



April 1, 2026

Hudi Pharma Srl
Marco Mattielli
Head of firm
Piazza Giuseppe Grandi 19
Milano, 20129
ITALY

Re: K260007
Trade/Device Name: Hyaluronic Acid Vaginal Suppository (HA 5 mg);
Hyaluronic Acid Vaginal Suppository (HA 10 mg)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 2, 2026
Received: January 2, 2026

Dear Marco Mattielli:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Monica D. Garcia, Ph.D.

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

Indications for Use

510(k) Number (if known)
K260007

Device Name

Hyaluronic Acid Vaginal Suppository (HA 5 mg)
Hyaluronic Acid Vaginal Suppository (HA 10 mg)

Indications for Use (Describe)

The Hyaluronic Acid Vaginal Suppository (HA 5 mg) and Hyaluronic Acid Vaginal Suppository (HA 10 mg) are personal lubricants designed for vaginal application to moisturize and lubricate, enhancing comfort and ease during intimate sexual activity, and supplementing the body's natural lubrication. This product is not compatible with 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.

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510(k) Summary
Hyaluronic Acid Vaginal Suppository (HA 5 mg)
Hyaluronic Acid Vaginal Suppository (HA 10 mg)
K260007

1. General Information

Submitter: HUDI PHARMA SRL
Manufacturer: Piazza G. Grandi, 20129 Milano (MI), Italy
Official correspondent: Mr. Marco Mattielli
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Date prepared: March 31, 2026

2. Device classification

Trade Name: Hyaluronic Acid Vaginal Suppository (HA 5 mg)
Hyaluronic Acid Vaginal Suppository (HA 10 mg)
Common Name: Personal lubricant suppository
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Device Class: Class II
Product Code: NUC (Lubricant, Personal)

3. Predicate Device

Predicate Device	510(k) Number	Manufacturer
Revaree plus vaginal suppositories	K213220	FARMA-DERMA srl

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

4. Indications for Use

The Hyaluronic Acid Vaginal Suppository (HA 5 mg) and Hyaluronic Acid Vaginal Suppository (HA 10 mg) are personal lubricants designed for vaginal application to moisturize and lubricate, enhancing comfort and ease during intimate sexual activity, and supplementing the body's natural lubrication. This product is not compatible with condoms.

5. Device Description

Hudi Pharma's Hyaluronic Acid Vaginal Suppository (HA 5 mg) and Hyaluronic Acid Vaginal Suppository (HA 10 mg) are vaginal lubricants which contain hyaluronic acid sodium salt for over-the-counter use. The subject device is a solid preparation lubricant containing Hyaluronic acid sodium salt, vitamin E, Cocoa Butter and semi-synthetic glycerides.

The subject device is presented in the form of vaginal suppositories of 1.8 g each. Each vaginal suppository is individually packed in a non-sterile polyvinyl chloride (PVC)/polyethylene (PE) blister. The subject device is available for sale in a cardboard box containing 10 vaginal suppositories (two strips of 5 vaginal suppositories

each).It is provided in two configurations having 5 mg and 10 mg Hyaluronic Acid Sodium Salt content, respectively.

Due to its shape the device can be introduced into the vaginal cavity using the fingers, where it gradually dissolves in the presence of vaginal fluid.

Once in contact with the vaginal mucosa, the device melts due to body temperature, releasing hyaluronic acid sodium salt (HA) and becomes a viscous mass which remains in contact with the vaginal mucosa, creating a moist environment to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

The specifications for both configurations of the subject device are provided in the following tables.

Table 1. Device Specifications of Hyaluronic Acid Vaginal Suppository – 5 mg HA content.

Parameter	Specification
Appearance (color)	white-ivory white vaginal suppositories
Odor	characteristic
Disintegration time	≤ 60 minutes
Average weight	1.8 g
Content of HA	5 mg
TAMC	≤100 cfu/g
TYMC	≤10 cfu/g
Absence of pathogenic organisms (<i>Pseudomonas Aeruginosa</i> , <i>Staphylococcus Aureus</i> , <i>Candida Albicans</i>)	Absent

Table 2. Device Specifications of Hyaluronic Acid Vaginal Suppository – 10 mg HA content.

