June 21, 2022

Farma-Derma S.R.L.
Mara Calzolari
Business Development Manager
Via Dell'artigiano 6-8
Sala Bolognese, Bologna 40010
Italy

Re: K213220
Trade/Device Name: Revaree plus vaginal suppositories
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 11, 2022
Received: May 16, 2022

Dear Mara Calzolari:

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, 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)*
K213220

Device Name
Revaree plus vaginal suppositories

Indications for Use *(Describe)*
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.

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 for Revaree plus vaginal suppositories

K213220

1. General Information

Submitter: FARMA-DERMA S.r.l.
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Preparation Date: June 21, 2022

2. Device Information

Trade Name:	Revaree plus vaginal suppositories
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	II
Product Code:	NUC (lubricant, personal)

3. Predicate Device

Repagyn vaginal suppositories (K153372)

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

4. Device Description

Farma-Derma's Revaree plus vaginal suppositories is a non-sterile solid preparation personal lubricant containing hyaluronic acid, sweet almond oil, and glycerides. It is presented in the form of vaginal suppositories, 2 g in weight. Each vaginal suppository is individually packed in a polyvinyl chloride (PVC)/polyethylene (PE) blister. The device is available for sale in a pack containing 10 vaginal suppositories (two blisters of 5 vaginal suppositories each) while the sample pack contains 3 vaginal suppositories (one blister).

Due to its shape the device can be easily introduced into the vaginal cavity by finger.

When the vaginal suppository is in contact with the vaginal mucosa, it melts due to body temperature and becomes a viscous mass which remains in contact with the vaginal mucosa, creating a moist environment to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

The specifications for Revaree plus vaginal suppositories are provided in the table below.

Parameter	Specification
Appearance	Off-white opaque vaginal suppositories
Odor	Practically odorless
Disintegration time	≤ 30 minutes (according to Eu. Ph.)
Average weight	2 g
Uniformity of weight	According to Eu. Ph.
Content of HA	10 mg
TAMC	≤100 cfu/g
TYMC	≤10 cfu//g
Pseudomonas Aeruginosa, Staphylococcus Aureus, Candida Albicans	Absent/g

Furthermore, the endotoxin level will be checked according to Kinetic test (LAL test) on each lot of finished product.

5. Indications for Use

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.

6. Substantial Equivalence Discussion

The following table compares the intended use and key technological characteristics of the subject and predicate device.

	Revaree plus vaginal suppositories	**Repagyn vaginal suppositories (K153372)**
Indications for Use	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.	Repagyn is 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.
Base type	Glyceride	Glyceride
Ingredients	HA, glycerides, and sweet almond oil	HA and glycerides
Appearance	Off-white opaque vaginal suppositories	Off-white opaque vaginal suppositories
Average weight	2 g	2 g
Content of HA	10 mg	5 mg
TAMC	≤100 cfu/g	≤100 UFC/g
TYMC	≤10 cfu/g	≤10 UFC/g
Absence of *Pseudomonas Aeruginosa, Staphylococcus Aureus,*	Absent/g	Absent/g

Candida Albicans		
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms
Packaging	PVC/PE blister of 3 or 5 vaginal suppositories	PVC/PE blister of 3 or 5 vaginal suppositories

The subject and the predicate device have similar 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, include different formulations and device specifications. The different technological characteristics do not raise different questions of safety and effectiveness.

7. Performance Data

Biocompatibility

Biocompatibility studies including cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity were 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 10993-1:2018, as follows:

- Acute systemic toxicity, ISO 10993-11:2017
- Cytotoxicity, ISO 10993-5:2009
- Vaginal Irritation Testing, ISO 10993-10:2010
- Guinea pig maximization test (GPMT), ISO 10993-10:2010

The results demonstrated that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing and not systemically toxic.

Shelf Life

The shelf life of Revaree plus vaginal suppositories is 24 months. This is based on the results of intermediate and real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life.

Condom Compatibility

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

8. Conclusions

The results of the testing described above demonstrate that Revaree plus vaginal suppositories are as safe and effective as the predicate device and supports a determination of substantial equivalence.