaree Plus Vaginal Suppositories (predicate device) – K213220	Comparison
Indication for use	HydraDose Vaginal Suppositories are a personal lubricant, for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Revaree plus vaginal suppositories are a personal lubricant for 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 not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Same
Percentage of Hyaluronic Acid	0.25-2%	0.5%	Different
Over the Counter	Yes	Yes	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Hyaluronic acid, cocoa butter, triglycerides, cera alba	Hyaluronic acid, glycerides, sweet almond oil	Different: The ingredients of the predicate device are different; the ingredients do not raise different questions of Safety & Effectiveness (S & E)
Microbial Limits	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Same
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms	Not compatible with natural rubber latex, polyisoprene condoms, and polyurethane condoms	Same

The subject and predicate devices have identical indications for use and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations and device specifications. The different technological characteristics do not raise different types of safety and effectiveness questions.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the subject lubricant was performed in accordance with the 2020 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 (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Shelf Life

The subject device is a non-sterile personal lubricant weighing 2g and packaged in blister packs with an 8.5-month shelf-life in accordance with the results of an accelerated aging study, conducted for 3 months at 40°C per ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*. The device specifications listed in **Table 1** were tested across the device shelf-life and the subject device met the specifications at all time points.

Condom Compatibility

Condom compatibility testing was not conducted for the subject device. Therefore, HydraDose Vaginal Suppositories is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms

VIII. Conclusion

The results of the testing described above demonstrate that HydraDose Vaginal Suppositories are as safe and effective as the predicate device and supports a determination of substantial equivalence.