June 7, 2023

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

Re: K231430
Trade/Device Name: Intimate Rose Vaginal Dilators
Regulation Number: 21 CFR§ 884.3900
Regulation Name: Vaginal stent
Regulatory Class: II
Product Code: HDX
Dated: April 9, 2023
Received: May 17, 2023

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 (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,

Reginald K. Avery -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231430

Device Name

Intimate Rose Vaginal Dilators

Indications for Use *(Describe)*

The Intimate Rose Vaginal Dilators are tools intended to dilate the vagina in controlled stages to help relieve symptoms of vaginismus.

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

I. SUBMITTER

Plus EV Holdings dba Intimate Rose
1419 Murray Street
North Kansas City, MO 64116
Phone: 816-805-6722

Contact Person: Aaron Wilt

Date Prepared: June 5, 2023

II. DEVICE

Name of Device:	Intimate Rose Vaginal Dilators
Common or Usual Name:	Vaginal Dilators
Classification Number:	21 CFR 884.3900
Classification Name:	Vaginal Stent
Regulatory Class:	II
Product Code:	HDX (Dilator, Vaginal)
Classification Panel:	Obstetrics/Gynecology

III. PREDICATE DEVICE

510(k) Number	Trade or Proprietary Name	Manufacturer
K130273	Vaginal Dilators	Panpac

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

IV. DEVICE DESCRIPTION

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.

Intimate Rose

Dilators Dimensions & Circumference

V. INDICATIONS FOR USE

The Intimate Rose Vaginal Dilators are tools intended to dilate the vagina in controlled stages to help relieve symptoms of vaginismus.

Differences in indications for use:

SUBJECT DEVICE INDICATIONS FOR USE: "The Intimate Rose Vaginal Dilators are tools intended to dilate the vagina in controlled stages to help relieve symptoms of vaginismus."

PREDICATE DEVICE INDICATIONS FOR USE: "Panpac Vaginal Dilators are indicated for women who need vaginal dilation for an examination, a surgical procedure, or for the relief of vaginismus. Panpac Vaginal Dilators has four different size (small, medium, large and extra large) in three family types; Family A, Family B and Family C with variant sizes."

The difference between the subject and predicate device indications for use is that the predicate device includes 2 additional indications: vaginal dilation for examination and vaginal dilation for surgical procedure. The subject device is not intended for these uses; it is intended solely for use to provide dilation to help relieve the symptoms of vaginismus.

As the subject device indications are a subset of the predicate device indications, this difference does not raise intended use concerns.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	SUBJECT DEVICE	PREDICATE DEVICE
Device Name	Intimate Rose Vaginal Dilators	Panpac Vaginal Dilators
510(k) Number	K231430	K130273
Regulation Number	21 CFR§ 884.3900	21 CFR§ 884.3900
Regulation Name	Vaginal Stent	Vaginal Stent
Regulatory Class	II	II
Product Code	HDX (Dilator, Vaginal)	HDX (Dilator, Vaginal)
Over the Counter	No	No
Feature	Vaginal dilator, controlled stages	Vaginal dilator, controlled stages
Target Population	Women suffering from vaginismus	Women suffering from vaginismus
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes

	SUBJECT DEVICE	PREDICATE DEVICE
Sterile	Non-sterile	Non-sterile
Device Design	Conical	Conical
Materials	Medical Grade Silicone	Medical Grade Silicone
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	Twelve varying sizes (mm; length, Small OD, Large OD): 150, 30, 38 138, 25.5, 32 128, 22.5, 28 120, 19.5, 24 95, 26, 33 86, 22.5, 28 78, 19.5, 23 75, 12.5, 17 75, 13.5, 18 65, 12, 16 60, 10.5, 14 50, 9.5, 13
Packaging	Packaged in a cardboard box with instructions for use.	Packaged in a cardboard box with instructions for use.
Operating Principle	Dilate the vagina in controlled stages.	Dilate the vagina in controlled stages.
Resistive component	Progressively larger dilators	Progressively larger dilators
Maintenance	Clean with mild soap and warm water. Towel dry.	Clean with mild soap and hot water. Towel dry.
Color	Shades of purple, yellow, blue and green	White
Biocompatibility Testing	Yes	Yes

As noted in the table above, the subject device and predicate device are similar in all aspects, except for the following:

Differences in available sizes: The predicate device provides 12 total progressively sized dilators as compared to 8 for the subject device. The smallest diameter of the subject device is 0.45" (11.4 mm) while the smallest diameter for the predicate is 9.5 mm. The largest diameter of the subject device is 1.5" (38.1 mm) while the largest diameter for the predicate is 38 mm.

Differences in color: The subject device comprises 8 different sizes of dilators. Each of the 8 varying sizes is produced in one of 8 colors. The predicate device comprises 12 different sizes of dilators, all colored white.

These differences do not raise different questions of safety or effectiveness and can be evaluated through performance testing.

VII. NON-CLINICAL PERFORMANCE TESTING

Biocompatibility:
The following biocompatibility testing was performed for all 8 colors of the subject device, as recommended in the FDA's 2020 guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"":

- Cytotoxicity testing per ISO10993-5:2009
- Guinea pig maximization sensitization testing per ISO10993-10:2010
- Vaginal irritation testing per ISO10993-10:2010
- Acute systemic toxicity testing per ISO10993-11:2017

The test results demonstrate that the subject devices (8 various colors) are acceptable regarding all 4 of the above biocompatibility test standards. The subject devices were found to be non-cytotoxic, non-irritating, non-sensitizing, and not causing acute systemic toxicity.

Reprocessing:
The device labeling included reprocessing information per FDA's 2015 guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"

Physical Properties:
The following device characteristics were evaluated for all 8 colors of the subject device:

- Appearance
- Diameter
- Hardness
- Compression
- Density

VIII. CONCLUSION

Based on the results of the performance testing described above, the Intimate Rose Vaginal Dilators are as safe and effective as the predicate device and supports a determination of substantial equivalence.