September 2, 2021

Viramal Limited
℅ Joshua Crist, M.S.E.
Senior Consultant
Biologics Consulting Group, Inc
1555 King Street, Suite 300
Alexandria, VA 22314

Re: K201612
Trade/Device Name: Elegant™ 2 in 1 Vaginal Moisturizer, Elegant™ Advanced 5
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 5, 2021
Received: August 6, 2021

Dear Joshua Crist:

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 and Part 809); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201612

Device Name
Elegant™ 2 in 1 Vaginal Moisturizer, Elegant™ Advanced 5

Indications for Use *(Describe)*

Elegant™ 2 in 1 Vaginal Moisturizer/ Elegant™ Advanced 5 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 compatible with polyurethane condoms. This product is not compatible with natural rubber latex 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 – K201612

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.87(h) and 21 CFR § 807.92.

Submitter: Viramal Limited
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Date Prepared: September 1, 2021

Device Proprietary Names: Elegant™ 2 in 1 Vaginal Moisturizer
Elegant™ Advanced 5
Device Common Name: Personal Lubricant
Regulation Name: Condom
Regulation Number: 21 CFR. 884.5300
Regulatory Class: II
Product Code: NUC (lubricant, personal)

Predicate Device: K101098, Replens Long-Lasting Vaginal Moisturizer (Church & Dwight Co., Inc.)

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

5.1. Description of Device:
Elegant™ 2 in 1 Vaginal Moisturizer and Elegant™ Advanced 5:

The subject device is a non-sterile, water-based, personal lubricant that provides lubrication during intimate sexual activity.

The formulation contains purified water, polycarbophil, carbomer homopolymer type B, labrafac, emulfree P, sorbic acid and sodium hydroxide. The quantitative formulation is considered confidential commercial information.

Elegant™ 2 in 1 Vaginal Moisturizer is packaged in an aluminium tube and applied using a reusable plastic applicator marked to deliver 2ml of product.

Elegant™ Advanced 5, is packaged in an aluminium tube and applied using a reusable plastic applicator marked to deliver 3ml of product.

Elegant™ 2 in 1 Vaginal Moisturizer and Elegant™ Advanced 5 are personal lubricants for over-the-counter (OTC) use.

The device specifications are listed in Table 1 below:

Table 1 Device Specifications for Elegant™ 2 in 1 Vaginal Moisturizer and Elegant™ Advanced 5

Parameter	Specification (Test Method)
Appearance	White to off-white
Density USP <699>	0.9970 - 0.9995 g/cm^2
pH USP <791>	2.5-3.5
Consistency Ph.Eur 2.9.9	145 – 200 mm
Viscosity USP <912>	120 – 220 Pa-s
Osmolality USP <785>	15 – 35 mOsm/kg
Total Aerobic Microbial Count (TAMC) USP <61>	≤ 10^2 CFU/g
Total combined yeasts/molds count (TYMC) USP <61>	≤ 10^1 CFU/g
Absence of pathogenic organisms: *Staphylococcus Aureus, Pseudomonas Aeruginosa and Candida Albicans* USP <62>	Absent
Antimicrobial Effectiveness 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 day

5.2. Indications for Use:

Elegant™ 2 in 1 Vaginal Moisturizer/ Elegant™ Advanced 5 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 compatible with polyurethane condoms. This product is not compatible with natural rubber latex and polyisoprene condoms.

5.3. Comparison of the Intended Use and Technological Characteristics of the Subject and Predicate Device:

Table 2 below details a comparison of intended use and technological characteristics of the subject device configurations and the predicate device.

Table 2 Comparison of Intended Use and Technological Characteristics

Product Feature	Elegant™ Device Configurations (K201612)		Predicate Device (K101098)	Comparison
Device Name	Device Configuration 1: Elegant™ 2 in 1 Vaginal Moisturizer	Device Configuration 2: Elegant™ Advanced 5	Replens Long-Lasting Vaginal Moisturizer	-

Product Feature	Elegant™ Device Configurations (K201612)		Predicate Device (K101098)	Comparison
Manufacturer	Viramal Limited		Church & Dwight Co., Inc.	-
Classification	884.5300		884.5300	-
Product code	NUC		NUC	-
Description	Personal lubricant		Personal lubricant	No difference.
Over-the-counter Use	Yes		Yes	No difference.
Indications for Use	Elegant™ 2 in 1 Vaginal Moisturizer/ Elegant™ Advanced 5: 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 compatible with polyurethane condoms.		Replens 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 compatible with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.	Difference: The indication for use statements differ regarding condom compatibility, however this difference does not represent a new intended use.
Site of application	For vaginal use only.		Replens is a personal lubricant for vaginal application.	No differences.
Biocompatible	Yes		Yes	No difference.
Non-sterile	Yes		Yes	No difference.
Condom Compatible (labelled)	Yes Compatible with polyurethane condoms.		Yes Compatible with natural rubber latex, polyurethane and polyisoprene condoms.	Different: The condom compatibility for the subject and predicate devices are different. However, this difference does not represent a new intended use.
Shelf Life	17 months		36 months	Different
Delivery	Applicator	Applicator	Applicator	No difference.
Applied Amount	Device Configuration 1: 2g	Device Configuration 2: 3g	2.5g	Difference: The difference in applied amount does not raise different questions of safety and effectiveness and does not present a new intended use.

The indications for use for the subject device and the predicate device are similar, and the intended use of the subject and predicate device is the same (i.e., provides lubrication during intimate sexual activity). The subject device is compatible with polyurethane condoms, whereas the predicate device is compatible with natural rubber latex, polyurethane and polyisoprene condoms. This difference in condom compatibility does not raise different questions of safety and effectiveness.

As noted in Table 2, the subject device and the predicate device have similar technological characteristics. The differences identified in Table 2 do not raise different questions of safety and effectiveness.

5.4. Summary of Performance Data:

Biocompatibility Testing

- Biocompatibility studies 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- 1:2009 as follows: Cytotoxicity (ISO 10993-5:2009)
- Intra-vaginal tolerance with histological examination (ISO 10993-10:2010)
- Penile irritation (ISO 10993-10:2010)
- Sensitisation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that Elegant™ 2 in 1 Vaginal Moisturizer and Elegant™ Advanced 5 are non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

Shelf-life testing has been conducted in accordance with ICH Guideline Q1A (R2) - "Stability Testing of new Drug Substances and Products". Long term data at 25°C/60% RH and accelerated data at 35°C/65% RH for the specifications identified in Table 1 have been generated up to 6 months, for an equivalent of a 12 month shelf life.

Taken together, results from shelf life testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of a 12 month shelf life.

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 polyurethane condoms. The subject device is not compatible with natural rubber latex and polyisoprene condoms.

5.5. Conclusion:

The results of the performance testing described above demonstrate that Elegant™ 2 in 1 Vaginal Moisturizer/ Elegant™ Advanced 5 is as safe and effective as the predicate device and supports a determination of substantial equivalence.