July 11, 2023

InnoveMed Bio-tech Co., Ltd.
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, NJ 07436

Re: K221137
Trade/Device Name: Play and Joy Water-Based Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 8, 2023
Received: June 9, 2023

Dear Charles Shen:

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,
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Office of Product Evaluation and Quality
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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)*
K221137

Device Name
Play and Joy Water-Based Lubricant

Indications for Use *(Describe)*
Play and Joy Water-Based Lubricant is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, 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, polyurethane, and polyisoprene 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.

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510(k) Summary
K221137
Play and Joy Water-Based Lubricant

1 Submitter Information:

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2 Submission Correspondent:

Charles Shen
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Tel: 608-217-9358
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3 Date of Summary: July 6, 2023

4 Subject Device Information:

Proprietary Name:	Play and Joy Water-Based Lubricant
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (lubricant, personal)
Device Class:	Class II

5 Predicate Device Information:

K203654, Solvey Co. LLC Water-Based Lubricant

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

6 Device Descriptions

Play and Joy Water-Based Lubricant is a non-sterile, clear, semi-viscous water-based personal lubricant that provides lubrication during intimate sexual activity. The subject device is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Its formulation consists of water, xantham gum, glycerine, Chondrus crispus extract, sodium hyaluronate, saccharide isomerate, hydroxyethylcellulose, citric acid, sodium citrate, lactic acid, 1,2-pentanediol, phenoxyethanol, iodopropynyl butylcarbamate, hydroxyacetophenone, gluconolactone, and sodium benzoate.

Play and Joy Water-Based Lubricant is for over-the-counter use and is provided in volumes of 50 mL and 100 mL in polyethylene tubes closed with polypropylene caps.

Device specifications for the Play and Joy Water-Based Lubricant are listed in Table 1.

Table 1: Device specifications for Play and Joy Water-Based Lubricant

Physical Specification	Specifications
Appearance	Clear, semi-viscous liquid
Color	Colorless
Odor	Odorless
PH@25° C (per USP <791>	4.92-5.38
Viscosity (cps, per USP <912>)	1727-3463 cps
Specific Gravity (per USP <841>)	1.04-1.08
Osmolality (mOsm/Kg, per USP <785>)	(944-984) mOsm/kg
Antimicrobial effectiveness (per USP <51>)	Category 2 product: 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
Total yeast and mold count (TYMC, per USP <61>)	<10 cfu/g
Total aerobic microbial count (TAMC, per USP <61>)	<100 cfu/g
Absence of Pathogenic Organisms (*P. aeruginosa, S. aureus, Salmonella/Shigella, E. coli, and C. albicans)*	Absent

7 Indications for Use:

Play and Joy Water-Based Lubricant is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, 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, polyurethane, and polyisoprene condoms.

8 Comparison of Intended Use and Technological Characteristics with the Predicate Device

Table 2 below compares the intended use and technological characteristics of the subject and predicate device.

Table 2: Intended Use and Technological Characteristics Comparison

Characteristics	Subject device (K221137)	Predicate device (K203654)	Comparison
Device Name	Play and Joy Water-Based Lubricant	Solevy Co. LLC Water-Based Lubricant	N/A
Device Model	50 mL and 100 mL (1.7/3.4 fl. Oz)	1, 2.5, 4.5, 8, and 16 fl. oz	N/A
Manufacturer	InnoveMed Bio-tech Co., Ltd	Solevy Co. LLC	N/A
Indications for Use	Play and Joy Water-Based Lubricant is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, 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, polyurethane, and polyisoprene condoms.	Solevy Co. LLC Water-Based Lubricant is a water-based personal lubricant, for penile and/or vaginal application, intended to lubricate and moisturize, 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, polyurethane, and polyisoprene condoms.	The indications for use and intended use of the subject and predicate devices are the same.
Base type	Water-based	Water-based	Same
Rx/OTC	OTC	OTC	Same
Sterile	No	No	Same
Ingredients	Water (Aqua) Xantham gum Glycerine Chondrus crispus extract Sodium hyaluronate Saccharide isomerate Hydroxyethylcellulose Citric acid Sodium citrate Lactic acid 1,2-pentanediol Phenoxyethanol Iodopropynyl butylcarbamate Hydroxyacetophenone Gluconolactone Sodium benzoate	Glycerin Water Cellulose gum Methylparaben Propylparaben	**Different:** There are differences in the subject and predicate device formulations. These differences in device formulations do not raise different questions of safety and effectiveness (S&E).
Appearance	Clear, semi-viscous liquid	Clear, semi-viscous liquid	Same
Color	Colorless	Colorless	Same
Odor	Odorless	Odorless	Same
PH@25° C	4.92-5.38	6.0-7.0	**Different:** The pH for the subject device is lower than the predicate device. This difference in pH

			does not raise different questions of S&E.
Viscosity	1727-3463 cps	1,200 - 1,800 cps	**Different:** The viscosity range for the subject device is wider than the predicate device. This difference does not raise different questions of S&E.
Specific Gravity	1.04-1.08	1.12- 1.20	Similar
Osmolality	944-984 mOsm/kg	750 – 950 mOsm/kg	**Different:** The osmolality of the subject device is higher than the predicate device. This difference does not raise different questions of S&E.
Antimicrobial Effectiveness Tested per USP<62>	Yes	Yes	Same
Total yeast and mold (TYMC)	<10 cfu/g	<10 cfu/g	Same
Total aerobic microbial count (TAMC)	<100 cfu/g	<100 cfu/g	Same
Absence of Pathogenic Organisms per USP <62>	Yes	Yes	Same
Condom Compatibility	Compatible with natural rubber latex, polyurethane, and polyisoprene condoms	Compatible with natural rubber latex, polyurethane, and polyisoprene condoms	Same
Biocompatibility Tested	Yes	Yes	Same
Shelf life	6 months	36 months	**Different:** The shelf-life for the subject device is less than the predicate device. This difference does not raise different questions of S&E.

The subject device and predicate device have the same indications for use and intended use. As shown in the table, there are differences in the technological characteristics of the subject and

predicate devices, including formulation, specifications (pH, viscosity, and osmolality), and device shelf-life. These differences in technological characteristics do not raise different questions of safety and effectiveness.

9 Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies were performed in accordance with the 2020 FDA guidance *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:

a. Cytotoxicity (ISO 10993-5:2009)
b. Sensitization (ISO 10993-10:2010)
c. Vaginal Irritation (ISO 10993-10:2010)
d. Acute 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:

The compatibility of the subject devices with natural rubber latex, polyisoprene and polyurethane 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 testing demonstrated that the Play and Joy Water-Based Lubricant is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf Life:

The subject device has a shelf-life of 6 months based on the results of an accelerated aging study. The shelf-life study evaluated all device specifications listed in Table 1, Device Specifications. The subject device met all device specifications over the stated shelf-life duration.

10 Conclusions

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