July 10, 2023

InnoveMed Bio-tech Co., Ltd.
Elsa Li
Regulatory Consultant
6F, No. 184, Sec. 2, Chongqing N. Rd., Datong Dist.
Taipei City, 10357
Taiwan

Re: K220646
Trade/Device Name: Play & Joy InvisiLube Lubricant Capsule
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 9, 2023
Received: June 9, 2023

Dear Elsa Li:

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220646

Device Name
Play & Joy InvisiLube Lubricant Capsule

Indications for Use *(Describe)*
Play & Joy InvisiLube Lubricant Capsule is a personal lubricant for over-the counter use, 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, polyisoprene, 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.

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510(k)Summary
K220646
Play & Joy InvisiLube Lubricant Capsule

1. Submitter Information

Applicant: InnoveMed Bio-tech Co., Ltd.
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2. Correspondent Information

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Shenzhen, China 518132
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3. Date prepared: July 10, 2023

4. Device Information

Device Name:	Play & Joy InvisiLube Lubricant Capsule
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (lubricant, personal)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	K-Y Brand Liquibeads
510(k) Number:	K122061
Manufacturer:	Johnson & Johnson Healthcare Products

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

6. Device Description

Play & Joy InvisiLube Lubricant Capsule is a personal lubricant for over-the counter use, 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. Play & Joy InvisiLube Lubricant Capsule is a non-sterile, anhydrous silicone inner component encapsulated with a gelatin shell. It is compatible with natural rubber latex, polyisoprene, and polyurethane condoms. The inner component is composed of a blend of silicone with primary ingredients: Cyclopentasiloxane, Dimethiconol, and Dimethicone. The gelatin shell is composed of gelatin, glycerin, Phatic acid, and water.

Device specifications are listed in Table 1 below.

Table 1: Device Specifications for Play & Joy InvisiLube Lubricant Capsule

Property	**Specification**
Appearance	Colorless
Color	Clear
Odor	Odorless
Viscosity	75 – 201 cps
Total Aerobic Microbial Count (TAMC, per USP <61>)	<100cfu/g
Total Yeast and Mold Count (TYMC, per USP <61>)	<10cfu/g
Water Activity	<0.3 Aw
Presence of Pathogens (per USP <62>)	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Escherichia coli	Absent
Salmonella	Absent

7. Indications for Use

Play & Joy InvisiLube Lubricant Capsule is a personal lubricant for over-the counter use, 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, polyisoprene, and polyurethane condoms

8. 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: Comparator Table for Subject and Predicate Device

	Play & Joy InvisiLube Lubricant Capsule K220646 Subject Device	**K-Y Brand Liquibeads K122061 Predicate Device**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Indications for Use	Play & Joy InvisiLube Lubricant Capsule is a personal lubricant for over-the counter use, 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, polyisoprene, and polyurethane condoms	K-y(r) brand liquibeads(r) vaginal moisturizer is a personal lubricant for over-the-counter use, 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, polyisoprene, and polyurethane

		condoms. The product is delivered by an applicator.
Base type	Silicone	Silicone
Primary ingredients	Dimethicone, Dimethiconol, Cyclopentasiloxane, Glycerin, Gelatin, Phatic Acid, Water	Dimethicone, gelatin, glycerin, water
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance/color	Colorless	Colorless
Odor	Odorless	Odorless
Viscosity	75-201 cps	Not Specified
Total Aerobic Microbial count (TAMC)	<100 cfu/g	<100 cfu/g
Total Yeast and Mold Count (TYMC)	<10 cfu/g	<10 cfu/g
Absence of Pathogenic Organisms	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex, polyisoprene, and polyurethane condoms	Compatible with natural rubber latex, and polyisoprene condoms
Biocompatibility Tested	Yes	Yes
Shelf life	6 months	36 months

The subject and predicate device indications for use are similar and their intended uses are the same (i.e., provide lubrication during intimate sexual activity). The subject and predicate device have different technological characteristics, including formulation, condom compatibility, and shelf-life duration. 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 studies were performed in accordance with the 2020FDA 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 (ISO10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of testing demonstrate that the subject device is non-cytotoxic, non-sensitizing, non-irritation, and not systemically toxic.

Shelf-Life

The subject device has a shelf-life of 6 months. Results from accelerated aging per ASTM 1980-16

demonstrated that the device maintains its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

The compatibility of Play & Joy InvisiLube Lubricant Capsule 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 Play & Joy InvisiLube Lubricant Capsule to be compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Play & Joy InvisiLube Lubricant Capsule is as safe and effective as the predicate device and supports a determination of substantial equivalence.