May 20, 2021

J3 Bioscience, Inc.
R. Tyler McCabe, Ph.D.
President/CEO
825 North 300 West, Suite N231
Salt Lake City, UT 84103

Re: K203377
Trade/Device Name: VR101 Lubricating Intravaginal Ring
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: QPD
Dated: April 20, 2021
Received: April 21, 2021

Dear R. Tyler McCabe:

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,

for 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

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)*
K203377

Device Name
VR101 Lubricating Intravaginal Ring

Indications for Use *(Describe)*
VR101 Lubricating Intravaginal Ring 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 natural rubber latex and synthetic (polyurethane and polyisoprene) male condoms and FC2 female 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	J3 Bioscience, Inc.
	Address:	825 North 300 West, Suite N231 Salt Lake City, UT 84103
	Contact Person:	R. Tyler McCabe, PhD
	Telephone Number:	801-550-9956 (mobile)
	Fax Number:	866-768-9341
	Date of Preparation:	20 May 2021

Principle and Regulatory Contacts	**Submitted By/Principal Contact:**	
	Contact Name:	R. Tyler McCabe, PhD
	Title:	President/CEO
		J3 Bioscience, Inc.
	Address:	825 North 300 West, Suite N231
		Salt Lake City, UT 84103
	Phone Number:	801-550-9956 (mobile)
	Fax Number:	866-768-9341
	Email:	tmccabe@j3bio.com
	Regulatory Contact:	
	Name:	Moj Eram, PhD
	Title:	QA/RA Representative
		Sage BioPartners, LLC
	Phone Number:	801-230-8611
	Email:	moj.eram@sagebiopartners.com

Subject Device	Trade Name:	VR101 Lubricating Intravaginal Ring
	Common Name:	Personal Lubricant Ring
	Classification Name:	Condom
	Classification:	Class II
	Product Code:	QPD
	Regulation Number:	21 CFR 884.5300
	Regulatory Panel:	Obstetrics/Gynecology

Predicate Device	Predicate Trade Name:	Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators) – (hereafter Replens®)
	Manufacturer:	LIL' DRUG STORE PRODUCTS, INC.
	510(k) Number:	K101241
	Classification Name:	Condom
	Classification:	Class II
	Product Code:	NUC
	Regulation Number:	21 CFR 884.5300
	Regulatory Panel:	Obstetrics/Gynecology
	This device has not been subject to a design-related recall.	

Device Description

The VR101 Lubricating Intravaginal Ring device is a lubricating intravaginal ring designed to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. VR101 Lubricating Intravaginal Ring is constructed from a hollow biomedical grade hydrophilic polyether urethane (HPU) tube filled with a liquid vaginal lubricating solution comprised of a solution of glycerol (also known as glycerin), water, and sodium chloride. Upon insertion of VR101 Lubricating Intravaginal Ring in the vagina, the lubricating solution in the lumen ring is released through the semi-permeable wall of the tubing into the vagina, moisturizing and lubricating the vaginal mucosa without the use of any hormones or active pharmaceutical ingredients (APIs).

Each VR101 Lubricating Intravaginal Ring provides moisturization and lubrication for up to seven (7) days.

The VR101 device specifications can be seen in the table below.

Parameter	**Specification**
Lubricant Specifications	
Appearance	Colorless, Translucent
Odor	Odorless
pH	6.5-7.5
Viscosity	71-292 cP
Osmolality	498-603 mOsm/kg at 20x dilution (9,960-12,060 mOsm/kg)
Antimicrobial Effectiveness per USP <1112>	Water activity ≤ 0.60
Total Microbial Count per USP <61>	< 100 cfu/g
Fungal/Yeast/Mold Limits per USP <61>	< 10 cfu/g
Absence of Pathogenic Organisms per USP <62>	Absent
Ring Specifications	
Dimensional Inspection	Outer diameter – 55 ± 2 mm
Compression	1.0 – 2.2 N at 10% strain
Tensile Strength	Failure at > 100 N
Ring Breakage	No ring breakage
Ring Flatness	Largest measurable gap between the ring plane and a flat surface is ≤ 2 mm

Outer Tubing Deformities	No deformities or damage observed in the outer tubing
Weld misalignment	Any detectable misalignment in the weld is ≤ 0.13 mm
Weld Flashing	Maximum height of any detectable weld flashing is ≤ 0.25 mm
Bubbles in the Weld	Number of bubbles in weld volume is ≤ 10
Tubing and Weld Diameter	No visible apparent change in diameter between the tubing and weld plugs
Weld Volume Bubble Size	Diameter of the largest bubble is ≤ 0.5 mm
Foreign Material	No visually detectable loose foreign material, loose flash, or embedded foreign material in the ring
Ring/Lubricant System Specifications	
Mass	4.3 – 4.7 g
Glycerol Release (*in vitro*)	>70% glycerol released by 48 hours

Indications for Use	VR101 Lubricating Intravaginal Ring 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 natural rubber latex and synthetic (polyurethane and polyisoprene) male condoms and FC2 female condoms.