Parameter	Specification
Appearance (color)	white-ivory white vaginal suppositories
Odor	characteristic
Disintegration time	≤ 60 minutes
Average weight	1.8 g
Content of HA	10 mg
TAMC	≤100 cfu/g
TYMC	≤10 cfu/g
Absence of pathogenic organisms (<i>Pseudomonas Aeruginosa</i> , <i>Staphylococcus Aureus</i> , <i>Candida Albicans</i>)	Absent

6. Substantial Equivalence Discussion

The following table compares the intended use and key technological characteristics of the subject and predicate devices.

Table 3. Intended Use and Technological Characteristics of Subject Device Compared to Predicate Device

Characteristic	Hyaluronic Acid Vaginal Suppository	Revaree plus vaginal suppositories (K213220)	Comparison
Indications for Use	The Hyaluronic Acid Vaginal Suppository (HA 5 mg) and Hyaluronic Acid Vaginal Suppository (HA 10 mg) are personal lubricants designed for vaginal application to moisturize and lubricate, enhancing comfort and ease during intimate sexual activity, and supplementing the body's natural lubrication. This product is not compatible with condoms.	Revaree Plus vaginal suppositories are 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.	Similar Indications for use of the subject device are a subset of those of the predicate device.
Over the Counter	Yes	Yes	Same
Base Type	Glyceride	Glyceride	Same
Ingredients	Hyaluronic acid sodium salt, vitamin E, Cocoa Butter, semi-synthetic glycerides.	Hyaluronic acid, glycerides and sweet almond oil.	Different Same active ingredient (Hyaluronic acid) and similar solvent type (glycerides). The excipients are not the same.
Content of HA	5 mg or 10 mg	10 mg	Similar content of HA per suppository, considering the HA 10 mg Vaginal Suppository configuration.
Microbial Limits	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g	Same

Characteristic	Hyaluronic Acid Vaginal Suppository	Revaree plus vaginal suppositories (K213220)	Comparison
	Absence of pathogens (<i>Pseudomonas Aeruginosa</i> , <i>Staphylococcus Aureus</i> , <i>Candida Albicans</i>)	Absence of pathogens (<i>Pseudomonas Aeruginosa</i> , <i>Staphylococcus Aureus</i> , <i>Candida Albicans</i>)	
Sterilization method(s)	Non-sterile	Non-sterile	Same
Primary packaging materials	PVC/PE blister	PVC/PE blister	Same
Shelf life	1 year	24 months	Different

The subject and predicate devices have the same intended use (i.e., provide lubrication during intimate sexual activity). The subject device and predicate devices have different technological characteristics including formulation, content of HA for one of the subject device formulations, and shelf life. These differences do not raise different questions of safety or effectiveness.

7. Summary of Performance Testing

Biocompatibility Testing

Biocompatibility studies: cytotoxicity, sensitization, vaginal irritation, and acute systemic toxicity, were performed according to the 2023 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 10993-1:2018 as follows:

- Cytotoxicity, ISO 10993-5:2009
- Vaginal Irritation Testing, ISO 10993-23: 2021
- Skin sensitization, ISO 10993-10:2021
- Acute systemic toxicity, ISO 10993-11:2017

The results demonstrated that the subject device is non-cytotoxic, non-irritating, non-sensitizing and not systemically toxic.

Shelf Life and Stability Testing

The subject device is a vaginal suppository provided in non-sterile PVC/PE blister packaging configuration, with 1 year of shelf life, in accordance with the results of real-time aging studies.

Condom Compatibility

No condom compatibility testing was conducted on the subject device. The device is labeled as not compatible with condoms.

8. Conclusion

The results of the testing described above demonstrate that Hyaluronic Acid Vaginal Suppository (HA 5 mg) and Hyaluronic Acid Vaginal Suppository (HA 10 mg) are as safe and effective as the predicate device and support a determination of substantial equivalence.