DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 20, 2016

Dr. August Wolff Gmbh & Co. Kg Arzeimittel
% Alan Curtis
Regulatory Affairs Consultant
AEC Medical Device Consulting LLC
8300 E. Dixileta Drive 285
Scottsdale, AZ 85266

Re: K152507
Trade/Device Name: Vagisan® Moisturizing Cream
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: April 15, 2016
Received: April 18, 2016

Dear Alan Curtis,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152507

Device Name
Vagisan® Moisturizing Cream

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Prepared August 31, 2015)

REGULATORY AUTHORITY
This 510(k) Summary is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME
Dr. August Wolff GmbH & Co. KG Arzneimittel
Sudbrackstrasse 56
33611 Bielefeld, Germany

Contact Person:
Alan Curtis, RAC
Scottsdale, AZ

NAME OF DEVICE

Trade Name:	Vagisan® Moisturizing Cream
Common Name:	Personal Lubricant
Device Product Code:	NUC
Classification Name:	Condom (21 CFR 884.5300)
Device Panel:	Obstetrical and Gynecological Devices
Device Classification:	Class II

PREDICATE DEVICE
- Replens® Vaginal Moisturizer (K101098)

DEVICE DESCRIPTION
Vagisan Moisturizing Cream is a non-sterile, water-based, white, non-irritating, non-greasy, non-staining vaginal cream delivered in a tube with a reusable applicator or sachet (sample size) as a long-lasting moisturizer for vaginal dryness.

The quantitative formulation is considered confidential commercial information.

The specifications for the subject device include appearance, odor, pH, viscosity, osmolality, antimicrobial effectiveness, total microbial count, fungal/yeast/mold limits, and absence of pathogenic organisms.

INDICATION FOR USE STATEMENT

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.

SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison to Predicate Devices

The predicate device (K101098) has the same intended use as the subject device. The subject and predicate devices are water-based lubricants with similar primary ingredients. However, since the formulations of the subject and predicate devices are not identical, the devices do not have the same technological characteristics. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

PERFORMANCE DATA

Results of pre-clinical and clinical evaluations were used to demonstrate that Vagisan Moisturizing Cream is substantially equivalent to the predicate device and meets safety, and effectiveness criteria.

Biocompatibility Testing: The results of three clinical studies conducted on the subject lubricant, cytotoxicity testing, and a toxicological risk assessment were used to demonstrate the biocompatibility of the subject lubricant. The following clinical studies were conducted on the subject lubricant and applicator:

- Human repeat insult patch test (HRIPT) was conducted on 106 human subjects. The study consisted of a 14 day induction phase followed by a 7 day rest period before a 48 hour challenge phase for delayed hypersensitivity. Visual assessments of the treatment site were conducted on six days during the induction phase and following the challenge phase. 104 of 106 (98%) subjects did not show any signs or symptoms of cutaneous irritation. The HRIPT results demonstrated that the subject device is non-irritating and non-sensitizing.
- A prospective, multicenter, controlled, randomized study was conducted on 117 human subjects in whom the subject lubricant was compared to a previously cleared lubricant. The subjects were given either the subject lubricant or control lubricant for a 28 day therapy period followed by a 14 day rest period before

another 28 day therapy period with the second lubricant. Vaginal examinations were conducted on days 1 and 29 of both therapy periods for a total of four assessments per subject. The subjects also recorded self-assessed symptoms daily in a patient diary. The subject lubricant tolerability was assessed as very good or good by 93% of study subjects and 100% of physicians. The results demonstrated the subject lubricant is non-irritating and non-sensitizing.

- A prospective, non-randomized, non-controlled study was also conducted on 117 human subjects undergoing breast cancer treatment. The study subjects were given the subject lubricant for a 28 day therapy period. Vaginal examinations were conducted on days 1 and 29 for each subject. The study subjects also self-reported symptoms in a patient diary. The subject lubricant tolerability was assessed as very good or good by 90% of study subjects and 91% of physicians. The results demonstrated good tolerability of the subject lubricant.

Cytotoxicity testing was also conducted on the subject lubricant in accordance with ISO 10993-5:2009. Although the results showed a concentration-dependent cytotoxic effect, this is not uncommon for lubricants tested neat (worse-case exposure conditions) and does not preclude clearance of a personal lubricant. The subject lubricant also performed better than several other previously cleared lubricants. Based on the results from the clinical studies, the in vitro cytotoxicity testing does not raise significant safety concerns.

A toxicological risk assessment was also performed on the subject lubricant based on the total amount of each ingredient to assess for systemic toxicity. The toxicological risk assessment demonstrated that the total amount of each ingredient in the lubricant is less than the tolerable exposure values obtained from a literature review.

Stability Testing: The results of a real time aging study demonstrate that the subject lubricant maintains its specifications over 24 months.

CONCLUSION

Vagisan Moisturizing Cream is substantially equivalent to the proposed predicate device.