



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

August 30, 2017

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

Re: K171985
Trade/Device Name: Astroglide® O Oil Personal Lubricant & Massage Oil
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 30, 2017
Received: July 3, 2017

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

Indications for Use

510(k) Number (if known)

K171985

Device Name

Astroglide® O Oil Personal Lubricant & Massage Oil

Indications for Use (Describe)

Astroglide® O Oil Personal Lubricant & Massage Oil 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 not compatible with 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 – K171985
Astroglide® O Oil Personal Lubricant & Massage Oil

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:	August 29, 2017
Establishment Registration:	2025771

ii. General Information on Device

Proprietary Name:	Astroglide® O Oil Personal Lubricant & Massage Oil
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
O Glide Personal Lubricant Original Applicant: Grafenberg Labs	K142726

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

iv. Description of Device

Astroglide® O Oil Personal Lubricant & Massage Oil is non-sterile, light yellow, lightly coconut and ylang-ylang scented, and oil-based lubricant. All oils used in the subject formulation are certified organic, and the subject lubricant is a USDA certified organic final product. This product is not a spermicide or contraceptive. It is NOT compatible with natural rubber latex, polyurethane, or polyisoprene condoms.

This product primary packaging is a PETE amber bottle with a screw on polypropylene flip-top cap. The bottle and cap constitute the device are labeled front and back and then packaged in a cardboard carton which constitutes the final packaging.

The specifications for Astroglide® O Oil Personal Lubricant & Massage Oil are described in the following table.

Parameter	Specification (Test Method)
Color	Light yellow
Clarity	Clear
Odor	Coconut and ylang-ylang
Absence of particulate matter	Absent
Viscosity	60-120 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. Indication for Use

Astroglide® O Oil Personal Lubricant & Massage Oil 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 not compatible with condoms.

vi. Predicate Device Comparison

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

Characteristic / Feature	Astroglide® O Oil Personal Lubricant & Massage Oil (subject device)	O Glide Personal Lubricant (predicate device) - K142726	Comparison
Indication for use	Astroglide® O Oil Personal Lubricant & Massage Oil 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 not compatible with condoms.	O Glide 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 not compatible with condoms.	Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use.
Oil-Based Lubricant	Yes	Yes	Same
Over the Counter	Yes	Yes	Same
Odorless	No	No	Same

Not a contraceptive or Spermicide	Yes	Yes	Same
Non-sterile	Yes	Yes	Same
Primary Ingredients	Helianthus Annuus (Sunflower) Seed Oil*, Ricinus Communis (Castor) Seed Oil*, Cocos Nucifera (Coconut) Oil*, Prunus Amygdalus Dulcis (Sweet Almond) Oil*, Simmondsia Chinesis (Jojoba) Seed Oil *, Argania Spinosa Kernel (Argan Tree Nut) Oil*, Tocopherol, Cananga Odorata (Ylang Ylang) Flower Oil* *Indicates Organic	Olus (vegetable) oil, Olea Europeaea (olive) Fruit Oil, Argania Spinosa Kernel Oil, Pichia / Resveratrol Ferment Extract	Different: The ingredients of the predicate device are different; however, differences in device ingredients do not raise different questions of Safety & Effectiveness (S & E) (e.g., biocompatibility)
Microbial Limits	• Total mold/yeast count <10 cfu/mL • Total aerobic microbial count <100 cfu/mL • Absence of pathogens (<i>Candida albicans</i>, <i>Pseudomonas aeruginosa</i>, <i>Staphylococcus aureus</i>)	• Total mold/yeast count <10 cfu/mL • Total aerobic microbial count <100 cfu/mL • Absence of pathogens (<i>Candida albicans</i>, <i>Pseudomonas aeruginosa</i>, <i>Staphylococcus aureus</i>)	Same
Viscosity	60-120 cP	Unknown	Different: the viscosity of the predicate device is unknown; however, this does not raise different questions of Safety & Effectiveness (e.g., viscosity specification within the accepted range for these types of devices).
Osmolality	N/A – Oil-based, non-polar formula	N/A – Oil-based, non-polar formula	Same
pH	N/A – Oil-based, non-polar formula	N/A – Oil-based, non-polar formula	Same

As noted in the table above, the subject and predicate device are similar in that they are both clear, non-sterile, non-aqueous based lubricants. However, differences do exist in the formulation and viscosity. The differences identified do not raise new questions of safety and effectiveness.

vii. Summary of Non-Clinical Performance Testing

Biocompatibility

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® O Oil Personal Lubricant & Massage Oil 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® O Oil Personal Lubricant & Massage Oil is NOT compatible with natural rubber latex, polyurethane, and polyisoprene condoms.

Shelf life

Astroglide® O Oil Personal Lubricant & Massage Oil has a shelf-life of 18 months based on 6 months of accelerated aging testing results per ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The accelerated aging study demonstrated that the subject device maintained its specifications over the duration of its shelf life.

viii. Substantial Equivalence

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