August 4, 2022

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

Re: K221328
Trade/Device Name: Bloomi Smooth Water Based Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 3, 2022
Received: May 6, 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,

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)*
K221328

Device Name
Bloomi Smooth Water Based Personal Lubricant

Indications for Use *(Describe)*
The Bloomi Smooth Water Based Personal Lubricant is a water-based personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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.

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

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510(k) Summary – K221328
Bloomi Smooth Water Based Personal Lubricant

I. General Information on Submitter

Applicant:	The Bloomi, Inc.
Address:	71 Royal ridge court, California, 94507 USA
Telephone:	(510) 410-5570
Contact Person:	Louie Goryoka
Contact Title:	Sr. Regulatory/Quality Consultant Med-Device Consulting, Inc.
Email:	ndci@m-dci.us
Date Prepared:	July 27, 2022

II. General Information on Device

Proprietary Name:	Bloomi Smooth Water Based Personal Lubricant
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
The Sex Gel Personal Lubricant	K181078

This predicate device has never been the subject of a device recall.

IV. Description of Device

The Bloomi Smooth Water Based Personal Lubricant is a non-sterile, water-based 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. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Its formulation consists of Water, Hydroxyethylcellulose, Microcare SB (water, sodium benzoate, potassium sorbate), Activsoft S (Cyamopsis Tetragonoloba (Guar) Gum), Citric Acid, Sodium Hyaluronate, Organic Sunflower Extract, Organic Green Tea Extract (Organic Camellia Sinensis Leaf (Green Tea) Extract).

The Bloomi Smooth Water Based Personal Lubricant is packaged in a MDPE (medium density polyethylene) 3 oz tube, packaged in an outer box for OTC use.

The specifications for Bloomi Smooth Water Based Personal Lubricant are described in **Table 1**.

Table 1. Device Specifications

Parameter	**Specification (Test Method)**
Absence of particulate matter	Clear viscous liquid
Color	Off-white
Odor	None
Viscosity	1,800 – 4,500 cps
Osmolality	110 – 140 mOsm/kg
pH	4.0 - 5.0
Total yeast/mold count (TYMC)	<10 cfu/mL (USP <61>)
Total aerobic microbial count (TAMC)	<100 cfu/mL (USP <61>)
Presence of pathogenic organisms (*Staphylococcus aureus, Pseudomonas aeruginosa,* and *Candida albicans*)	Absent (USP<62>)
Antimicrobial effectiveness	Meets USP<51> acceptance criteria for Category 2 products.

V. Indications for Use

Bloomi Smooth Water Based Personal Lubricant is a water-based personal lubricant for penile and/or vaginal application, intended lubricate and moisturize, 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.

VI. Substantial Equivalence Discussion

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

Characteristic / Feature	Bloomi Smooth Water Based Personal Lubricant (subject device)	The Sex Gel Personal Lubricant (predicate device) – K181078	Comparison
Indication for use	Bloomi Smooth Water Based Personal Lubricant is a water-based personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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.	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 compatible with natural rubber latex and polyisoprene and polyurethane condoms.	Similar: The subject and predicate devices have similar indications for use, with the exception of condom compatibility statement, and they have the same intended use.
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, Microcare SB, Microcare SB, Hydroxyethylcellulose, Cyamopsis Tetragonoloba (Guar) Gum, Citric Acid, Sodium Hyaluronate, Organic Helianthus (Sunflower) Seed Extract, Organic Camellia Sinensis Leaf (Green Tea) Extract.	Water, aloe barbadensis leaf juice, sorbitol, hydroxyethylcellulose, allantoin, lactic acid / tocopherols (vitamin E), sodium hyaluronate, sodium benzoate & potassium sorbate	Different
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 <10 cfu/mL Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)*	Different
Viscosity	1,800–4,500 cps	3,000-5,000 cps	Different

Osmolality	110-140 mOsm/kg	435-535 mOsm/kg	Different
pH	4.0–5.0	4.0–5.0	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 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 (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 is a non-sterile personal lubricant packaged in a 3 oz. tube with a 8.5-month shelf-life in accordance with the results of an accelerated aging study, conducted for 3 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

Bloomi Smooth Water Based Personal Lubricant was tested for compatibility with natural rubber latex, polyisoprene, and polyurethane condoms using ASTM D7661-18, *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms*. The results show that Bloomi Smooth Water Based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. Bloomi Smooth Water Based Personal Lubricant is not compatible with polyurethane condoms.

VIII. Conclusion

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