July 9, 2021

RB Health (US) LLC
Elizabeth Viguerie
Regulatory Manager
399 Interpace Parkway
Parsippany, NJ 07054

Re: K211088
Trade/Device Name: Grosz Play Feel
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: April 9, 2021
Received: April 12, 2021

Dear Elizabeth Viguerie:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211088

Device Name
Grosz Play Feel

Indications for Use *(Describe)*
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.

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.

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510(k) Summary
K211088
Grosz Play Feel

1. Submitter Information

Applicant: RB Health (US) LLC
Address: 399 Interpace Parkway Parsippany NJ, 07054-0224

2. Correspondent Information

Contact: Elizabeth Viguerie, Regulatory Manager
Address: 399 Interpace Parkway Parsippany NJ, 07054-0224
Phone: (862) 702-6117
Email: Elizabeth.Viguerie@rb.com

3. Date prepared: July 7, 2021

4. Device Information

Device Name:	Grosz Play Feel
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:	KY Banksy Aloe
510(k) Number:	K183302
Manufacturer:	RB Health (US) LLC

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

6. Device Description

Grosz Play Feel is a personal lubricant that is non-sterile, water-based, and provides lubrication during intimate sexual activity. This device is compatible with natural rubber latex and polyisoprene condoms and is not compatible with polyurethane condoms. Its formulation consists of Water, Propylene Glycol, Xanthan Gum, Carbomer, Benzoic Acid, and Sodium Hydroxide. Grosz Play feel is packaged in 50 mL bottles composed of High Density Polyethylene (HDPE) and fitted with a Polypropylene (PP) cap.

The bottle is packaged in an outer cardboard carton. Grosz Play Feel is a personal lubricant for over-the-counter (OTC) use. Device specifications are listed in Table 1 below.

Table 1: Device Specifications for Grosz Play Feel

Property	Specification
Appearance	Viscous, clear gel
Odor	Odorless
Viscosity	3,400 – 10,000 cPs
pH	3.5 – 4.5
Osmolality	663 – 1,063 mOsm/kg
Total Yeast and Mold Count (TYMC, per EP 8.0 Section: 2.6.12)*	<100 cfu/g
Total Aerobic Microbial Count (TAMC, per EP 8.0 Section: 2.6.12)*	<10 cfu/g
Presence of Pathogens (per EP 8.0 Section: 2.6.13)*	**Specification**
Pseudomonas aeruginosa	Absent/g
Staphylococcus aureus	Absent/g
Candida albicans	Absent/g
Escherichia coli	Absent/g
Preservative Effectiveness Testing (PET, per EP 8.0 Section: 2.6.13)*	**Specification**
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 8.0 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.

7. Indications for Use

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.

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

	Grosz Play Feel K211088 Subject Device	**KY Banksy Aloe K183302 Predicate Device**
Device Classification Name	Lubricant, Personal	Lubricant, Personal
Indications for Use	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.	This product 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	This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Physical Features	Homogeneous Clear Gel	Homogeneous Clear Gel
Base type	Water	Water
Primary ingredients	Water, Propylene Glycol, Xanthan Gum, Carbomer, Benzoic Acid, and Sodium Hydroxide	Water, Propanediol, Xanthan Gum, Benzoic Acid, Aloe Barbadensis Leaf Juice, Potassium Lactate, Lactic Acid
Rx/OTC	OTC	OTC
Sterile	No	No
Condom Compatibility	Compatible with natural rubber latex and polyisoprene	Compatible with natural rubber latex and polyisoprene
Biocompatibility Tested	Yes	Yes
Antimicrobial Effectiveness Tested	Yes	Yes
Shelf life	2.5 years	2 years

The subject and predicate device indications for use have a minor difference in wording; however, the intended use of the subject and predicate devices is the same (i.e., provides lubrication during intimate sexual activity).

The subject and predicate device have different technological characteristics included a different formulation and different shelf life as shown in the table above. 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"* and ISO 10993- 1:2009 as follows:

- 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 this testing demonstrated that Grosz Play Feel is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Shelf-Life

The subject device has a shelf-life of 30-months. Results from accelerated testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf-life.

Condom Compatibility

Grosz Play Feel 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.

10. Conclusion

The results of the performance testing described above demonstrate that Grosz Play Feel is as safe and effective as the predicate device and supports a determination of substantial equivalence.