Technological Comparison with Predicate Device

Device Characteristics	Subject Device	Predicate Device	Comparison
Device Name	VR101 Lubricating Intravaginal Ring	Replens Long Lasting Vaginal Moisturizer	N/A
Sponsor	J3 Bioscience, Inc.	Lil' Drug Store Products, Inc.	N/A
510(k) Number	K203377	K101241	N/A
Indications for Use Statement	VR101 Lubricating Intravaginal Ring 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 natural rubber latex and synthetic (polyurethane and polyisoprene) male condoms and FC2 female condoms.	Replens is a personal lubricant for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex condoms and synthetic (polyurethane and polyisoprene) condoms.	Similar
Condom Compatibility	NRL, Polyisoprene, Polyurethane,	NRL, Polyisoprene, Polyurethane	Different

	FC2 female condoms		
Base Type	Glycerol/water	Water	Similar
Primary Ingredient	Glycerol Water Sodium Chloride	Purified water Glycerin Mineral oil Polycarbophil Carbon homopolymer type B Hydrogenated palm oil glyceride Sorbic acid Sodium hydroxide	Different
Ring Component	Yes	No	Different
Ring Material	Hydrophilic polyurethane	N/A	Different
Appearance/color	Clear	Smooth homogenous gel/white to off-white	Different
Sterility	Non-sterile	Non-sterile	Same
Shelf-life	3 years	3 years	Same
Application	7 days continuous	Intermittent (every 3 days and/or as needed)	Different
OTC use	OTC	OTC	Same

Although the formulation of the predicate device lubricant is different from the subject device, it does not pose any concern for safety and effectiveness of the subject device when compared to the predicate device. The results of the subject device non-clinical and clinical performance testing demonstrate that performance and safety of the lubricants are equivalent.

In both the subject device, VR101 Lubricating Intravaginal Ring, and the predicate device, Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators), lubricant is delivered from within a polymeric container. The predicate device is a single-use applicator for bolus application, while

VR101 Lubricating Intravaginal Ring, is a single-use hollow ring for controlled release of lubricant solution for up to seven (7) days. No different questions of safety and efficacy are raised for the subject device by differences in the formulation or incorporation of different polymeric container components.

Safety and Performance Tests

To establish substantial equivalence and a shelf-life period for the subject device, VR101 Lubricating Intravaginal Ring, the tests identified in the table below were performed with results demonstrating that acceptance criteria were met and demonstrated that the subject device is substantially equivalent in performance as compared to the cited predicate device, Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators).

Risk management, including a failure mode and effects analysis (FMEA), of the subject device was conducted in accordance with BS EN ISO 14971:2007 and 2012, *Medical Devices – Application of risk management to medical devices*.

Summary of Performance Tests Conducted on VR101 Lubricating Intravaginal Ring		
Test	**Test Method Summary**	**Results**
Visual Inspection of Packaging	Each pouch was visually inspected by trained individuals for holes and gross damage prior to removal of the VR101 Lubricating Intravaginal Ring sample.	**Pass** No holes or defects were seen.
Cytotoxicity	ISO 10993-5:2009 L929 MEM Elution Method and Agar Overlay was conducted to assess the cytotoxic potential of the device.	**Pass**
Sensitization	ISO 10993-10:2010 and ISO 10993-12:2012 A Guinea Pig Maximization Test was conducted on the device.	**Pass**

Irritation	ISO 10993-10:2010 and ISO 10993-12:2012 A Vaginal Mucosal Irritation Test was conducted to assess the irritation potential of the device.	**Pass**
Acute Systemic Toxicity	ISO 10993-11:2006 and ISO 10993-12:2012 Intraperitoneal and Intravenous Systemic Injection routes were used when conducting the acute systemic toxicity study on the device.	**Pass**
Genotoxicity	ISO 10993-3:2014 and ISO 10993-12:2012 An Ames Test and Mouse Lymphoma Assay were conducted on the device.	**Pass**
Material Mediated Pyrogenicity	USP <151>, ISO 10993-11:2017 and ISO 10993-12:2012 A material mediated pyrogenicity study was conducted on the device.	**Pass**

Implantation	ISO 10993-6:2016 and ISO 10993-12:2012 A Subcutaneous Implantation Test was conducted using the subject device.	**Pass**
Chemical Characterization and Toxicological Risk Assessment	ISO 10993-18:2005 A chemical characterization and toxicological risk assessment were conducted on the device to address chronic systemic toxicity.	**Pass**
Visual Inspection of Intravaginal Rings	VR101 Lubricating Intravaginal Ring test articles were visually inspected to determine if rings are intact, not broken, are colorless and translucent, and are odor free.	**Pass** All samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions exhibited a yellow tint but met all other acceptance criteria. Samples aged under ambient room-temperature conditions for 57 months exhibited no discoloration. All unaged (t=0) samples met acceptance criteria.

