December 22, 2023

Viramal Limited
% Joshua Crist
Senior Consultant
Biologics Consulting Group, Inc.
100 Dangerfield Road, Suite 400
Alexandria, VA 22314

Re: K231794
Trade/Device Name: Elegant™ Advanced CompHort
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 27, 2023
Received: September 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,
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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)*
K231794

Device Name

Elegant™ Advanced CompHort

Indications for Use *(Describe)*

Elegant™ Advanced CompHort 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 – K231794

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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Contact Person: Simona Fiore, MD, OBGYN, MSC, PhD
Chief Medical Officer
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Date Prepared: December 19, 2023

Device Proprietary Names: Elegant™ Advanced CompHort
Device Common Name: Personal Lubricant
Regulation Name: Condom
Regulation Number: 21 CFR 884.5300
Regulatory Class: II
Product Code: NUC (Lubricant, Personal)

Predicate Device to Which Substantial Equivalence is Claimed:
K201612, Elegant™ Advanced 5

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

Description of Device:

Elegant™ Advanced CompHort is a line extension to the "Elegant™" range to extend claims.

It is a non-sterile, water-based, pearly white, non-irritating, non-greasy, hormone-free, paraben-free, fragrance-free, moisturizing creams for vaginal dryness. It is a personal lubricant that provides lubrication, and it is intended for ongoing use and is not exclusively for use during intimate sexual activity.

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

Elegant™ Advanced CompHort is to be sold as an over-the-counter (OTC) product.

The device specifications are listed in Table 1:

Table 1. Device Specifications for Elegant™ Advanced CompHort

Parameter	Test Method	Specification
Appearance	Visual inspection	White to off-white
Density (g/cm^3)	Ph. Eur 2.2.5; USP <699>	0.9970 - 0.9995
pH	USP <791>	2.5-3.5
Consistency (1/10mm)	Ph. Eur 2.9.9	145 - 200
Viscosity (Pa.s)	USP <912>	120 - 220
Osmolality (mOsm/kg)	USP <785>	15-35
Total Aerobic Microbial Count (TAMC)	USP <61>	$\leq 10^2$ CFU/g
Total combined yeasts/molds count (TYMC)	USP <61>	$\leq 10^1$ CFU/g
Absence of pathogenic organisms: *Staphylococcus Aureus, Pseudomonas Aeruginosa, and Candida Albicans*	USP <62>	Absent
Antimicrobial Effectiveness Test	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

Indications for Use:

Elegant™ Advanced CompHort 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.

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

All of the technological characteristics of the subject device are identical to the legally marketed predicate device with respect to design and materials, principle of operation, function, formulation, and intended use.

The ingredients of the subject device are identical to the predicate device Elegant™ Advanced 5 (K201612).

The labeling of the subject device compared to the predicate has been updated with additional claims.

- Compatible with Vaginal pH
- Natural Feeling
- pH Balanced Formulation

- Gynecologist Clinically Tested

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

Table 2. Comparison of Intended Use and Technological Characteristics

Product Feature	Subject Device K231794	Predicate Device K201612	Comparison
Device Name	Elegant™ Advanced CompHort	Elegant™ Advanced 5	-
Manufacturer	Viramal Limited	Viramal Limited	-
Base Type	Water	Water	Same
Over-the-counter Use	Yes	Yes	Same
Indications for Use	Elegant™ Advanced CompHort 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.	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.	Same: The indications for use for the subject and predicate device are the same. Therefore, the subject and predicate device have the same intended use.
Ingredients	Purified water, Polycarbophil, Carbomer Homopolymer Type B, Labrafac, Emulfree Duo, Sorbic Acid and Sodium Hydroxide.	Purified water, Polycarbophil, Carbomer Homopolymer Type B, Labrafac, Emulfree Duo, Sorbic Acid and Sodium Hydroxide.	Same
Packaging Material	Aluminium	Aluminium	Same
Color	White to Off-white	White to Off-white	Same
pH	2.5 - 3.5	2.5 - 3.5	Same
Osmolality (mOsm/kg)	15-35	15-35	Same
Viscosity (Pa.s)	120 - 220	120 - 220	Same
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
Antimicrobial effectiveness (per USP <51>)	Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days	Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days	Same

Product Feature	Subject Device K231794	Predicate Device K201612	Comparison
Biocompatible	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Condom Compatibility	Compatible with polyurethane condoms.	Compatible with polyurethane condoms.	Same
Delivery	Applicator	Applicator	Same
Applied Amount	3g	3g	Same
Claims	Relief from vaginal dryness and discomfort Compatible with vaginal pH Natural Feeling pH Balanced Formulation Gynecologist Clinically Tested	Relief from vaginal dryness and discomfort	**Different:** The subject and predicate device have different labeling claims. Differences in labeling claims do not raise different questions of S&E.
Shelf-Life	24 months	17 months	**Different:** The subject and predicate device have different shelf-life durations. Differences in shelf-life durations do not raise different questions of S&E.

The indications for use and the intended use of the subject and predicate device are the same (i.e., provides lubrication during intimate sexual activity). The subject device has a 24-month shelf-life, whereas the predicate device has a 17-months shelf-life. The subject device has additional labeling claims. The differences in shelf-life and labeling claims do 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 of effectiveness.

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'." The following biological evaluation tests have been conducted to assess the biocompatibility of the subject device:

- Cytotoxicity per ISO 10993-5
- Vaginal Irritation per ISO 10993-10
- Sensitization per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11:2017

The subject device was also clinically tested in women and no adverse events were reported. The results of this testing demonstrate that Elegant™ Advanced CompHort are non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

Shelf-life testing has been conducted at 25°C/60% RH and data for the specifications identified in Table 1 have been generated up to 24 months. Results from shelf-life testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of a 24-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.

Conclusion:

The results of the performance testing described above demonstrate Elegant™ Advanced CompHort for OTC use, is safe and effective for the proposed indications and substantially equivalent to the predicate device in regard to intended use, formulation, safety and fundamental technological characteristics. Any minor differences in formulation, technological characteristics or condom compatibility do not raise any new issues regarding safety or efficacy.