January 8, 2021

XR, LLC
% Louie Goryoka
Sr. QA/RA Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K202017
Trade/Device Name: Passion Natural Water Based Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 25, 2020
Received: December 1, 2020

Dear Louie Goryoka:

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)*
K202017

Device Name
Passion Natural Water Based Lubricant

Indications for Use *(Describe)*
Passion Natural Water Based 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. This product is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane 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.

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510(K) SUMMARY
K202017
Passion Natural Water Based Lubricant

I. Submitter Information

Applicant: XR LLC.
Company Address: 5251 PIPELINE LANE
HUNTINGTON BEACH, CA 92649

Company Phone: (714) 907-1034
Company Contact: Gerardo Ramos

Contact Person: Louie Goryoka
Sr. Regulatory and Quality Consultant
Med-Device Consulting, Inc.
Email: mdci@m-dci.us
(818) 585-7488

II. Date Prepared: January 7, 2021

III. Device Information

Trade name: Passion Natural Water Based Lubricant
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC (lubricant, personal)

IV. Predicate Device:

Pulse H20h!
510(k) number: K152628

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

V. Device Description

The Passion Natural Water Based Lubricant is a non-sterile, water-based personal lubricant that is intended for penile and vaginal application 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 polyisoprene condoms, and is not compatible with natural rubber latex and polyurethane condoms. Its formulation consists of purified water, propanediol, xanthan gum, methocel, sodium benzoate, potassium sorbate, citric acid, and hydroxyethylcellulose. Passion Natural Water Based Lubricant is packaged in 4 oz polyethylene terephthalate bottles with a cap. Passion Natural Water Based Lubricant is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in the Table below

Property	Specification
Appearance	Clear, viscous liquid
Color	Colorless
Odor	Odorless
Viscosity@25°C Spindle LV#3hu@60rpm (cps)	700 cps – 900 cps
Specific Gravity@25°C	1.00 – 1.20
pH	4.0 – 5.0

Osmolality	92.5 – 192.5 mOsm/kg (1:10 dilution)
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<100 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Presence of Pathogenic organisms (*Staphylococcus aureus, Pseudomonas aeruginosa,* and *Candida albicans* per USP <62>)	Absent

VI. Indications for Use

Passion Natural Water Based 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. This product is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane condoms.

VII. Predicate Device Comparison

A comparison of the indications for use an technological characteristics of the subject and predicate device is summarized in the table below:

Characteristic/Feature	**Passion Natural Water Based Lubricant (K202017)**	**Pulse H20h! (K152628)**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Product Code	NUC	NUC
Indications for Use	Passion Natural Water Based 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. This product is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane condoms.	The Pulse H2Oh! Personal lubricant is intended for vaginal and/or penile application to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This personal lubricant is compatible with naural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Water Soluble	Yes	Yes
Contains water	Yes	Yes

Primary ingredients	Purified Water, Propanediol, Xanthan Gum, Methocel, Sodium Benzoate, Potassium Sorbate, Citric Acid, Hydroxyethylcellulose (HEC).	Purified water, Propanediol/Zemea Propanediol, Hydroxyethylcellulose/Natrosol 250H Pharm, Potassium Sorbate, Chia Seed Extract, Citric Acid.
Over-the-Counter Use	Yes	Yes
Labeled condom compatible	Yes	Yes
Condom Compatibility	Polyisoprene	Natural Rubber Latex, Polyisoprene
Biocompatibility Tested	Yes	Yes
pH	4.0 – 5.0	4.8 – 5.2
Osmolality	92.5 mOsm – 192.5 mOsm (1:10 dilution)	Tested – specification not stated in predicate summary
Microbial Limits	• Total mold/yeast count <10 cfu/g • Total aerobic microbial count <100 cfu/g • Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Parameters Tested – specifications not stated in predicate summary
Antimicrobial Effectiveness Tested (USP <51> Category 2 Product)	Yes	Yes
Viscosity	700 cps – 900 cps	Tested – specification not stated in predicate summary
The product is not a contraceptive and does not contain spermicide	Yes	Yes
Non-Sterile	Yes	Yes
Shelf life	8.5 months	2 years

The subject and predicate device have similar indications for use and have the same intended use (i.e., provides lubrication during intimate sexual activity). The subject and predicate device have different technological characteristics, including different formulations, specifications (e.g., pH, etc.), and shelf-life. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness as compared to the predicate device.

VIII. Summary of Non-Clinical Performance Testing

Biocompatibility

Passion Natural Water Based Lubricant has undergone biocompatibility testing in accordance with the 2020 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." Testing included:

- Cytotoxicity (ISO Direct Contact Method, ISO 10993-5:2009)
- Sensitization (ISO Guinea Pig Maximization Sensitization, ISO 10993-10:2010)
- Vaginal Irritation (ISO Vaginal Irritation Study in Rabbits, ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO Tests for Systemic Toxicity, ISO 10993-11:2017)

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating, and non-systemically toxic.

Condom Compatibility

Passion Natural Water Based Lubricant was tested in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." Results showed that Passion Natural Water Based Lubricant is compatible with polyisoprene condoms. This product is not compatible with natural rubber latex and polyurethane condoms.

Shelf Life Testing

Passion Natural Water Based Lubricant has a shelf-life of 8.5 months, according to the results of an accelerated aging study per ASTM F1980-16. All device specifications listed in **Section V. Device Description** of this summary were evaluated in the shelf-life study. The subject device met the device specificaitons at all time points.

IX. Conclusion

The results of performance testing described above demonstrate that the Passion Natural Water Based Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.