May 17, 2019

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

Re: K183505
Trade/Device Name: KY Banksy Moisture
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: NUC
Dated: April 15, 2019
Received: April 16, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Sharon Andrews
Assistant Division 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)*
K183505

Device Name
KY Banksy Moisture

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.

510 (k) Summary – K183505

1. Submitter Information

Applicant: RB Health (US) LLC.
Contact: Elizabeth Viguerie
Senior Regulatory Associate
Address: 399 Interpace Parkway
Parsippany NJ 07054-0224, USA
Phone: (973) 404-2600

2. Correspondent Information

Contact: Elizabeth Viguerie
Address: 399 Interpace Parkway
Parsippany NJ 07054-0224, USA
Phone: (973) 404-2600
Email: elizabeth.viguerie@rb.com

3. Date prepared: May 17, 2019

4. Device Information

Device Name:	KY Banksy Moisture
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

5. Predicate Device Information

Device Name:	KY Marilyn
510(k) Number:	K151884
Manufacturer:	Reckitt Benckiser LLC
Regulatory Class:	Class II
Product Code:	NUC (lubricant, personal)

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

6. Device Description

KY Banksy Moisture will be marketed as a non-sterile, non-prescription medical device for over-the-counter (OTC) use. This device is a water-based personal lubricant that contains: Water, Glycerin, Propanediol, Xanthan Gum, Benzoic Acid, Sodium Hyaluronate, Potassium Lactate and Lactic Acid. The tube material is composed of High-Density Polyethylene (HDPE) and Low-Density Polyethylene (LDPE), covered with a 50-micron aluminum/linear low-density polyethylene seal and fitted with the Polypropylene (PP) cap. The tube will be packaged in an outer cardboard carton.

Table 1: Device Specifications for KY Banksy Moisture

Property	Specification
Appearance	Clear colorless and homogeneous gel, free from extraneous matter
Odor	Odorless

Viscosity	Release: 3,000 – 6,500 cps Stability: 3,000 - 8,000 cps
Osmolality	850 – 1,200 mOsm/kg
pH at 25	3.5 – 4.5
Benzoic Acid	Release: 0.207 – 0.253 %w/w Stability: 0.150 - 0.253 %w/w
Osmolality	1050 to 1250 mOsm/kg
Total Yeast and Mold Count (TYMC ≤10 cfu/g per EP 8.0 Section: 2.6.12) *	<10 cfu/g
Total Aerobic Microbial Count (TAMC ≤100 cfu/g per EP 8.0 Section: 2.6.12) *	<100 cfu/g
Preservative Effectiveness Testing (per EP 8.0 Section: 5.1.3) *	
Escherichia coli	NLT 3.0 log reduction from the initial count at 7 days, and no increase from the 7 days' count at 28 days
Pseudomonas aeruginosa	NLT 3.0 log reduction from the initial count at 7 days, and no increase from the 7 days' count at 28 days
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	2.0 log reduction from the initiation count at 14 days, and no increase from the 14 days' count at 28 days
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
Total Specified Organisms (per EP 8.0 Section: 2.6.13)	**Specification**
Pseudomonas aeruginosa	Absent
Staphylococcus aureus	Absent
Candida albicans	Absent

*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

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.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below lists the comparative indications for use and technological characteristics of the subject and predicate device.

Table 2: Comparator Table for Subject Device – KY Banksy Moisture and Predicate Device KY Marilyn

Feature	**KY Banksy Moisture (K183505)**	**KY Marilyn (K151884)**

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 and/or 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.
Physical Features	Homogeneous Clear Gel/Odorless	Homogeneous Clear Gel/Odorless
Manufacturer	RB Health (US) LLC*	Reckitt Benckiser LLC
Base Type	Water	Water
Sterile	No	No
Primary Ingredients	Xantham Gum, Propanediol, Glycerin, Benzoic Acid, Purac BF P/41, Sodium hyaluronate, Water	Hydroxyethylcellulose, Propylene Glycol, Glycerol, Multisensate Flavor, Sodium Hydroxide, PEG-40 Hydrogenated Castor Oil, Benzoic Acid, Water
Biocompatibility Tested	Yes	Yes
Antimicrobial Tested	Yes	Yes
Condom Compatibility	Yes	Yes
Shelf-life	2-years	2-years

* **Please note: Reckitt Benckiser LLC underwent a company name change in 2018 to RB Health (US) LLC.**

The subject and predicate device have similar indications for use. The indication for the subject device has been expanded to also include anal use. This change does not represent a new intended use as the intended use of this device is the same as the predicate device, i.e., lubrication of an orifice during intimate sexual activity. The subject and predicate device have similar technological characteristics, including similar formulation. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

9. Summary of Non-Clinical Performance Testing

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: Based on the results of the below testing, this device was determined to be biocompatible and supports the intended use of the subject lubricant.

- ISO10993-5:2009: Cytotoxicity: The subject device test article showed no evidence of causing cell lysis or cytotoxicity to L-929 cells and therefore is not cytotoxic.
- ISO10993-10:2010: Vaginal Irritation: 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 nonirritant to vaginal tissue of the rabbit.
- ISO10993-10:2010: Guinea Pig Maximization Sensitization Test: 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.

- ISO10993-11:2006: Acute Systemic Toxicity: There was no mortality or evidence of systemic toxicity of the subject device therefore the subject device met the requirements of ISO10993-11.

Shelf-Life

Accelerated shelf-life testing was conducted on the subject device to support its labeled shelf-life period of 2 years. Results from testing demonstrated that the device can maintain its specifications over the duration of its shelf-life.

Condom Compatibility

KY Banksy Moisture was tested in accordance with ASTM D7661-10 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 the KY Banksy Moisture Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.