DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 10, 2017

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

Re: K163395
Trade/Device Name: Astroglide® Diamond Silicone Gel Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 1, 2016
Received: December 5, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163395

Device Name
Astroglide® Diamond Silicone Gel Personal Lubricant

Indications for Use *(Describe)*
Astroglide® Diamond Silicone Gel Personal Lubricant 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, 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.

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

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510(k) Summary – K163395
Astroglide® Diamond Silicone Gel 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:	Richard Hines
Contact Title:	Regulatory Affairs Manager
Email:	richard@biofilm.com
Date Prepared:	February 9, 2017
Establishment Registration:	2025771

ii. General Information on Device

Proprietary Name:	**Astroglide® Diamond Silicone Gel Personal Lubricant**
Common Name:	Personal Lubricant
Classification Name:	Condom (21 CFR 884.5300)
Regulatory Class:	II
Product Code:	NUC (lubricant, personal)

iii. Predicate Device

Predicate Device	510(k) Number
ONE® SILICONE Personal Lubricant Original Applicant: ONE®	K110690

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

iv. Description of Device

Astroglide® Diamond Silicone Gel Personal Lubricant is non-sterile, clear, odorless, and silicone-based lubricant. This product is not a spermicide or contraceptive. It is compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

This product primary packaging is a white LDPE 3 ounce tube with a screw on polypropylene flip-top cap. The tube and cap constitute the device final packaging.

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

Parameter	Specification (Test Method)
Color	Colorless
Clarity	Clear
Odor	Odorless
Absence of particulate matter	Absent
Viscosity	12,000-22,000 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>)

v. Predicate Device Comparison

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

Characteristic / Feature	Astroglide® Diamond Silicone Gel Personal Lubricant (subject	One Silicone Personal Lubricant (predicate device) - K110690	Comparison
Indication for use	Astroglide® Diamond Silicone Gel Personal Lubricant 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, polyurethane, and polyisoprene condoms.	ONE® Silicone Personal lubricant 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, polyisoprene, and polyurethane condoms.	Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use.
Silicone-based lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Non-greasy & odorless	Yes	Yes	Same
Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same

Primary Ingredients	Dimethicone, Cyclomethicone Dimethicone / Vinyl Dimethicone Crosspolymer, Cocos Nucifera (Coconut) Oil	Information is unknown	Different: The ingredients in the predicate device are not known; however, differences in device ingredients do not raise different questions of Safety & Effectiveness (S & E) (e.g., biocompatibility, condom compatibility)
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)*	Information is unknown	Different: the microbial limits specifications for the predicate device are not known; however this does not raise different questions of S & E (e.g., microbial specifications within accepted range for these types of devices).
Viscosity	12,000-22,000 cP	Information is unknown	Different: the viscosity of the predicate device is not known; however this does not raise different questions of S & E (e.g., viscosity specification within the accepted range for these types of devices).

As noted in the table above, the subject and predicate device are similar in that they are both clear, non-sterile, silicone-based lubricants, and are compatible with natural rubber latex, polyisoprene, and polyurethane condoms. However, differences do exist in the formulation and product specification for microbial limits and viscosity. The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

vi. Summary of Non-clinical Performance Testing

<u>Biocompatibility</u>

Biocompatibility testing 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.

Biocompatibility Testing	**Astroglide® Diamond Silicone Gel Personal Lubricant Results**
Cytotoxicity, ISO 10993-5: 2009/(R)2014	The test article was found to be non-cytotoxic.
Guinea Pig Maximization, ISO 10993-10: 2010/(R)2014	The test article was found to be non-sensitizing.
Vaginal Irritation, ISO 10993-10: 2010/(R)2014	The test article was found to be non-irritating.
Systemic Toxicity, ISO 10993-11: 2006/(R)2010	The test article was found to be non-systematically toxic.

Condom Compatibility

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

Shelf life

Astroglide® Diamond Silicone Gel Personal Lubricant has a shelf-life of 2 years based on 8 months of accelerated aging testing results per ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Preservative effectiveness per USP <51> was demonstrated at critical time-points throughout the stability testing including at the time zero (0) and eight-month (8) time points for the accelerated aging study. All specifications for the subject lubricant were met during the shelf-life study.

vii. Substantial Equivalence

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