June 20, 2023

RB Health (US) LLC
Kaitlyn Chan
Regulatory Associate
399 Interpace Parkway
Parsippany, NJ 07054-0224

Re: K230781
Trade/Device Name: Belle Sensilube
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: March 15, 2023
Received: March 22, 2023

Dear Kaitlyn Chan:

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,

Reginald K. Avery -S

for
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)*
K230781

Device Name
Belle Sensilube

Indications for Use *(Describe)*
Belle Sensilube 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. Belle Sensilube is compatible with natural rubber latex and polyisoprene condoms. Belle Sensilube 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary – K230781
Belle Sensilube

I. General Information on Submitter

Applicant: RB Health (US) LLC
Address: 399 Interpace Parkway
Parsippany NJ 07054-0224
Telephone: 862-702-0012
Contact Person: Kaitlyn Chan
Contact Title: Regulatory Associate
RB Health (US) LLC
Email: kaitlyn.chan@reckitt.com
Date Prepared: June 12, 2023

II. General Information on Device

Proprietary Name: Belle Sensilube
Common Name: Personal Lubricant
Regulation Name: Condom
Regulation Number: 21 CFR 884.5300
Regulatory Class: II
Product Code: NUC (Lubricant, Personal)

III. Predicate Device

Predicate Device	510(k) Number
KY Banksy Aloe	K183302

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

IV. Description of Device

Belle Sensilube is a water-based personal lubricant for over-the-counter use. The subject device is a non-sterile liquid preparation containing water, propylene glycol, hyroxyethylcellulose, polyacrylamide anionic, lactic acid and potassium lactate, and benzoic acid.

The subject device will be packaged in a 40 mL high-density polyethylene bottle fitted with a polypropylene cap. The lubricant is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms.

The specifications for Belle Sensilube are described in **Table 1.**

Table 1. Device Specifications

Parameter	Test Method	Specification
Appearance	Visual	Clear, colorless liquid gel, free from lumps and extraneous matter
Odor	Olfactory	No objectionable odor
pH	USP <791>	3.5 - 4.5
Viscosity	USP <912>	400 - 1,500 cPs
Osmolality	USP <785>	260 - 380 mOsm/kg
Antimicrobial Effectiveness	EP 5.1.3 / USP <51>*	Meets USP <51> acceptance criteria for Category 2 products. Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from the 14-day count to the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Total Microbial Count	EP 2.6.12 / USP <61>*	<100 cfu/g
Fungal/Yeast/Mold Limits	EP 2.6.12 / USP <61> *	<10 cfu/g
Absence of Pathogenic Organisms *(Staphylococcus Aureus, Pseudomonas Aeruginosa, Candida Albicans)*	EP 2.6.13 / USP <62>*	Absent
Content of benzoic acid	Spectrophotometric	0.13 - 0.22% w/w

*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.

V. Indications for Use

Belle Sensilube 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. Belle Sensilube is compatible with natural rubber latex and polyisoprene condoms. Belle Sensilube is not compatible with polyurethane condoms.

VI. Substantial Equivalence Discussion

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

Characteristic / Feature	Belle Sensilube (subject device)	KY Banksy Aloe (predicate device) – K183302	Comparison
Indication for use	Belle Sensilube 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. Belle Sensilube is compatible with natural rubber latex and polyisoprene condoms. Belle Sensilube 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.	Same
Water-Based Lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Water, propylene glycol, hydroxyethylcellulose, polyacrylamide anionic, lactic acid and potassium lactate, and benzoic acid	Water, propanediol, xanthan gum, benzoic acid, aloe barbadensis leaf juice, potassium lactate, and lactic acid	Different: The ingredients of the predicate device are different; the ingredients do not raise different questions of Safety & Effectiveness (S & E)
Microbial Limits	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <100 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Same
Viscosity	400 - 1,500 cPs	3,000 – 8,000 cPs	Different
Osmolality	260 - 380 mOsm/kg	270 – 670 mOsm/kg	Different

pH	3.5 - 4.5	3.5 – 4.5	Same
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	Same

The subject and predicate devices have identical indications for use and have the same intended use – to provide lubrication during intimate sexual activity. The subject and predicate devices have different technological characteristics, including different formulations and device specifications. The different technological characteristics do not raise different types of safety and effectiveness questions.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the subject lubricant was performed 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/(R)2014)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10: 2010)
- Vaginal Irritation (ISO 10993-23: 2021)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The results of this testing demonstrate that the subject lubricant is non-cytotoxic, non-irritating, non-sensitizing, and not systemically toxic.

Shelf Life

The subject device is a non-sterile personal lubricant packaged in a 40 mL bottle with a 24-month shelf-life in accordance with the results of an accelerated aging study, conducted for 9 months at 40°C per ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*. The device specifications listed in **Table 1** were tested across the device shelf-life and the subject device met the specifications at all time points.

Condom Compatibility

The subject device was tested for compatibility with natural rubber latex, polyisoprene, and polyurethane condoms using ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms". The results show that Belle Sensilube is compatible with natural rubber latex and polyisoprene condoms. Belle Sensilube is not compatible with polyurethane condoms.

VIII. Conclusion

The results of the testing described above demonstrate that the Belle Sensilube is as safe and effective as the predicate device and supports a determination of substantial equivalence.