March 3, 2022

BioFilm, Inc.
Jennifer Keller
R&D Formulation Chemist II
3225 Executive Ridge
Vista, CA 92081

Re: K213671
Trade/Device Name: Astroglide® Sensual Strawberry Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 17, 2021
Received: November 22, 2021

Dear Jennifer Keller:

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,

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)*
K213671

Device Name
Astroglide® Sensual Strawberry Personal Lubricant

Indications for Use *(Describe)*
Astroglide® Sensual Strawberry Personal Lubricant is a personal lubricant for penile, vaginal, and/or anal 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 condoms. This product is not compatible with 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.

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510(k) Summary
K213671
Astroglide® Sensual Strawberry Personal Lubricant

I. Submitter Information

Applicant:	BioFilm, Inc.
Address:	3225 Executive Ridge Vista, CA 92081 USA
Telephone:	760-727-9030
Fax:	760-727-8080
Contact Person:	Jennifer Keller
Contact Title:	Research & Development
Email:	Jennifer@biofilm.com
Date Prepared:	2/25/2022

II. General Information on Device

Proprietary Name:	**Astroglide® Sensual Strawberry Personal Lubricant**
Common Name:	Personal Lubricant
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Product Code:	NUC (Lubricant, Personal)
Regulatory Class:	II

III. Predicate Device

Predicate Device	510(k) Number
Glycerin & Paraben Free Astroglide Applicant: BioFilm, Inc.	K072647

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

IV. Description of Device

Astroglide® Sensual Strawberry Personal Lubricant is a non-sterile, clear, strawberry-scented and flavored, water-based personal lubricant intended for penile, anal, or vaginal application. This product is not a spermicide or contraceptive. Astroglide® Sensual Strawberry Personal Lubricant is compatible with natural rubber latex condoms. It is not compatible with polyisoprene and polyurethane condoms. This product's primary packaging is a PETE clear bottle

with a screw on polypropylene flip-top cap. The bottle is then packaged in a cardboard carton which constitutes the final packaging.

The specifications for Astroglide® Sensual Strawberry Personal Lubricant are described in the following table.

Physical Specification Tests	Ranges/Specifications
Particulate matter	No particles
Color	Clear to slight golden
Clarity	Clear
Odor	Strawberry sent
pH (per USP <791>)	3.5-5.5
Viscosity (per USP <912>	200 - 450 cps
Osmolality (per USP <785>)	200 - 450 mOsm/kg, dilution factor of 5
Antimicrobial effectiveness (per USP <51>)	Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days
Total yeast/mold count (per USP <61> & USP <62>)	< 10 cfu/mL
Total aerobic microbial count (per USP <61> & USP <62>)	< 100 cfu/mL
Absence of pathogenic organisms (*Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans* – per USP <61> & USP <62>)	Absent

V. Indications for Use

Astroglide® Sensual Strawberry Personal Lubricant is a personal lubricant for penile, vaginal, and/or anal 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 condoms. This product is not compatible with polyisoprene or polyurethane condoms.

VI. Predicate Device Comparison

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

Product Name	Astroglide® Sensual Strawberry Personal Lubricant K213671 Subject Device	Glycerin & Paraben Free Astroglide K072647 Predicate Device	Comparison
Indications for Use	Astroglide® Sensual Strawberry Personal Lubricant is a personal lubricant for penile, vaginal, and/or anal 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 condoms. This product is not compatible with polyisoprene or polyurethane condoms.	Glycerin & Paraben Free Personal Lubricant Astroglide® is a personal lubricant, for penile, anal, 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 latex condoms.	Same: The indications for use for the subject and predicate device are the same. Therefore, the subject and predicate device have the same intended use.
Over-the-Counter Device	Yes	Yes	Same
Base Type	Water	Water	Same
Ingredients	Purified Water, Glycerin, Propylene Glycol, Methyl Gluceth-20, Natural & Artificial Strawberry Flavor, Clear Xanthan Gum, Hydroxyethylcellulose, Sodium Gluconate, Sodium Saccharin, Sodium Benzoate, Potassium Sorbate, Citric Acid	Purified Water, Butylene Glycol, Propylene Glycol, Xylitol, Polyquaternium-15	**Different:** The subject and predicate device have differences in formulation. These differences do not raise different questions of safety and effectiveness (S&E).
Condom compatibility	Natural rubber latex condoms.	Natural rubber latex condoms.	Same
pH	3.5-5.5	3.5-5.5	Same
Osmolality	200 - 450 mOsm/kg, 1:5 dilution factor	N/A	**Different:** The subject and predicate device have different osmolality specifications. Differences in osmolality specifications do not raise different questions of S&E.
Viscosity	200 - 450 cps,	1,100-1,500 cps	**Different:** The subject and predicate device have different viscosity specifications. Differences in

Product Name	Astroglide® Sensual Strawberry Personal Lubricant K213671 Subject Device	Glycerin & Paraben Free Astroglide K072647 Predicate Device	Comparison
			viscosity specifications do not raise different questions of 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
Antimicrobial effectiveness (per USP <51>)	Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days	Category 2, bacteria should show not less than 2.0 log reduction at 14 days and no increase from 14-day count at the 28-day count. Yeast and molds should show no increase from the initial calculated count at 14 and 28 days	Same
Sterile	Non-sterile	Non-sterile	Same
Packaging	2.5 oz PETE bottle polypropylene cap	2.5 oz PETE bottle with HDPE cap	**Different:** The subject and predicate device have different packaging. Differences in packaging do not raise different questions of S&E.
Shelf-life	8.5 months	2 years	**Different:** The subject and predicate device have different shelf-life durations. Differences in shelf-life durations do not raise different questions of S&E.

As noted in the table above, the subject and predicate device have the same indications for use and intended use (i.e., to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication). The subject and predicate device have differences in their technological characteristics.

However, as stated in the table, the differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on Astroglide® Sensual Strawberry Personal Lubricant was conducted 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." Testing included the following assessments:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization and irritation testing using the human repeat insult patch test, an alternative test method to ISO 10993-10:2010
- Acute systemic toxicity testing per ISO 10993-11:2017.

The testing demonstrated that Astroglide® Sensual Strawberry Personal Lubricant is non-cytotoxic, non-sensitizing, non-irritating, and not systemically toxic

Condom Compatibility

Astroglide® Sensual Strawberry Personal Lubricant was tested for compatibility with condoms using ASTM D7661-10, "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." Results show that Astroglide® Sensual Strawberry Personal Lubricant is compatible with natural rubber latex condoms and not compatible with polyisoprene or polyurethane condoms.

Shelf-Life

Astroglide® Sensual Strawberry Personal Lubricant has a shelf-life of 8.5 months based on accelerated aging testing results per ASTM F1980-16, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices." All specifications for the subject lubricant, as stated in Section IV of the summary, were met throughout the shelf-life study.

VIII. Conclusion

The results of the testing described above demonstrate that the Astroglide® Sensual Strawberry Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.