December 4, 2020

Dr. August Wolff GmbH & Co. KG Arzneimittel
% Oliver Eikenberg, Ph.D.
Senior Consultant QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K193444
Trade/Device Name: Vagisan MoistCream Cremolum
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: October 30, 2019
Received: November 6, 2019

Dear Oliver Eikenberg:

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,

For
Monica D. Garcia, Ph.D.
Acting 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)*
K193444

Device Name
Vagisan MoistCream Cremolum

Indications for Use *(Describe)*
Vagisan MoistCream Cremolum is a personal lubricant, a suppository 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 condoms and synthetic (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 – K193444

1. Submitter Information

Applicant: Dr. August Wolff GmbH & Co. KG Arzneimittel
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2. Correspondent Information

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3. Date prepared: December 3, 2020

4. Device Information

Device Name:	Vagisan MoistCream Cremolum
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (lubricant, personal)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Vagisan Moisturizing Cream
510(k) Number:	K152507
Manufacturer:	Dr. August Wolff GmbH & Co. KG Arzneimittel
Product Code:	NUC (lubricant, personal)

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

6. Device Description

The Vagisan MoistCream Cremolum is a ready-to-use, non-sterile, glycerin-based personal lubricant suppository for intravaginal application that melts after digital insertion to form a smooth cream. The device is intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

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Vagisan MoistCream Cremolum consists of hydrogenated coco-glycerides, cetearyl alcohol, lactic acid, calcium lactate, PEG-20 glyceryl stearate, and sodium carbomer. Each vaginal suppository is individually packaged in a foil blister pack, which are sold in boxes of eight or 16 vaginal suppositories.

The device specifications for Vagisan MoistCream Cremolum are listed in the table below:

Table 1: Device Specifications for Vagisan MoistCream Cremolum

Property	**Specification**
Appearance	Smooth surface, no cracks, torpedo shaped suppository
Color	White
pH	4.0-5.0
Osmolality	600 - 1200 mOsm/kg (1:1 Dilution)
Average Mass per Ph. Eur. 2.9.5	1960-2040 mg
Uniformity of Mass per Ph. Eur. 2.9.5	≥18/20 inside ø ± 5 % 20/20 inside ø ± 10 %
Disintegration Time per Ph. Eur. 2.9.2	≤30 minutes
Particle Size	100% ≤150 µm
Total aerobic microbial count (TAMC) per USP <61> and <1111>	≤ 100 CFU/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	≤ 10 CFU/g
Presence of Pathogens per USP <62>	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent

7. Indications for Use

Vagisan MoistCream Cremolum is a personal lubricant, a suppository 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 condoms and synthetic (polyurethane and polyisoprene) condoms.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

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

Table 2: Comparator Table for Subject and Predicate Devices

	Vagisan MoistCream Cremolum K193444 Subject Device	**Vagisan Moisturizing Cream K152507 Predicate Device**	**Comparison**
Device Classification Name	Lubricant, Personal	Lubricant, Personal	**Same**

Product Code	NUC	NUC	**Same**
Indications for Use	Vagisan MoistCream Cremolum is a personal lubricant, a suppository 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 condoms and synthetic (polyurethane and polyisoprene) condoms.	Vagisan Moisturizing Cream 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 condoms and synthetic (polyurethane and polyisoprene) condoms.	**Same:** The indications have a minor difference in wording; however, the intended uses of both devices are the same
Form	Vaginal suppository	Cream	**Different:** The subject and predicate devices are provided in different forms. Differences in form do not raise different questions of safety and effectiveness (S&E)
Water soluble	Yes	Yes	**Same**
Water-Based	No	Yes	**Different:** The base type of the subject and predicate devices is not the same. Differences in personal lubricant base type do not raise different questions of S&E
Primary ingredients	Hydrogenated coco-glycerides Lactic acid Calcium acetate Cetearyl alcohol PEG-20 glyceryl stearate Sodium carbomer	Cetyl palmitate Lactic acid Sodium lactate Cetyl steraryl alcohol Sorbitan stearate Polysorbate 60 Octyldecanol Benzyl alcohol Water	**Different:** The primary ingredients of the subject and predicate devices are not the same. Differences in personal lubricant base type do not raise different questions of S&E
Over the counter use	Yes	Yes	**Same**
Sterile	No	No	**Same**
pH	4.0-5.0	4.0-5.0	**Same**
Osmolality	600 – 1200 mOsm/kg (1:1 Dilution factor)	374 mOsm/kg	**Different:** The osmolality of the subject device is higher than the predicate device. Differences in personal lubricant osmolality do not raise different questions of S&E
Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, or polyurethane condoms	Not compatible with natural rubber latex, polyisoprene, or polyurethane condoms	**Same**
Biocompatibility Tested	Yes	Yes	**Same**
Antimicrobial Effectiveness Tested	No	Yes	**Different:** The subject device was not assessed for

			this parameter as it is not a water-based device. This difference does not raise different questions of S&E.
Microbial Limits	Total mold/yeast count ≤ 10 cfu/g Total aerobic microbial count ≤ 100 cfu/g Absence of pathogenic organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g Absence of pathogenic organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	**Same:**
Packaging	Foil blister pack	Aluminum tubes and sachets	**Different:** The packaging forms are not the same between the subject and predicate device. Differences in packaging do not raise different questions of S&E
Shelf life	3 years	2 years	**Different:** The subject device has a longer shelf-life than the predicate device. Differences in shelf-life do not raise different questions of S&E.

The subject and predicate device indications for use have a minor difference in wording; however, the intended use of the subject and predicate devices is the same (i.e., provides lubrication during intimate sexual activity).

In addition, the subject and predicate devices have different technological characteristics as shown in the table above. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing 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 (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrated that the Vagisan MoistCream Cremolum is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

The subject device has a shelf-life of 36-months. Results from testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

Condom compatibility testing was not conducted on the subject device, Therefore, the subject device is considered not compatible with natural rubber latex, polyisoprene or polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that the Vagisan MoistCream Cremolum is as safe and effective as the predicate device and supports a determination of substantial equivalence.