DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 1, 2015

Fidia Farmaceutici Spa
% Vivian Kelly
US Agent/Regulatory Affairs Manager
Fidia Pharma Usa Inc
Morris Corporate Center 1, Building C, 300 Interpace Parkway
Parsippany, New Jersey 07054

Re: K150883
Trade/Device Name: HyaloGYN Vaginal Hydrating Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: August 4, 2015
Received: August 4, 2015

Dear Vivian Kelly:

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,

Joyce M. Whang -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)*

K150883

Device Name

HyaloGYN® Vaginal Hydrating Gel

Indications for Use *(Describe)*

HyaloGYN® 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 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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K150883

510(k) Summary

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

Applicant:	Fidia Farmaceutici, S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme (PD) - Italy
Contact Person:	Vivian Kelly, MS, RAC Regulatory Affairs Manager Phone: 973-577-6202 Fidia Pharma USA Inc. Morris Corporate Center 1, Building C 300 Interpace Parkway, Parsippany, New Jersey 07054
Date Prepared:	September 1, 2015

Device Information:

Proprietary Name:	HyaloGYN® Vaginal Hydrating Gel
Device Common Name	Vaginal Moisturizer
Device Classification Name:	Personal Lubricant
Regulation Number	21 CFR 884.5300
Regulation Name	Condom
Regulatory Class	II
Product Code	NUC (lubricant, personal)

Legally Marketed Predicate Device to Which Substantial Equivalence is Claimed:

- HyaloGYN® Vaginal Hydrating Gel, Fidia Farmaceutici, S.p.A. - K094039

Legally Marketed Reference Device Used to Support Substantial Equivalence:

- Replens Long-Lasting Vaginal Moisturizer, Lil' Drug Store Products, Inc. - K101098
- Elegance Woman's Lubricant, Elegance - K070587

Description of Device:

HyaloGYN is a line extension to add a formulation of HyaloGYN not made with parabens. It is a non-sterile, colorless, odorless, transparent, aqueous, hydrating gel that contains "Hydeal-D®" (a partial benzyl ester of hyaluronic acid), propylene glycol, a carbomer, preservatives and sodium hydroxide (to balance the pH). The hyaluronic acid is manufactured using a bacterial fermentation process.

HyaloGYN is a non-hormonal vaginal moisturizer intended to hydrate and lubricate the vaginal epithelium because of the strong hydrating properties of its hyaluronic acid derivative component. The carbomer and propylene glycol combine with the hyaluronic acid derivative to enable HyaloGYN to achieve its thick, viscous gel form, and the mucoadhesive properties to allow it to adhere to the vaginal mucosa, enhancing the residence time, thus hydrating and protecting this tissue. It is provided in an aluminum tube and packaged together with single-use applicators in a cardboard box. HyaloGYN has a shelf life of 3 years.

Technological Characteristics of the Device:
The proposed device formula is proprietary and consists of safe, water-soluble ingredients similar to the identified predicate device. The comparison of key design features and the performance testing demonstrate that HyaloGYN is substantially equivalent to its predicate in regards its technological characteristics including intended use, indications for use, design, materials, operational principles and performance characteristics.

The device is designed to meet the following Product Specifications at release: Appearance, odor, color weight, pH, hyaluronic acid content, Total Aerobic Microbial Count, Total combined yeasts/molds count, absence of common pathogens (*Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans),* viscosity, and osmolality.

Indications for Use:
HyaloGYN® 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 polyisoprene condoms.

Summary of Performance Data:

Biocompatibility Testing
The following biocompatibility studies were conducted and confirm it is safe for the proposed indication:

- In vitro Cytotoxicity Assay per ISO 10993-5
- Sensitization (Guinea Pig Maximization Test) per ISO 10993-10
- Vaginal Irritation Test per ISO 10993-10
- Acute Systemic Toxicity Rat per ISO 10993-11

Performance Testing - Bench
Condom compatibility testing was conducted per ASTM D7661-10. The results concluded that the subject device product is compatible with polyisoprene condoms.

Performance Testing – Clinical

Fidia conducted the following study on the subject device and a summary is provided below:

•Tempera G, Evaluation of the Tolerability and Efficacy of Hyalgel Vaginal (HYALOgin™) for the Treatment of Vaginal Dryness and Irritation Final Clinical Report, September 22, 1998

A pilot, open, uncontrolled clinical study conducted in Italy to assess the safety and effectiveness of HyaloGYN. A total of 80 women were enrolled at a single site. They were instructed to use the test product every three days for 30 days. Follow-up visits were performed on Days 7 and 21, with the final visit taking place three days after the last application of test product. The results obtained in this study demonstrated that the test material had moisturizing effects on the vaginal mucosa. Safety was considered to be excellent as demonstrated by the absence of adverse events and the investigator's overall assessment of tolerability score (98.7%). There were no alterations of the vaginal ecosystem.

This study supports the substantial equivalence of the subject device to Replens, the reference device, cleared in K101098 as a personal lubricant/moisturizer and demonstrates the safe and effective use of HyaloGYN as a personal lubricant to successfully supplementing the body's natural lubrication.

Stability Testing
HyaloGYN® has a 36-months shelf life based on the results of shelf life testing.

Conclusion:

HyaloGYN® Hydrating Gel is substantially equivalent to the predicate HyaloGYN® Hydrating Gel and the reference predicate device, Replens Long-lasting Vaginal Moisturizer and Elegance Woman's Lubricant. The intended use and fundamental technology of the system remain unchanged. Furthermore, performance testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject device to other vaginal moisturizers. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy.