April 28, 2021

BioFilm, Inc.
Kevin Jamil
Regulatory Affairs
3225 Executive Ridge
Vista, CA 92081

Re: K210242
Trade/Device Name: Astroglide® X Silicone Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: January 27, 2021
Received: January 29, 2021

Dear Kevin Jamil:

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 and Part 809); 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)*
K210242

Device Name
Astroglide® X Silicone Personal Lubricant

Indications for Use *(Describe)*
Astroglide® X Silicone 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 and 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 – K210242
Astroglide® X Silicone Personal Lubricant

i. General Information on Submitter

Applicant:	BioFilm, Inc.
Address:	3225 Executive Ridge Vista, CA 92081 USA
Telephone:	760-727-9030
Fax:	760-727-8080
Contact Person:	Kevin Jamil
Contact Title:	Regulatory Affairs
Email:	kevin@biofilm.com
Date Prepared:	4/27/2021
Establishment Registration:	2025771

ii. General Information on Device

Proprietary Name:	**Astroglide® X Silicone 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
pjur® Backdoor Anal Glide and pjur® Analyse Me!	K141913

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

iv. Description of Device

Astroglide® X Silicone Personal Lubricant is non-sterile, clear, odorless, and silicone-based lubricant. This product is not a spermicide or contraceptive. Astroglide® X Silicone Personal Lubricant is compatible with natural rubber latex condoms. Astroglide® X Silicone Personal Lubricant is not compatible with polyurethane, or polyisoprene condoms. This product's primary packaging is a PETE clear bottle with a screw on polypropylene flip-top cap. The bottle is packaged in a cardboard carton which constitutes the final packaging.

The specifications for Astroglide® X Silicone Personal Lubricant are described in the following table.

Table 1. Physical Specifications of Astroglide® X Silicone Personal Lubricant

Parameter	Specification (Test Method)
Appearance	Clear
Odor	Characteristic
Viscosity	225 to 350 centipoise
Total yeast/mold count (USP <61>)	<10 cfu/mL
Total aerobic microbial count (USP <61>)	<100 cfu/mL
Absence of Pathogenic Organisms, *Staphylococcus aureus, Pseudomonas aeruginosa*, and *Candida albicans* (USP <62>)	Absent
Water activity (USP<1112>)	0.3 A_w

v. Indications for Use

Astroglide® X Silicone 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 and 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	Astroglide® X Silicone Personal Lubricant (Subject Device)	pjur® Backdoor Anal Glide and pjur® Analyse Me! (Predicate device)	Comparison
Indications for use	Astroglide® X Silicone 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 and polyurethane condoms.	pjur® Backdoor Anal Glide 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, synthetic polyisoprene, and polyurethane condoms.	The subject and predicate devices have the same indications for use except for a difference in condom compatibilities.
Condom Compatibility	This product is compatible with natural rubber latex condoms. This product is not compatible with polyisoprene and polyurethane condoms.	This product is compatible with natural rubber latex, synthetic polyurethane, and polyisoprene condoms.	The condom compatibility of the predicate device is different, but it does not raise different questions of safety and effectiveness.
Silicone-Based Lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Appearance	Clear	Clear	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Cyclopentasiloxane Dimethicone Cyclohexasiloxane	cyclopentasiloxane, dimethicone, dimethiconol, Simmondsia Chinensis (Jojoba) Seed Oil	The ingredients of the predicate device are different; however, differences in device ingredients do not raise different questions of safety & sffectiveness

Characteristic / Feature	Astroglide® X Silicone Personal Lubricant (Subject Device)	pjur® Backdoor Anal Glide and pjur® Analyse Me! (Predicate device)	Comparison
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	225 - 350 centipoise	600 – 1,000 centipoise	The viscosities of the subject and predicate devices are different; however, differences in viscosities do not raise different questions of safety and effectiveness.
Water Activity	< 0.3 A_w	< 0.3 A_w	Same
Shelf-Life	3 years	3 years	Same

As noted in the table above, the subject and predicate device have similar indications for use statements nad have the same intended use – to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. The subject and predicate device have difference technological characteristics, including different formulations, specifications, and condom compatibilities. The different technological characteristics identified do not raise different questions of safety and.

vii. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing on the subject lubricant was performed in accordance with ISO 10993-1: 2009/(R)2013, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process.*

Table 3. Biocompatibility of Astroglide® X Silicone Personal Lubricant

Test Performed
Cytotoxicity per ISO 10993-5: 2009/(R)2014
Human Repeat Insult Patch Testing (HRIPT) per ASTM D6355 to address sensitization and irritation
Acute Systemic Toxicity per ISO 10993-11: 2017

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

Condom Compatibility

Astroglide® X Silicone Personal Lubricant was tested for compatibility with natural rubber latex condoms using ASTM D7661-10, *Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.* Results show that Astroglide® X Silicone Personal Lubricant is compatible with natural rubber latex condoms only.

Shelf Life

Astroglide® X Silicone Personal Lubricant has a shelf-life of 3 years based on 12 months of 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 listed in Table 1 were met throughout the shelf-life study.

viii. Substantial Equivalence

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