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 6, 2014

BioFilm, Inc.
Sherry Castello
Regulatory Affairs and Quality Assurance Associate
3225 Executive Ridge
Vista, CA 92081

Re: K141581
Trade/Device Name: Astroglide® Natural
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: June 10, 2014
Received: June 13, 2014

Dear Sherry Castello,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Joyce M. Whang -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)*
K141581

Device Name
Astroglide Natural

Indications for Use *(Describe)*
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 ONLY compatible with natural rubber latex 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Astroglide® Natural

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:	Sherry Castello
Email:	Regulatory Affairs Associate sherry@biofilm.com
Date Prepared:	Aug 5, 2014
Establishment Registration:	2025771

General Information on Device

Proprietary Name:	**Astroglide® Natural**
Common Name:	Personal Lubricant
Classification Name:	Lubricant, Personal, 21 CFR 884.5300 Condom, Product Code: NUC

Predicate Device

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

Description of Device

Astroglide Natural personal lubricant is non-sterile, clear and water based. Astroglide® Natural is a proprietary blend consisting mainly of water soluble ingredients similar to other lubricants currently on the market. This product is not a spermicide or contraceptive. It is compatible with natural rubber latex and polyisoprene condoms. It is not compatible with polyurethane condoms. This product primary packaging is a clear PET bottle with a screw on flip top cap comprised of polypropylene. Each bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Indications for Use

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 ONLY compatible with natural rubber latex and polyisoprene condoms.

Technological Characteristics
There are no fundamental differences in Astroglide® Natural as compared to the predicate device Glycerin and Paraben Free Astroglide. Both lubricants are clear, water based lubricants formulated without glycerin and paraben. Both formulas use Xylitol as a humectant, thickener, and preservative aid.

Table 5-1. Technological Characteristics Comparison

Attribute	**Astroglide® Natural Lubricant**	**Predicate: Glycerine and Paraben Free Astroglide**
510(k) Number	**To Be Determined**	**K072647**
Indications for use	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 ONLY compatible with natural rubber latex and polyisoprene condoms.	Glycerin and Paraben Free 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.
Ingredients	Water, Xylitol , Hydroxyethylcellulose, Phenoxyethanol, Aloe Barbadensis Leaf Juice Extract, Chamomilla Recutita (Matricaria) Flower Extract, Pectin, Potassium Ascorbyl Tocopheryl Phosphate, Lactic Acid	Water, Butylene Glycol, Xylitol, Propylene Glycol, Polyquaternium-15
Storage Instruction	Room Temperature	Room Temperature
pH	4.0 – 7.0	3.5 – 6.0
Osmolarity	769 mOsm/kg	727 mOsm/kg
Viscosity	2200-3400 cP	1100 – 1500 cP
Condom compatibility	Natural rubber latex and polyisoprene	Latex

Biocompatibility
Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices.

Table 5-2. Biocompatibility of Astroglide® Natural

Biocompatibility Testing	Astroglide Natural Results
Cytotoxicity	Passed Test – Non-cytotoxic
Guinea Pig Maximization, ISO 10993-10	Passed test - The test article did not elicit any reactions
Vaginal Irritation, ISO 10993-10	The test article was considered non-irritating to the vaginal mucosa in New Zealand White Rabbits as compared to the control article.
Penile Irritation, ISO 10993-10	The test article was considered non-irritating to the penile tissue in New Zealand White Rabbits as compared to the control article.
Systemic Toxicity, ISO 10993-11	All extracts of the test article met the requirements of ISO 10993-11. No test animals exhibited any biological reactivity.

Specifications

Astroglide Natural has the following lot release specifications: color, clarity, odor, absence of particulate matter, pH, viscosity, total yeast/mold count, total aerobic microbial count, and absence of pathogens including *Staphylococcus aureus, Pseudomonal aeruginosa, and Candida albicans.*

Shelf Life

Astroglide Natural shows a shelf-life of 3 years based on a 3-year real-time stability study and a 1 year accelerated aging study. Preservative effectiveness was demonstrated at critical time-points throughout the stability testing.

Condom Compatibility

Astroglide® Natural 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® Natural is compatible with latex and polyisoprene condoms but not compatible with polyurethane condoms.

Substantial Equivalence

Astroglide® Natural personal lubricant has the same intended use and basic technological characteristics as the predicate device. Astroglide® Natural performed well in biocompatibility and performance bench testing proving it is as safe and effective as the predicate device.