November 13, 2020

BioFilm Inc,
Richard Hines
Regulatory Affairs Manager
3225 Executive Ridge
Vista, CA 92081

Re: K200239
Trade/Device Name: Astroglide® Organix® Gel
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: October 2, 2020
Received: October 14, 2020

Dear Richard Hines:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200239

Device Name
Astroglide® Organix® Gel

Indications for Use *(Describe)*
Astroglide® Organix® Gel 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 compatible with natural rubber latex and polyisoprene condoms. The 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.

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

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510(K) Summary – K200239
Astroglide® Organix ® Gel

i. Submitter Information

Applicant: BioFilm, Inc.

Address: 3225 Executive Ridge
Vista, CA 92081 USA

Telephone: 760-727-9030
Fax: 760-727-8080

Contact Person: Richard Hines
Contact Title: Regulatory Affairs Manager
Email: richard@biofilm.com

Date Prepared: November 12, 2020

ii. Device Information

Trade Name: **Astroglide® Organix ® Gel**
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
Astroglide Natural Original Applicant: BioFilm Inc.	K141581

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

iv. Description of Device

Astroglide® Organix ® Gel is non-sterile, translucent, colorless to slight yellow, water-based personal lubricant 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 and is not compatible with polyurethane condoms. This product is for over-the-counter (OTC) use.

Astroglide® Organix ® Gel's formulation consists of water, glycerine, xanthan gum, gellan gum, aloe barbabensis powder, chamomilla recutita (matricaria) flower extract, calendula officinalis flower extract, vaccinium macrocarpon (cranberry) fruit extract, passiflora incarnata flower extract, sodium benzoate, potassium sorbate, and citric acid. It is packaged in white LDPE tube with a screw on flip top cap comprised of polypropylene. This product is also provided in 2.5 ml foil packs.

Device specifications are listed in the table below.

Parameter	Specification (Test Method)
Color	Colorless to slight yellow
Clarity	Hazy liquid
Odor	Odorless
Osmolality	500-1000 mOsm/kg (1:5 dilution)
pH	3.5-5.5
Viscosity	200,000-300,000 cP
Total yeast/mold count	<10 cfu/mL (USP <61>)
Total aerobic microbial count	<100 cfu/mL (USP <61>)
Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans	Absent (USP <62>)
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

v. Indications for Use

Astroglide® Organix ® Gel 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

vi. Summary of Intended Use and Technological Characteristics of the Subject Device in Comparison to the Predicate Device

The following table compares the Indications for Use and technological characteristics of the subject and predicate device:

Characteristic / Feature	**Astroglide® Organix ® Gel (subject device)**	**Astroglide ® Natural (predicate device) - K141581**	**Comparison**
Indication for use	Astroglide® Organix Gel 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Astroglide® Natural 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 compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Same: The subject and predicate devices have the same indication for use with the exception that the it is not compatible with polyurethane condoms. Therefore, the subject and predicate devices have the same intended use (provides lubrication during intimate sexual activity).
Water-Based Lubricant	Yes	Yes	Same
Over the	Yes	Yes	Same
Odorless	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Purified Water, Glycerin*, Xanthan Gum, Gellan Gum, Aloe Barbadensis Powder*, Chamomilla Recutita (Matricaria) Flower Extract*, Calendula Officinalis Flower Extract*, Vaccinium Macrocarpon (Cranberry) Fruit Extract*, Passiflora Incarnata Flower Extract*, Sodium Benzoate, Potassium Sorbate, Citric Acid *Indicates Organic	Water, Xylitol, Hydroxyethylcellulose, Phenoxyethanol, Aloe Barbadensis Leaf Juice Extract, Chamomilla Recutita (Matricaria) Flower Extract, Pectin, Potassium Ascorbyl Tocopheryl Phosphate, Lactic Acid	Different: The ingredients of the predicate device are different; however, differences in device ingredients do not raise different questions of Safety & Effectiveness (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,*	• Total mold/yeast count <10 cfu/mL • Total aerobic microbial count <100 cfu/mL • Absence of pathogens (*Candida albicans, Pseudomonas aeruginosa,*	Same
Viscosity	200,000-300,000 centipoise	2200-3400 centipoise	Different: the viscosity of the subjective device is higher. This difference does not raise different questions of S & E.
pH	3.5-5.5	4.0-7.0	Different: The subject device has a lower pH than the predicate. This difference does not raise different questions of S& E.
Osmolality	500-1000 mOsm/kg (1:5 dilution)	769 mOsm/kg	Different: The osmolality specification for the subject device is different than the predicate device. Difference in osmolality specifications do not raise different questions of S&E.

Packaging	LDPE tube and foil	PETE Bottle	Different: The subject device is packaged in a LDPE tube and the predicate is packaged in PETE bottles. The subject device in also packaged a foil pack. These differences do not raise different questions of S &E.
Shelf-life	Bottle: 6 months Foil: 3months	Three years	Different: The subject devices have a shorter shelf-life than the predicate device. This difference does not raise different questions of S &E.

The subject and predicate device indications for use are not identical, as the predicate device indications for use does not specifically state that it is not compatible with polyurethane condoms. However, the intended use of the subject and predicate devices is the same (i.e., provides lubrication during intimate sexual activity).

In addition, the subject and predicate devices have different technological characteristics as shown in the table above. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

vii. Summary of Non-Clinical Performance Testing

Biocompatibility

Astroglide®Organix® Gel has undergone biocompatibility testing 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:

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

The testing demonstrated that Astroglide® Organix® Gel is non-cytotoxic, non-sensitizing, non-irritating, and not acutely-systemically toxic.

Condom Compatibility

Astroglide® Organix® Gel was tested in accordance with ASTM D7661-10 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms." Results showed that Astroglide® Organix® Liquid is compatible with natural rubber latex and polyisoprene condoms. Astroglide® Organix® Liquid is not compatible with polyurethane condoms.

Shelf life

Astroglide® Organix® Gel has a shelf-life of 6 months in 3 oz. LDPE tubes and 3 months in foils packs. Results from testing demonstrated that the device can maintain its specifications (as shown in Section IV) over the duration of its shelf-life in both packaging forms.

viii. Conclusion

The results of the testing described above provide reasonable assurance that the Astroglide® Organix Gel Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.