August 7, 2026

Bumlicious, LLC (DBA "Bumlicious")
Louie Goryoka
Sr. VP. Regulatory and Quality Consultant
515 E. Las Olas Blvd.
Suite 1301-K25
Fort Lauderdale, Florida 33301

Re: K261905
Trade/Device Name: BUM Oil
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 5, 2026
Received: June 8, 2026

Dear Louie Goryoka:

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261905

Device Name
BUM Oil

Indications for Use *(Describe)*
BUM Oil is an Oil-based personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. BUM Oil is not compatible with natural rubber latex, polyisoprene, or 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K261905
BUM Oil

I. Submitter

Applicant:	Bumlicious LLC (DBA "Bumlicious")
Address:	515 East Las Olas Blvd., Suite 1201-K25 Fort Lauderdale, FL, 33301 USA
Telephone:	(413) 286-7529
Contact Person:	Jonathan Campbell
Contact Title:	Chief Operating Officer – Bumlicious LLC
Date Prepared:	August 3, 2026

II. Correspondent Information

Contact Person:	Louie Goryoka
Contact Title:	Sr. VP. Regulatory/Quality Consultant Med-Device Consulting, Inc.
Phone:	(818) 515-7488
Email:	mdci@m-dci.us

III. Device Information

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

IV. Predicate Device

Predicate Device	510(k) Number
Bloomi Delight Oil-Based Personal Lubricant	K222175

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

V. Device of Description

BUM Oil is an Oil-based personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. BUM Oil is neither a contraceptive nor a spermicide. BUM Oil is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

Its formulation consists of Fractionated Coconut Oil (MCT), Coconut Oil (92°F MP), Golden Wax Akasoy (Soy Wax), White Beeswax, and Vitamin E Oil (Tocopheryl Acetate). BUM Oil is packaged in a 100 mL PE bottle.

Specifications for the BUM Oil are shown in **Table 1**.

Table 1. Device Specifications

Property	**Specification (Test Method)**
Appearance	Liquid
Color	White
Odor	Odorless
Viscosity (USP<911>)	8,000 cps – 30,930 cps
Total aerobic microbial count (TAMC) per USP <61> and <1111>	<10 cfu/g
Total yeast and mold count (TYMC) per USP <61> and <1111>	<10 cfu/g
Antimicrobial effectiveness per USP <51>	Meets USP <51> acceptance criteria for Category 2 products. Category 2 bacteria should show a log reduction of less than 2.0 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.
Presence of pathogenic organisms (USP<62>, including *Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans*)	Absent

VI. Indications for Use

BUM Oil is an oil-based personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. BUM Oil is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.

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

The following table compares the intended use and key technological characteristics of the subject and predicate device:

Characteristic/Feature	**BUM Oil (subject device) – K261905**	**Bloomi Delight Oil-Based Personal**	**Comparison**

		Lubricant (predicate device) – K222175	
Indication for use	BUM Oil is an oil-based personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. BUM Oil is not compatible with natural rubber latex, polyisoprene, or polyurethane condoms.	The Bloomi Delight Oil-Based Personal Lubricant is a personal lubricant for penile and/or vaginal application, intended to lubricate, moisturize, and enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Same intended use.
Oil-Based Lubricant	Yes	Yes	Same
Contains Water	No	No	Same
Over the Counter	Yes	Yes	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Fractionated Coconut Oil (MCT), Coconut Oil (92°F MP), Golden Wax Akasoy (Soy Wax), White Beeswax, and Vitamin E Oil (Tocopheryl Acetate)	Extra Virgin Coconut Oil, Organic Sunflower Seed Oil, Organic Cocoa Butter, Shea Butter (low melt), Sunflower Wax, Sea Buckthorn Fruit Oil	Different
Appearance/Color	Liquid, White	Semi-fluid, Yellow	Different
Odor	Odorless	Odorless	Same
Microbial Limits	Total mold/yeast count <10 cfu/g Total aerobic microbial count <10 cfu/g Absence of pathogens (including *Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g Absence of pathogens (including *Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Different
Viscosity	8,000 cps – 30,930 cps	2,000 cps – 20,000 cps	Different

Condom Compatibility	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	Not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.	Same

The subject and predicate devices have similar indications for use and have the same intended use – to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubricant. The subject and predicate device have different technological characteristics, including different formulations, microbial limits, appearances, and viscosity. The different technological characteristics do not raise different questions of safety and effectiveness.

VIII. 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." The following testing was conducted:

- Cytotoxicity (ISO 10993-5:2009/(R)2014)
- Guinea Pig Maximization Sensitization (ISO 10993-10:2021)
- 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 has a shelf-life of eight and a half months based on the results accelerated aging study results. 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

Condom compatibility testing was not conducted for the subject device. Therefore, BUM Oil is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

IX. Conclusion

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