



Food and Drug Administration
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Farma-Derma s.r.l.
Mara Calzolari
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Re: K153372
Trade/Device Name: Repagyn Vaginal Suppositories
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: May 31, 2016
Received: June 2, 2016

Dear Mara Calzolari,

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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K153372

Device Name

Repagyn vaginal suppositories

Indications for Use (Describe)

Repagyn 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, 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 for Repagyn Vaginal Suppositories

This 510(k) Summary is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. General Information

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Summary Preparation Date: November 19, 2015

2. Names

Device Name: Repagyn Vaginal Suppositories
Regulation number: 21 C.F.R. 884.5300
Classification: II
Product Code: NUC
Common Name: Lubricant, Personal

3. Predicate Devices

Repagyn Vaginal Suppositories are substantially equivalent to Hyalo Gyn, K094039, registered by Fidia Pharmaceuticals.

4. Device Description

The Farma-Derma Repagyn Vaginal Suppositories are a non-sterile hyaluronic acid and glycerides based semi-solid preparation presented in the form of vaginal suppositories of 2 g in weight individually packed in a polyvinyl chloride (PVC)/polyethylene (PE) blister. The device is available for sale in a pack containing 10 vaginal suppositories (two blisters of 5 vaginal suppositories each) while the sample pack contains 3 vaginal suppositories (one blister).

Due to its specific shape the device can be introduced into the vaginal cavity using a finger.

Repagyn Vaginal Suppositories are a Hyaluronic acid (HA) based product; the HA is mixed in with semi-synthetic glycerides that represent the major quantity of material used in the formulation.

When the vaginal suppository is in contact with the vaginal mucosa it melts due to body temperature and becomes a viscous mass which remains in contact with the vaginal mucosa.

It acts similarly to other vaginal creams or gels for topical application with Hyaluronic acid based formulations.

The specifications for Repagyn Vaginal Suppositories are described in Table 1.

Specifications	
Appearance	Off-white opaque vaginal suppositories
Disintegration time	According to Eu. Ph.
Average weight	2 g
Uniformity of weight	According to Eu. Ph.
Content of HA	5 mg
TAMC	≤100 UFC/g
TYMC	≤10 UFC/g
Pseudomonas Aeruginosa, Staphylococcus Aureus, Candida Albicans	Absent/g

Table 1: Repagyn Vaginal Suppositories specifications

Furthermore the endotoxins level will be checked according to the kinetic test (LAL test) on each lot of finished product.

5. Indications for Use

The intended use for Repagyn vaginal suppositories is:

“Repagyn 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, polyurethane, and polyisoprene condoms.”

6. Technological Characteristics

A comparison between the technological characteristics of Repagyn vaginal suppositories and the predicate device Hyalo Gyn is provided in Table 2.

	Repagyn Vaginal Suppositories	Hyalo Gyn (Predicate Device K094039)
Base type	Glycerides	Water
Primary ingredient	Glycerides	Propylene glycol and water
Condom compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Compatible with lubricated/non-lubricated latex, lubricated polyurethane, lubricated natural skin condoms
Packaging	PVC/PE blister of 3 or 5 vaginal suppositories	Tube

Table 2: Technological characteristics – Comparison between Repagyn vaginal suppositories and Hyalo Gyn

Repagyn Vaginal Suppositories and Hyalo Gyn differ in their shape, Repagyn is in the form of vaginal suppositories and Hyalo Gyn is an aqueous gel. However, when the suppositories are introduced in the vaginal cavity, they melt because of body temperature and become a viscous mass that act in the same way as the predicate device.

The components used for the predicate device are similar to the ones used for Repagyn vaginal suppositories.

The area of application for both medical devices is the vaginal mucosa. The only difference is that the predicate device Hyalo Gyn (K094039) can be applied also on the penis during sexual intercourses while Repagyn is designed for vaginal application only.

7. Performance Data

Biocompatibility:

Biocompatibility studies including acute system toxicity, vaginal irritation, cytotoxicity, and guinea maximization sensitization were performed according to the ISO standards as described below:

- Acute Systemic Toxicity: ISO 10993-11:2006
- Cytotoxicity: ISO 10993-5:2009
- Vaginal Irritation Testing: ISO 10993-10:2010
- Guinea Pig Maximization Test (GPMT): ISO 10993-10:2010.
- Endotoxin levels determination: USP <85>

Shelf Life:

The shelf life of Repagyn vaginal suppositories is 24 months. This is based on the results of real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life.

Condom Compatibility:

Condom compatibility was performed using the FDA recognized consensus standard ASTM D7661-10 *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The Repagyn Vaginal Suppositories were found to be not compatible with natural rubber latex, polyisoprene and polyurethane condoms.

8. Conclusion

Repagyn Vaginal Suppositories are substantially equivalent to the predicate device, Hyalo Gyn.