November 23, 2021

Thai Nippon Rubber Industry Public Company Limited
℅ Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, CO 80127

Re: K210095
Trade/Device Name: Playboy Premium Silicone Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 23, 2021
Received: October 26, 2021

Dear Kevin Walls:

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)*
K210095

Device Name
Playboy Premium Silicone Lubricant

Indications for Use *(Describe)*
Playboy Premium Silicone Lubricant is indicated for penile, vaginal and/or anal 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
K210095
Playboy Premium Silicone Lubricant

1. Submitter Information

Applicant: Thai Nippon Rubber Industry Public Company Limited
Contact: Tossaporn Nilkhamhang,
Address: 789/139 Moo 1 Pinthong Industrial Estate
Nongkham Sriracha Chonburi 20110
Thailand
Phone: (+66-38-317999)

2. Correspondent Information

Company: Regulatory Insight
Contact: Kevin Walls
Phone: (720) 962-5412
Email: kevin@reginsight.com

3. Date prepared: November 22, 2021

4. Device Information

Device Name:	Playboy Premium Silicone Lubricant
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 Silicone
510(k) Number:	K173504
Manufacturer:	Reckitt Benckiser LLC

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

6. Device Description

Playboy Premium Silicone Lubricant is a non-sterile, silicone-based personal lubricant for penile, anal, 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 device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists of dimethicone. Playboy Premium Silicone Lubricant is sold as an over-the-counter (OTC) product and is provided in 88.7 mL LDPE bottles.

Device specifications are listed in Table 1 below.

Table 1: Device Specifications for Playboy Premium Silicone Lubricant

Property	**Specification**
Appearance	Clear, free from suspended matter and sediment
Color	Clear
Odor	Odorless
Viscosity	315 – 385 cps
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	Absent

7. Indications for Use

Playboy Premium Silicone Lubricant is indicated for penile, vaginal and/or anal 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.

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

	Playboy Premium Silicone Lubricant K210095 Subject Device	**K-Y Silicone K173504 Predicate Device**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Indications for Use	Playboy Premium Silicone Lubricant is indicated for penile, vaginal and/or anal 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.	K-Y® Silicone is indicated for penile, vaginal, and/or anal 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.
Base type	Silicone	Silicone

Primary ingredients	Dimethicone	Dimethicone
Rx/OTC	OTC	OTC
Sterile	No	No
Appearance/color	Clear, free from suspended matter and sediment	Colorless
Odor	Odorless	Odorless
Viscosity	315-385 cps	80-110 cps
Total Aerobic Microbial count (TAMC)	<100 cfu/g	<100 cfu/g
Total Yeast and Mold Count (TYMC)	<10 cfu/g	Absent
Absence of Pathogenic Organisms	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex, polyisoprene, and polyurethane condoms
Biocompatibility Tested	Yes	Yes
Shelf life	36 months	24 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 appearance, viscosity, and TYMC specifications, 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 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 support the biocompatibility of the device materials.

Shelf-Life

The subject device has a shelf-life of 36 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 Playboy Premium Silicone Lubricant 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 Playboy Premium Silicone Lubricant to be compatible with natural rubber latex and polyisoprene condoms. Results showed Playboy Premium Silicone Lubricant not to be compatible with polyurethane condoms.

10. Conclusion

The results of the performance testing described above demonstrate that Playboy Premium Silicone Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.