VR101 Lubricating Intravaginal Ring Dimensional Inspection	Outer diameter (OD) of the VR101 Lubricating Intravaginal Ring tubing and the ring measured both parallel (OD1) and perpendicular (OD2) to the joint surface were determined.	**Pass** All t=0 samples and samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met all dimensional acceptance criteria.
Intravaginal Ring (IVR) Massing Test	The mass of each VR101 Lubricating Intravaginal Ring test article was determined using a calibrated analytical balance.	**Pass** All t=0 samples and samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the acceptance criterion for mass.
Force of Compression Test	Each of the VR101 test articles was subjected to compression testing on two perpendicular axes using a tensile testing apparatus.	**Pass** All t=0 samples and samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the acceptance criterion for the force required to compress the devices by 10% of initial outer diameter on 2 axes.
IVR Tensile Strength Test	VR101 Lubricating Intravaginal Ring test articles were subjected to tensile tests using a tensile testing apparatus to assess weld integrity.	**Pass** All t=0 samples and samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the acceptance criterion.

IVR Glycerol Release Test	The release of lubricating solution from VR101 test articles was assessed using a colorimetric assay to quantify glycerol present in the release medium after immersion for 24, 48, and 72 hours at 37°C.	**Pass** All samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the release criteria.
Lubricating Solution Viscosity Determination	Viscosity of the lubricating solution in each VR101 sample was assessed at 25°C and 10 rpm using a calibrated viscometer.	**Pass** All samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the viscosity specification.
Lubricating and Packaging Solution Osmolality Determination	Osmolality of the lubricating solution in each VR101 sample was assessed using a calibrated osmometer.	**Pass** All as-prepared lubricating and packaging solution samples and lubricating solution samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the specification for osmolality.
Lubricating Solution pH Determination	The pH of the lubricating glycerol solution in each VR101 sample was assessed using litmus paper.	**Pass** All samples exposed to accelerated aging conditions equivalent to 54 months storage under ambient conditions met the specification for pH.

Lubricating and Packaging Solution Water Activity Determination	The water activity of the lubricating glycerol solution in each VR101 Lubricating Intravaginal Ring sample was assessed using a calibrated water activity meter.	All lubricating and packaging solution samples exposed to real-time and accelerated aging storage conditions exhibited sufficiently low water activity to justify reduced microbial testing.
Determination of compatibility of lubricating solution with male condoms composed of natural rubber latex, polyurethane, and polyisoprene and female condoms composed of nitrile rubber	ASTM 7661-10 Condom samples were soaked in the lubricating solution for one hour and the tensile and burst properties of the condoms exposed to the lubricating solution were compared to those of control condoms.	All condoms met the acceptance criterion for burst after exposure to the lubricating solution, allowing labeling of the device that documents its compatibility with male condoms composed of natural rubber latex, polyurethane, and polyisoprene and female condoms composed of nitrile rubber.

Summary of Clinical Data

J3 Bioscience, Inc. sponsored three clinical investigations (CI01, CI02, and CI03) to assess the safety and efficacy of VR101 Lubricating Intravaginal Ring device.

Study summaries

The first, CI01 *VR101: A Pilot Study to Evaluate the Preliminary Feasibility and Safety of a Lubricating Intravaginal Ring to Relieve the Symptoms of Vaginal Dryness*, was a pilot investigation conducted to assess the feasibility of VR101 Lubricating Intravaginal Ring as a personal lubricant device.

The second, CI02, *A Pivotal Clinical Investigation to Evaluate the Safety and Efficacy of J3 Bioscience Lubricating Intravaginal Ring (VR101) in Relieving Symptoms of Vaginal Dryness*, was a pivotal, double-blind, cross-over randomized trial that demonstrated the safety of VR101 Lubricating Intravaginal Ring during long-term continuous use (up to 13 weeks). In CI02, 890 total VR101 Lubricating Intravaginal Ring devices were used by study participants, and no serious adverse device effects were observed. The primary efficacy endpoint was not met as specified in the study protocol. Drawing a pivotal conclusion on efficacy from these data was ultimately confounded by the pre-specified missing data imputation plan and unexpected period and sequence effects in the cross-over design.

