510(k) Summary

K183302

KY Banksy Aloe

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Trade Name: KY Banksy Aloe

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): K-Y ® Marilyn Pleasure Gel
Reckitt Benckiser LLC
510(k) No.: K151884

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

Description of the Device:

KY Banksy Aloe 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, Propanediol, Xanthan Gum, Benzoic Acid, Aloe Barbadensis Leaf Juice, Potassium Lactate and Lactic Acid. KY Banksy Aloe is packaged in 100 mL tubes composed of High Density Polyethylene (HDPE) and Low-Density Polyethylene (LDPE), covered with a 50 micron aluminium/linear low-density polyethylene seal and fitted with the Polypropylene (PP)

cap. The tube is packaged in an outer cardboard carton. KY Banksy Aloe 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	Clear to slightly yellow color and homogenous gel, free from extraneous matter
Odor	Odorless
Viscosity	3,000 - 8,000 cps
Osmolality	270 - 670 mOsm/kg
pH at 25 °C	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)	**K183302** **Subject Device**	**K151884** **Predicate Device**
Device Name	KY Banksy Aloe	KY Marilyn Pleasure Gel
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.	KY Marilyn is indicated 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
Base Type	Water	Water
Sterile	No	No
Primary Ingredients	Water, Propanediol, Xanthan Gum, Benzoic Acid, Aloe Barbadensis Leaf Juice, Potassium Lactate, Lactic Acid	Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Flavor, 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.	Same
Shelf Life	2 years	9 months

The subject and predicate devices do not have identical indications for use statements. The indication for the subject devices 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 device and predicate devices also have different technological characteristics, including their formulation 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: KY Banksy Aloe has a 2-year shelf life 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 causing cell lysis or 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: 2006): There was no mortality or evidence of systemic toxicity for the subject device.

Condom Compatibility: KY Banksy Aloe 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 Banksy Aloe is as safe and effective as the predicate device and supports a determination of substantial equivalence