Fidia Farmaceutici S.p.A.
℅ Vivian Kelly, MS, RAC
US Agent / Associate Director, Regulatory Affairs
Fidia Pharma USA, Inc.
100 Campus Drive, Suite 105
Florham Park, NJ 07932

Re: K191052
Trade/Device Name: Hyalo GYN® Vaginal Moisturizing Suppositories
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: April 18, 2019
Received: April 19, 2019

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. 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,

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)*
K191052

Device Name
Hyalo GYN® Vaginal Moisturizing Suppositories

Indications for Use *(Describe)*
Hyalo GYN® Vaginal Moisturizing Suppositories are personal lubricants 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. Hyalo GYN® Vaginal Moisturizing Suppositories are not compatible with natural rubber latex, 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.

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510(k) Summary – K191052

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
Associate Director, Regulatory Affairs
Fidia Pharma USA Inc.
100 Campus Drive, Suite 105
Florham Park, NJ 07932
Phone: 973-577-6202

Date Prepared: January 8, 2020

Device Information:

Proprietary Name:	Hyalo GYN® Vaginal Moisturizing Suppositories
Device Common Name	Personal Lubricant
Regulation Number	21 CFR 884.5300
Regulation Name	Condom
Regulatory Class	II
Product Code	NUC (lubricant, personal)

Predicate device:
Hyalo GYN® Vaginal Hydrating Gel, K150833

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

Description of Device:

Hyalo GYN® Vaginal Moisturizing Suppositories are non-sterile, glyceride-based personal lubricants. The subject lubricant is intended to moisturize and lubricate the vaginal epithelium to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The Hyalo GYN® Vaginal Moisturizing Suppositories are provided in peel-to-open pre-cut strips, in an outer cardboard box with a package insert.

The device specifications are listed in the table below:

Parameter	Specification	Test Method
Appearance	White to ivory white suppositories in suitable plastic pre-formed shells, tightly sealed & easy to open	Visual
Odor	Wax-like smell	Olfactory
Antimicrobial Effectiveness	Meets requirements per the standard.	USP <51>
Uniformity of dosage unit	Meets requirements for Content Uniformity	Ph. Eur. <2.9.40>, current ed.
Hyaff11p50 assay	0.18 – 0.22 %w/w	HPLC internal method
Disintegration time	No more than (NMT) 60 minutes	Ph. Eur. <2.9.2>, current ed.
Osmolality	≤ 1200 mOsm/kg	Ph. Eur. <2.2.35>, current ed.
Consistency	0.1 – 5.0 mm	Internal method
Peroxide value (Ip)	≤ 10 mEqO_2 / kg	Ph. Eur <2.5.5>, current ed., method A
Microbiological quality - Total Microbial Count (TAMC) - Fungal/Yeast/Mold Limits (TYMC) - *Pseudomonas aeruginosa* - *Staphylococcus aureus* - *Candida albicans*	 ≤100 cfu/g ≤10 cfu/g Absent Absent Absent	 Ph. Eur. <2.6.12>, current ed. Ph. Eur. <2.6.13>, current ed.

Indications for Use:

Hyalo GYN® Vaginal Moisturizing Suppositories are personal lubricants 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. Hyalo GYN® Vaginal Moisturizing Suppositories are not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Predicate Device Comparison:

	Subject Device K191052	Predicate Device K150883
Indications for Use	Hyalo GYN®Vaginal Moisturizing Suppositories are personal lubricants 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. Hyalo GYN® Vaginal Moisturizing Suppositories are not compatible with natural rubber latex, polyurethane and polyisoprene condoms.	Hyalo GYN® 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.
Over the counter use	Yes	Yes
Sterile	No	No
Ingredients	Hyaluronic acid	Hyaluronic acid
	Glycerides of vegetable origin	Propylene glycol
	Glycerides of vegetable origin	Carbomer
	Methylpropanediol	Methylpropanediol
	Carprylyl glycol, 1-2 hexanediol	Carprylyl glycol, 1-2 hexanediol
	Lactic acid	Sodium hydroxide
	Purified water	Purified water
Packaging	PVC/PE blister pack of 10 or 3 vaginal suppositories	Tube and applicators

The subject and predicate device do not have identical indications for use statements; however, their intended uses are the same, i.e., lubrication during intimate sexual activity.

The subject device and predicate device have different technological characteristics, including their formulation and specifications. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Performance Data:

Biocompatibility:

Biocompatibility studies 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 10993-11:2006)

The results of this testing demonstrated that the subject lubricants are biocompatible.

Condom Compatibility:

Condom Compatibility testing was performed in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." Testing demonstrated that the subject device is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf-life Testing

Hyalo GYN® Vaginal Moisturizing Suppositories has a 24-month shelf life based on the results of real time shelf life testing. At baseline and following aging, the device met all specifications as listed in the device specifications table.

Conclusion:

The results of the performance testing described above demonstrate that the Hyalo GYN® Vaginal Moisturizing Suppositories is as safe and effective as the predicate device and supports a determination of substantial equivalence.