In the third study, J3 Bioscience further evaluated the efficacy of VR101 Lubricating Intravaginal Ring as a personal lubricant device in clinical investigation titled *CI03: A Clinical Investigation to Evaluate Efficacy of the J3 Bioscience Lubricating Intravaginal Ring VR101 as a Personal Lubricant Device in Women*. The study was a double-blind, two-site, randomized, sham-controlled trial conducted in the United States. In this study, the efficacy of VR101 Lubricating Intravaginal Ring to meet the intended use was successfully demonstrated by a statistically significant improvement in the lubrication domain of the female sexual function index (FSFI) when compared to a sham, non-lubricating ring. The study enrolled 175 participants, with 166 (94.9%) completing the study. There were 87 participants in the treatment group and 88 in the sham group.

Demographics

The tables below provide summaries of clinical investigations CI01, CI02, and CI03 participant demographics, menopausal status, and race/ethnicity representation.

VR101 Lubricating Intravaginal Ring Clinical Investigation (CI01, CI02, CI03) Baseline Participant Demographics			
	Age (Years)	**Height (Inches)**	**Weight (Pounds)**
CI01			
Minimum	38	59	105
Maximum	70	69	240
Mean	55.3	64.1	161.2
CI02			
Minimum	36	59	113
Maximum	79	69	350
Mean	59.2	64.4	178.1
CI03			
Minimum	21	57	84
Maximum	76	74	290
Mean	49.3	65.0	180.6

VR101 Lubricating Intravaginal Ring Clinical Investigation (CI01, CI02, and CI03) Menopausal Status			
	CI01 (N=21)	**CI02 (N=72*)**	**CI03 (N=175*)**
Pre-Menopausal	0/21	1/72	51/175
Peri-Menopausal	21/21	71/72	15/175
Post-Menopausal			109/175
Other	0/21	0/72	0/175
*includes both VR101 Lubricating Intravaginal Ring and Sham			

VR101 Lubricating Intravaginal Ring Clinical Investigation (CI01, CI02, and CI03) Race/Ethnicity Representation	
Participant-Reported Race/Ethnicity	**Number**
CI01 Race/Ethnicity	
White	19/21
Not Latina/Hispanic	18/19
Latina/Hispanic	1/19
White and Native American	1/21
Black/African-American	1/21
Not Latina/Hispanic	1/1
Latina/Hispanic	0/1
CI02 Race/Ethnicity	
Caucasian/White	70/72
Not Latina/Hispanic	63/70
Latina/Hispanic	7/70
Black/African-American	2/72

Not Latina/Hispanic	2/2
Latina/Hispanic	0/2
CI03 Race/Ethnicity	
Caucasian/White	170/175
Latina/Hispanic	10/170
Not Latina/Hispanic	160/170
Native Hawaiian/Other	1/175
Black/African-American	2/175
Latina/Hispanic	1/2
Not Latina/Hispanic	1/2
Asian	2/175

Effectiveness:
The primary efficacy hypothesis in the CI03 study was defined as follows: Compared to the sham device, a significantly greater proportion of participants who use VR101 for 4 consecutive weeks will experience increased vaginal lubrication that enhances ease and comfort of intimate sexual activity as assessed by the Lubrication domain of the FSFI (FSFI-LD > 4.5). The study results support the primary endpoint was met ($p = 0.02$).

Safety:
Adverse event data collected in CI03 support the prior conclusions from CI02 that VR101 Lubricating Intravaginal Ring is safe for its intended use. In the CI03 study, there were 95 adverse events reported, none of which were serious. Of the 95 adverse events, 36 were determined to be unrelated to the device. The most common adverse events reported in the study (including both VR101 Lubricating Intravaginal Ring and Sham) were excess vaginal secretions (17), pelvic cramping (14), vaginal pain/discomfort (5), and non-menstrual bleeding (5). There were also reports of urinary tract/bladder infection (3), vaginal irritation/vaginitis (2), and yeast infection (2). All adverse events in CI03 were rated as Mild or Moderate.

In summary, VR101 Lubricating Intravaginal Ring clinical results demonstrate that VR101 Lubricating Intravaginal Ring is safe and effective for the intended use and support substantial equivalence of safety and efficacy to the predicate device, Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators).

Summary of Substantial Equivalence	VR101 Lubricating Intravaginal Ring has the same intended use as the predicate device, Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators) - (K101241), and although it has some different technological characteristics, they do not raise different questions of safety or efficacy. Performance data support that the VR101 Lubricating Intravaginal Ring is as safe and effective as the predicate device. The subject device, VR101 Lubricating Intravaginal Ring, is substantially equivalent to its predicate device, Replens® Long-Lasting Vaginal Moisturizer (Pre-filled Applicators) (K101241).