July 23, 2020

Church & Dwight Co., Inc.
Joelle Reinson
Senior Regulatory Affairs Specialist
500 Charles Ewing Boulevard
Ewing, NJ 08628

Re: K193450
Trade/Device Name: Pre-Seed™ Fertility Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: PEB
Dated: June 25, 2020
Received: June 26, 2020

Dear Joelle Reinson:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193450

Device Name
Pre-Seed™ Fertility Lubricant

Indications for Use *(Describe)*
Pre-Seed™ Fertility Lubricant is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Pre-Seed™ Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. It is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

Pre-Seed™ Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

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.

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"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 - K193450

Submitter Name: Church & Dwight Co., Inc.

Submitter Address: 500 Charles Ewing Boulevard
Ewing, NJ 08628

Contact Person: Joelle Reinson
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Princeton, NJ 08543
Tel: (609) 806.1671
Fax: (609) 403.7415

Date Prepared: July 23, 2020

Device Trade Name: Pre-Seed™ Fertility Lubricant
Device Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: PEB (lubricant, personal, gamete, fertilization, and embryo compatible)

Predicate Device: K072741: Pre~Va Vaginal Lubricant

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

Description of Device:

Pre-Seed™ Fertility Lubricant is a non-sterile, water-based personal lubricant formulated to supplement the body's own natural lubrication. The product is also compatible with sperm, oocytes, and embryos, can be used by trying to conceive couples, and can also be used to lubricate diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

Pre-Seed™ Fertility Lubricant is packaged in a High-Density Polyethylene tube with a Polypropylene closure. A foil seal is present over the tube opening under the cap closure. The product is provided with single-use, piston type, Low Density Polyethylene applicators for delivering the product to the vagina.

Table 1: Specifications for Pre-Seed™ Fertility Lubricant

Specification	Recommended Acceptance Criteria
Appearance/Color	Hazy, colorless to slightly yellow, viscous liquid
Odor	Characteristic, no off odor (25 °C ± 2)

pH	7.0-7.4
Osmolality	260-370 mOsm/kg
Viscosity	2800-11500 cps
Total Aerobic Microbial Count (TAMC)- USP <61> and <1111>	<100 cfu/g
Total Yeast & Mold Count (TYMC)- USP<61> and <1111>	<10 cfu/g
Absence of Pathogenic organisms (*P. aeruginosa, S. aureus, E. coli, Salmonella sp. and C. albicans)* - USP <62>	Absent
Antimicrobial Effectiveness USP<51>	Bacteria- Not less than 2.0 log reduction from the initial count at 14 days. No increase from 14 days count to 28 days. Yeast & Mold- not increase from the initial calculated count at 14 and 28 days.
Endotoxin	<0.7 EU/mL
Human Sperm Survival Assay (HSSA)	HSSA: ≥ 80 of control motility at 24 hours after 30 minutes exposure to 10% of subject lubricant.

Indication for Use:

Pre-Seed™ Fertility Lubricant is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Pre-Seed™ Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. It is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

Pre-Seed™ Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.

Table 2. Comparator Table for Subject Device and Predicate Device

Device & Predicate Device(s):	K193450 Subject Device	K072741 Predicate Device	Comments
Sponsor	Church & Dwight	INGfertility, LLC	NA
Regulation Number Product Code Device Class	884.5300 PEB II	884.5300 PEB II	Same
Indications for Use	Pre-Seed™ Fertility Lubricant is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and	To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied	Same intended use

