April 14, 2020

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

Re: K192982
Trade/Device Name: KY Grosz UltraGel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 11, 2020
Received: March 12, 2020

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, Ph.D.
Acting 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)*
K192982

Device Name
KY Grosz UltraGel

Indications for Use *(Describe)*
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. 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.

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510K Summary
K192982

KY Grosz UltraGel

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

Contact Person: Elizabeth Viguerie
Regulatory Manager
RB Health (US) LLC
973-404-2715

Date Prepared: April 9th, 2020

Trade Name: KY Grosz UltraGel

Common Name: Personal Lubricant

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Product Code: NUC (Lubricant, Personal)

Regulatory Class: Class II

Predicate Device(s): KY Banksy Aloe
RB Health (US) LLC
510(k) No.: K183302

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

Description of the Device:

KY Grosz UltraGel 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, Glycerin, Propylene Glycol, Hydroxyethylcellulose, Benzoic acid, Sodium Saccharin, and Sodium Hydroxide. KY Grosz UltraGel is packaged in 1.5 fl. oz. (44 mL) or 4.5 fl. oz. (133 mL) bottles composed of high density polyethylene (HDPE), sealed and fitted with a polypropylene (PP) cap. The individual bottles are packaged in an outer cardboard carton. KY Grosz UltraGel is a personal lubricant for over-the-counter (OTC) use.

Device specifications are listed in Table 1 below.

Table 1: Subject Device Specifications

Property	**Specification**
Appearance	Colorless to slightly yellow, clear to translucent liquid
Odor	No objectionable odor
Viscosity	100-950 cPs
Osmolality	780-1180 mOsm/kg
pH	3.5 – 4.5
Total Yeast and Mold Count (TYMC, per EP 8.0 Section: 2.6.12)*	< 10 cfu/g
Total Aerobic Microbial Count (TAMC, per EP 8.0 Section: 2.6.12)*	< 100 cfu/g
Total Specified Organisms (per EP 8.0 Section: 2.6.13)*	
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent
Preservative Effectiveness Testing (PET, per EP 8.0 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 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.

Indications of Use Statement: 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Summary of Technological Characteristics of New Device in Comparison to Predicate:
Comparison of the technological features of the subject and predicate devices is provided in Table 2 below:

Table 2: Technological Characteristics of Subject Device Compared to Predicate

510(k)	K192982 Subject Device	K183302 Predicate Device
Device Name	KY Grosz UltraGel	KY Banksy Aloe
Indications for Use	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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Rx/OTC	OTC	OTC
Physical Features	Colorless to slightly yellow, clear to translucent liquid/Odorless	Homogeneous Clear Gel / Odorless
Base Type	Water	Water
Sterile	No	No
Primary Ingredients	Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, Benzoic acid, Sodium Saccharin, Sodium Hydroxide	Water, Propanediol, Xanthan Gum, Benzoic Acid, Aloe Barbadensis Leaf Juice, Potassium Lactate, Lactic Acid
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	2 years	2 years

The subject device and predicate devices have different technological characteristics, including their formulation. 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: KY Grosz UltraGel has a shelf-life of 2 years in accordance with the results of an accelerated aging stability study. Results from testing demonstrated that the device can maintain its specifications (as shown in Table 1) over the duration of its shelf life.

Biocompatibility: Biocompatibility studies were performed in accordance with the 2016 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): The subject device test article showed no evidence of cytotoxicity to L-929 cells and therefore is not cytotoxic.

- Vaginal Irritation (ISO 10993-10: 2010): The Irritation Index for the subject device test article was 0. Macroscopically, the vaginal tissue was found to be normal. Therefore, the subject device was considered a non-irritant to vaginal tissue of the rabbit

- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010): The subject device test article solution showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

- Acute Systemic Toxicity (ISO 10993-11: 2017): There was no mortality or evidence of systemic toxicity for the subject device.

Condom Compatibility: KY Grosz UltraGel 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 KY Grosz UltraGel is as safe and effective as the predicate device and supports a determination of substantial equivalence.