January 30, 2023

Playground For All
Sandy Vukovic
Official Correspondent
4645 California Street
San Francisco, CA 94118

Re: K222567
Trade/Device Name: Playground For All Love Sesh
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 29, 2022
Received: December 29, 2022

Dear Sandy Vukovic:

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,

Monica D. Garcia -S

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)*
K222567

Device Name
Playground For All Love Sesh

Indications for Use *(Describe)*
Playground For All Love Sesh 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 natural rubber latex and polyisoprene condoms. This product is not compatible with 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.

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
K222567
Playground For All Love Sesh

1. **Submitter Information**

Applicant: Playground For All
Contact: Sandy Vukovic
Official Correspondent
Address: 4645 California Street, San Francisco, CA 94118 USA
Phone: (650) 246-9653
Email: sandy@helloplayground.com

2. **Date prepared:** January 25, 2023

3. **Subject Device Information**

Device Trade Name: Playground For All Love Sesh
Common Name: Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Product Code: NUC (lubricant, personal)
Device Class: Class II

4. **Predicate Device Information**

Device Name: Medley
510(k) Number: K212000
Manufacturer: Good Clean Love, Inc

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

5. **Device Description**

Playground For All Love Sesh is a non-sterile, unscented, water-based personal lubricant that provides lubrication during intimate sexual activity. The subject device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms.

Its formulation consists of Water, Glycerin, Propanediol, Bamboo Bioferment PF, Sodium Hyaluronate, CMC Cellulose, Citric Acid, Carubba Blend, Tocopheryl Acetate, Sodium Benzoate, Potassium Sorbate

Playground For All Love Sesh is for over-the-counter (OTC) use and is offered in 3.7 fl. oz PET bottles and 0.17 fl. oz PET/Foil packettes.

Device specifications for the Playground For All Love Sesh are listed in Table 1 below.

Table 1: Device Specifications for Playground For All Love Sesh

Property	Specification
Appearance	Gel
Color	Clear to hazy white cream

Odor	Characteristic
Viscosity (per USP<912>)	1000 – 6000 cps
pH (per USP<791>)	4.0 – 5.5
Osmolality (per USP<785>)	2000 – 6000 mOsm/kg
Total Aerobic Microbial Count (TAMC, per USP <61>)	<100 cfu/g
Total Yeast and Mold Count (TYMC, per USP <61>)	<10 cfu/g
Presence of Pathogens (per USP <62>)	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli	Absent
Salmonella/Shigella	Absent
Antimicrobial Effectiveness Testing (per USP <51>)	**Specification**
Bacteria	Meets USP <51> criteria for category 2. No less than 2.0 log reduction from initial count at 14 days and no increase from the 14-day count at 28 days
Yeast and Molds	No increase from the initial calculated count at 14 and 28 days

6. Indications for Use

Playground For All Love Sesh 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 natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

7. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Intended Use and Technological Characteristics Comparison of the Subject and Predicate Device

	Playground For All Love Sesh K222567 Subject Device	**Medley K212000 Predicate Device**
Indications for Use	Playground For All Love Sesh 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 natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Medley 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 natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

Base type	Water	Water
Primary ingredients	Water, Glycerin, Propanediol, Bamboo Bioferment PF, Sodium Hyaluronate, CMC Cellulose, Citric Acid, Carubba Blend, Tocopheryl Acetate, Sodium Benzoate, Potassium Sorbate	Water, Hydroxyethylcellulose, Xanthan Gum, Hyaluronic Acid, Zemea Propanediol, Glycerin Water, Dimethicone, Hydrogenated Lecithin, Sodium Benzoate, Potassium Sorbae, DL Lactic Acid
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance	Gel, Clear to hazy white cream	Gel, Colorless to Yellow and Cloudy
Odor	Characteristic	Characteristic
Viscosity per USP <912>	1000 – 6000 cps	12500 – 25000 cps
pH per USP <791>	4.0 – 5.5	3.5 – 4.0
Osmolality per USP <785>	2000 – 6000 mOsm/Kg	250 – 400 mOsm/kg
Total Aerobic Microbial count (TAMC) per USP <61>	<100 cfu/g	<10 cfu/g
Total Yeast and Mold Count (TYMC) per USP <61>	<10 cfu/g	<10 cfu/g
Absence of Pathogenic Organisms per USP <62>	Yes	Yes
Antimicrobial Effectiveness Tested per USP <51>	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex and polyisoprene condoms
Biocompatibility Tested	Yes	Yes

The subject and predicate device have similar indications for use and the same intended use – to provide lubrication for intimate sexual activity. The subject and predicate device have different technological characteristics, including different formulations, and specifications for appearance, TAMC, viscosity, pH, and osmolality. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing was performed 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."* The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non-irritating, non-sensitizing,

and not acutely, systemically toxic.

Shelf-Life

The subject device has a shelf-life of 6 months. Results from real-time testing demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

The compatibility of Playground For All Love Sesh with condoms was evaluated in accordance with ASTM D7661-10(R) 2017 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." The results of this test showed Playground For All Love Sesh is compatible with natural rubber latex and polyisoprene condoms. Results showed Playground For All Love Sesh is not compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Playground For All Love Sesh is as safe and effective as the predicate device and supports a determination of substantial equivalence.