November 15, 2022

The Bloomi, Inc.
℅ Louie Goryoka
Sr. QA/RA Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K222175
Trade/Device Name: Bloomi Delight Oil-Based Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 28, 2022
Received: October 14, 2022

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 (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,

Michael T. Bailey -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222175

Device Name
Bloomi Delight Oil-Based Personal Lubricant

Indications for Use *(Describe)*
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.

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 – K222175
Bloomi Delight Oil-Based Personal Lubricant

I. Submitter

Applicant:	The Bloomi, Inc.
Address:	3987 First Street Unit K Livermore, CA 94551
Telephone:	(510)-410-5570
Contact Person:	Rebecca Story
Date Prepared:	November 10, 2022

II. Correspondent Information

Contact Person:	Louie Goryoka
Contact Title:	Sr. Regulatory/Quality Consultant Med-Device Consulting, Inc
Phone:	(818) 585-7488
Email:	mdci@m-dci.us

III. Device Information

Proprietary Name:	Bloomi Delight Oil-Based Personal Lubricant
Common Name:	Personal Lubricant
Regulation Name:	Condom
Regulation Number	21 CFR 884.5300
Regulatory Class:	II
Product Code:	NUC (Lubricant, Personal)

IV. Predicate Device

Predicate Device	510(k) Number
Astroglide O Oil Personal Lubricant & Massage Oil	K171985

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

V. Description of Device

The Bloomi Delight Oil-Based Personal Lubricant is a non-sterile, oil-based, over-the-counter use personal lubricant that is intended for penile and vaginal application

to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The product is not compatible with natural rubber latex, polyurethane and polyisoprene condoms.

Its formulation consists of Extra Virgin Coconut Oil, Organic Sunflower Seed Oil, Organic Cocoa Butter, Shea Butter (low melt), Sunflower Wax and Sea Buckthorn Fruit Oil. The Bloomi Delight Oil-Based Personal Lubricant is packaged in a 3 oz tube and is secondarily packaged in an outer box.

Specifications for the Bloomi Delight Oil-Based Personal Lubricant are shown in **Table 1**.

Table 1. Device Specifications

Parameter	**Specification (Test Method)**
Appearance	Semi-fluid
Color	Yellow
Odor	Odorless
Viscosity (USP<971>)	2,300-20,000 cps
Total yeast/mold count (TYMC, USP <61>)	<10 cfu/g
Total aerobic microbial count (TAMC, USP <61>)	<100 cfu/g
Presence of pathogenic organisms (USP<62>, including *Staphylococcus aureus, Pseudomonas aeruginosa,* and *Candida albicans*)	Absent

VI. Indications for Use

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.

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	Bloomi Delight Oil-Based Personal Lubricant (subject device) – K222175	Astroglide O Oil Personal Lubricant & Massage Oil (predicate device) – K171985	Comparison
Indication for use	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.	Astroglide O Oil Personal Lubricant & Massage Oil is a personal lubricant 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 not compatible with 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	Extra Virgin Coconut Oil, Organic Sunflower Seed Oil, Organic Cocoa Butter, Shea Butter (low melt), Sunflower Wax, Sea Buckthorn Fruit Oil	Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Cocos Nucifera (Coconut) Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinesis (Jojoba) Seed Oil, Argania Spinosa Kernel (Argan Tree Nut) Oil, Tocopherol, Cananga Odorata (Ylang Ylang) Flower Oil	Different
Appearance/Color	Semi-fluid, yellow	Clear, light yellow	Different
Odor	Odorless	Coconut and ylang-ylang	Different

Microbial Limits	Total mold/yeast count <10 cfu/g Total aerobic microbial count <100 cfu/g Absence of pathogens (including *Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Total mold/yeast count <10 cfu/mL Total aerobic microbial count <10 cfu/mL Absence of pathogens (including *Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Different
Viscosity	2,300-20,000 cps	60-120 cps	Different
Condom Compatibility	Not compatible with condoms	Not compatible with condoms	Same

The subject and predicate devices have similar 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, device specifications, odor, color, viscosity, etc. 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 10993-10:2010/(R)2014)
- Vaginal Irritation (ISO 10993-10:2010/(R)2014)
- 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 six months based on the results of real-time aging testing. 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, Bloomi Delight Oil-Based Personal Lubricant is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

IX. Conclusion

The results of the testing described above demonstrate that Bloomi Delight Oil-Based Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.