March 1, 2022

RB Health (US)
Lisa Burns
Sr. Manager Regulatory Affairs
399 Interpace Parkway
Parsippany, NJ 07054

Re: K213400
Trade/Device Name: Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, Grosz Play Strawberry
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 19, 2022
Received: January 27, 2022

Dear Lisa Burns:

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, 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)*
K213400

Device Name
Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, Grosz Play Strawberry

Indications for Use *(Describe)*
Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry are personal lubricants intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. They are compatible with natural rubber latex and polyisoprene condoms. They are 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.

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510K Summary
K213400

Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, Grosz Play Strawberry

Submitted by: RB Health (US) LLC
399 Interpace Parkway
Parsippany NJ 07054-0224
973-404-2715

Contact Person: Lisa Burns
Regulatory Sr.
Manager RB
Health (US) LLC
862-325-0012

Date Prepared: February 25, 2022

Device/Trade Name: Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, Grosz Play Strawberry

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Product Code: NUC (Lubricant, Personal)

Regulatory Class: II

Predicate Device(s):
Device Name: Grosz Play Feel
Manufacturer: RB Health (US) LLC
510(k) Number: K211088

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

Description of the Device:

Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry are water-based personal lubricants intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The products are compatible with natural rubber latex and polyisoprene condoms. The products are not compatible with polyurethane condoms. They are for over-the-counter (OTC) use. The formula consists of water, propylene glycol, xanthan gum, carbomer, benzoic acid, sodium hydroxide, sodium saccharin and flavor. Grosz Play Aloe, Grosz Play Ylang, and Grosz Play Guarana are packaged in a 200 mL polyethylene terephthalate (PET) bottle fitted with a polypropylene (PP) cap. Grosz Play Cherry and Grosz Play Strawberry are packaged in a 50 mL high density polyethylene (HDPE) bottle fitted with a polypropylene (PP) cap. The bottle and cap feature a tamper evident shrink seal label. The

individual bottles may be packaged in an outer cardboard carton.

Subject Device Specifications:

Specification	**ALOE**	**YLANG**	**GUARANA**	**CHERRY**	**STRAW-BERRY**
Appearance	Clear to slightly translucent, colourless to slightly yellow colour homogeneous gel and free from particulate matter			Colorless, transparent gel, free from lumps and particulate matter	
Odor	No objectional odor			Characteristic of cherry	Characteristic of strawberry
Viscosity (cps)	3,300 – 10,000			3,400 – 10,000	
Osmolality (mOsm/kg)	695 – 1,095	720 – 1,120	710 – 1,110	683-1,083	742 – 1,143
Benzoic Acid	0.15 – 0.22 %w/w				
pH at 25ºC	3.5 - 4.5				
Total Yeast and Mold Count (TYMC)*	< 10 cfu/g				
Total Aerobic Microbial Count (TAMC)*	< 100 cfu/g				
Total Specified Organisms	per EP 10.0 Section: 2.6.13*				
Pseudomonas aeruginosa	Absent				
Staphylococcus aureus	Absent				
Candida albicans	Absent				
Escherichia coli	Absent				
Preservative Effectiveness Testing	PET, per EP 10.0 Section: 5.1.3*				
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus	NLT 3.0 log reduction from the initial count at 7 days, and no increase from the 7 days' count at 28 days				
Candida albicans, Aspergillus niger (A. brasiliensis)	2.0 log reduction from the initiation count at 14 days, and no increase from the 14 days' count at 28 days				

* European Pharmacopoeia (EP) standards EP 10.0 Sections 2.6.12, 2.6.13, and 5.1.3 have harmonized with or have comparable specifications to USP standards USP <61>, <62>, and <51>, respectively.

Indications for Use Statement: Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry are personal lubricants intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. They are compatible with natural rubber latex and polyisoprene condoms. They are not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics with the Predicate Device: A comparison of the technological features of the subject and predicate devices is provided in the table below:

510(k)	**K2134000 Subject Device**	**K211088 Predicate Device**
Device Name	Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, Grosz Play	Grosz Play Feel

	Strawberry	
Indications for Use	Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry are personal lubricants intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. They are compatible with natural rubber latex and polyisoprene condoms. They are not compatible with polyurethane condoms.	Grosz Play Feel is intended for penile, vaginal and/or anal application to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. Grosz Play Feel is compatible with natural rubber latex and polyisoprene condoms. Grosz Play Feel is not compatible with polyurethane condoms.
Rx/OTC	OTC	OTC
Physical Features	Homogenous transparent gel	Homogeneous clear gel
Base Type	Water	Water
Sterile	No	No
Primary Ingredients	Water, Propylene Glycol, Xanthan Gum, Carbomer, Benzoic Acid, Sodium Hydroxide, Sodium Saccharin, Flavor.	Water, Propylene Glycol, Xanthan Gum, Carbomer, Benzoic Acid, Sodium Hydroxide.
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.
Shelf Life	Grosz Play Aloe, Grosz Play Cherry, Grosz Play Strawberry: 2 years Grosz Play Ylang, Grosz Play Guarana: 1.5 years	2.5 years

The subject and predicate device have identical indications for use statements and have the same intended use.

The subject device and predicate devices have different technological characteristics, including different formulations and shelf-life. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

Summary of Performance Testing:

Shelf life: Grosz Play Aloe, Grosz Play Cherry, and Grosz Play Strawberry have a proposed shelf-life of 2 years (24 months). Grosz Play Ylang and Grosz Play Guarana have a proposed shelf-life of 1.5 years (18 months). All device specifications listed in the device specifications table above were tested based on accelerated aging conditions per ASTM F1980-16. Results from testing demonstrated that the device can maintain its specifications over the duration of its shelf life

Biocompatibility: Biocompatibility studies were performed for all variants of the subject device 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" and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5: 2009)
- Vaginal Irritation (ISO 10993-10: 2010)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Acute Systemic Toxicity (ISO 10993-11: 2006)

The results of this testing demonstrated that the subject lubricants are non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Condom Compatibility: Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry was tested in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" and was determined to be compatible with natural rubber latex and polyisoprene condoms. It was determined not to be compatible with polyurethane condoms.

Conclusion: The results of the performance testing described above demonstrate that the Grosz Play Aloe, Grosz Play Ylang, Grosz Play Guarana, Grosz Play Cherry, and Grosz Play Strawberry is as safe and effective as the predicate device and supports a determination of substantial equivalence.