August 14, 2024

Plus EV Holdings dba Intimate Rose
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K241748
Trade/Device Name: Intimate Rose Vaginal Dilators
Regulation Number: 21 CFR 884.3900
Regulation Name: Vaginal Stent
Regulatory Class: II
Product Code: HDX
Dated: July 30, 2024
Received: July 31, 2024

Dear Dave Yungvirt:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Jason Roberts -S

Jason R. Roberts, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241748

Device Name
Intimate Rose Vaginal Dilators

Indications for Use *(Describe)*
The Intimate Rose Vaginal Dilators are tools intended for controlled dilation of the vagina. They can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related painful sex.

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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K241748 Intimate Rose Vaginal Dilators 510(k) Summary

Submitter Name: Plus EV Holdings dba Intimate Rose

Submitter Address: 1419 Murray St North Kansas City MO 64116 United States

Submitter Contact Telephone: 816-805-6722

Submitter Contact: Mr. Aaron Wilt

Submitter Contact Email: aaron@plusevholdings.com

Correspondent Name: FDA Compliance Group

Correspondent Address: 33 Golden Eagle Lane Littleton CO 80127 United States

Correspondent Contact Telephone: 720-254-5756

Correspondent Contact: Mr. Kevin Walls

Correspondent Contact Email: kevin@reginsight.com

Date Prepared: August 14, 2024

Device Trade Name: Intimate Rose Vaginal Dilators

Common Name: Vaginal Dilators

Classification Name: Vaginal stent

Classification Number: 884.3900

Product Code(s): HDX

Predicate Device:

1. K220035, Milli Vaginal Dilator, Product Code HDX

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

Reference Device:

2. K231430, Intimate Rose Vaginal Dilators, Product Code HDX

Device Description Summary: The Intimate Rose Vaginal Dilators are intended to treat women suffering from vaginismus (including related dyspareunia). Vaginismus is the involuntary spasm of the muscles in the vaginal wall which then inhibits sexual intercourse by making it painful or impossible. Dyspareunia is the pain experienced during sexual intercourse caused by physical and/or emotional problems. The device is used as a tool to dilate the vagina in controlled stages. It is a reusable device that comes into contact with the vaginal mucosal membrane for a prolonged (> 24 hours to <= 30 days) duration. The Intimate Rose Vaginal Dilators are comprised of 8 progressively larger and color-coded medical-grade silicone dilators.

Indications for Use:

The Intimate Rose Vaginal Dilators are tools intended for controlled dilation of the vagina. They can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of

the vaginal muscles) and related painful sex.

The indications for use are the same as the predicate's indication for use.

Technological Comparison:

The technology between the subject device and the predicate device is similar. Both the subject and predicate device are indicated for over the counter (OTC) use. While there are technological differences between the subject and predicate device, the technology between the subject device and the reference device is the same. The differences in technological characteristics do not raise different questions of safety or effectiveness.

	SUBJECT DEVICE	REFERENCE DEVICE	PREDICATE DEVICE
Device Name	Intimate Rose Vaginal Dilators	Intimate Rose Vaginal Dilators	Milli Vaginal Dilator
510(k) Number	K241748	K231430	K220035
Regulation Number	21 CFR§ 884.3900	21 CFR§ 884.3900	21 CFR§ 884.3900
Regulation Name	Vaginal Stent	Vaginal Stent	Vaginal Stent
Regulatory Class	II	II	II
Product Code	HDX (Dilator, Vaginal)	HDX (Dilator, Vaginal)	HDX (Dilator, Vaginal)
Over the Counter	Yes	No	Yes
Indications for Use	The Intimate Rose Vaginal Dilators are tools intended for controlled dilation of the vagina. They can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related painful sex.	The Intimate Rose Vaginal Dilators are tools intended to dilate the vagina in controlled stages to help relieve symptoms of vaginismus.	The Milli Vaginal Dilator is a tool intended for controlled dilation of the vagina. It can be used for dilation for an examination (by your doctor), in preparation for a surgical procedure, or to help relieve the symptoms of vaginismus (condition that involves tightening of the vaginal muscles) and related painful sex.
Feature	Vaginal dilator, controlled stages	Vaginal dilator, controlled stages	Vaginal dilator, controlled stages

Target Population	Women suffering from vaginismus	Women suffering from vaginismus	Women suffering from vaginismus
Anatomical Site	Vagina	Vagina	Vagina
Single Patient Device	Yes	Yes	Yes
Reusable	Yes	Yes	Yes
Sterile	Non-sterile	Non-sterile	Non-sterile
Device Design	Conical	Conical	Conical
Materials	Medical Grade Silicone	Medical Grade Silicone	Unknown
Dimensions	Eight varying sizes (Inches; diameter/ length): 0.45/2.8 0.7/3.5 0.83/3.7 0.95/4.45 1.0/5.0 1.07/5.6 1.3/6.1 1.5/6.5	Eight varying sizes (Inches; diameter/length): 0.45/2.8 0.7/3.5 0.83/3.7 0.95/4.45 1.0/5.0 1.07/5.6 1.3/6.1 1.5/6.5	Adjustable 15-40mm in 1 mm increments.
Packaging	Packaged in a cardboard box with instructions for use.	Packaged in a cardboard box with instructions for use.	Hard charging case
Operating Principle	Dilate the vagina in controlled stages.	Dilate the vagina in controlled stages.	Dilate the vagina in controlled stages.
Resistive component	Progressively larger dilators	Progressively larger dilators	Progressively larger dilator via electronic adjustments
Maintenance	Clean with mild soap and warm water. Towel dry.	Clean with mild soap and warm water. Towel dry.	Clean with mild soap and warm water. Towel dry.
Color	Shades of purple, yellow, blue and green	Shades of purple, yellow, blue and green	Light blue
Biocompatibility Testing	Yes	Yes	Yes

Summary of Non-Clinical and/or Clinical Performance Testing: The subject device labeling (website) was aligned with that of the predicate device to support leveraging the self-selection study conducted for the predicate device in the current submission. The results of the previously

conducted self-selection study support that users are able to accurately determine whether they are indicated for use of the subject device based on the device labeling (website).

The subject and reference device are technologically identical. Therefore, the non-clinical testing conducted to support the clearance of K231430 is applicable to the subject device.

Conclusion

The subject device has same intended use as the predicate device and has identical technological characteristics to the reference device. The subject device does not raise different questions of safety and effectiveness as compared to the predicate device. The predicate device self-selection study was leveraged in the current submission to demonstrate that the subject device can be used safely and effectively in the OTC population to support a substantial equivalence determination.