	supplement the body's natural lubrication. Pre-Seed™ Fertility Lubricant is compatible with sperm, oocytes, and embryos and can be used by trying to conceive couples. It is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. Pre-Seed™ Fertility Lubricant can be used to lubricate genital tissues and devices to facilitate use of diagnostic and therapeutic devices during fertility interventions and reproductive medicine.	directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions. As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be appied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condom.	
Condom Compatibility	Natural rubber latex and polyisoprene	Natural rubber latex and polyurethane	Different
Base Type	Water	Water	Same
Primary Ingredients	Water Hydroxyethylcellulose SymOcide PH Pluronic F-127 Sodium Chloride Dibasic Sodium Phosphate Anhydrous Carbopol 934P Sodium Hydroxide Arabinogalactan Potassium Phosphate Monobasic	Water Hydroxyethylcellulose Pluronic 127 Sodium Chloride Arabinogalactan Sodium Phosphate Carbopol 934P Methylparaben Sodium Hydroxide Potassium Phosphate	Different
Appearance	Hazy, colorless to slightly yellow viscous liquid	Not provided	Different
Odor	Characteristic, no off odor	Not provided	Different

Viscosity	2800-11500 cps	8500-12000 cps	Different
pH	7.0-7.4	7.20-7.45	Different
Osmolality	260-370 mOsm/kg	260-360 mOsm/kg	Similar
Total Microbial Count	<100 cfu/g	<100 cfu/g	Same
Fungal/Yeast/Mold Limits	<10 cfu/g	<10 cfu/g	Same
Absence of Pathogenic organism	Absent	Absent	Same
Antimicrobial effectiveness per USP <51> and <1112>	Bacteria: Not less than 2.0 log reduction from the initial count at 14 days. No increase from 14 days' count 28 days. Yeast & Mold: No increase from the initial calculated count at 14 and 28 days.	Bacteria: Not less than 2.0 log reduction from the initial count at 14 days. No increase from 14 days' count 28 days. Yeast & Mold: No increase from the initial calculated count at 14 and 28 days.	Same
Endotoxin	<0.7 EU/mL	<0.5 Eu/ml	Different
HSSA	HSSA: motility ≥ 80 of control motility at 24 hours after 30 minutes exposure to 10% lubricant	Sperm motility following 30-minutes incubation with 10% diluted lubricant solution equals >80% of sperm motility in control medium	Same
Shelf-life	22 months	2 years	Different
OTC use	Yes	Yes	Same

The subject and predicate devices do not have identical indications for use statements; however, these differences do not alter the intended use of the subject device, which is identical to the predicate device.

As noted in the table, the subject and predicate device have different technological characteristics, including different formulations, condom compatibility, specifications (e.g., endotoxin, appearance, odor, pH, viscosity, etc.). The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

Performance Data:

As part of demonstrating substantial equivalence to the predicate device, the following non-clinical performance tests were conducted:

Biocompatibility:

Pre-Seed™ Fertility Lubricant underwent biocompatibility testing including cytotoxicity per ISO 10993-5:2009, vaginal irritation per ISO 10993-10:2010, guinea pig maximization sensitization per ISO 10993-10:2010 and acute systemic toxicity per ISO 10993-11:2006. The testing demonstrated that the Pre-Seed™ Fertility Lubricant is biocompatible.

Non-clinical Performance Testing.

Human sperm survival assay (HSSA), and lubricant barrier assay testing was conducted and indicates that Pre-Seed™ Fertility Lubricant is compatible with sperm and does not inhibit sperm motility.

Condom Compatibility:

Pre-Seed™ Fertility Lubricant was tested for condom compatibility per ASTM D7661-10: *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results of this test indicate that Pre-Seed™ Fertility Lubricant is compatible with natural rubber latex and polyisoprene condoms. Pre-Seed™ Fertility Lubricant is not compatible with polyurethane condoms.

Shelf-Life:

Pre-Seed™ Fertility Lubricant has a 22-month shelf-life based on the results from accelerated and real-time stability testing. The results of accelerated aging shelf-life testing demonstrated that Pre-Seed™ Fertility Lubricant maintains its specifications for appearance/color, odor, pH, osmolality, viscosity, TAMC, TYMC, absence of pathogenic organisms, antimicrobial effectiveness, endotoxins, HSSA, and lubricant barrier testing over the duration of its proposed shelf-life of 22 months.

Substantial Equivalence:

The results of performance testing described above demonstrate that the Pre-Seed™ Fertility Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.