NOV 3 0 2004

K041432

510(k) SUMMARY

Date Prepared May 21, 2004

Submitter
BioFilm, Inc.
3225 Executive Ridge
Vista, CA 92081

Contact Person
Robert L. De Armond
V.P. Operations / Regulatory Affairs
(760)727-9030 Phone (760)477-2424 Fax

Proprietary Name
Astroglide® Brand
WARMING LIQUID Personal Lubricant

Common Name Personal Lubricant

Classification Name Patient lubricant

Predicate Device
K-Y Brand WARMING LIQUID Personal Lubricant
510(k) Number K021492

Device Classification

The General Hospital and Personal Use Device section of the General Medical Devices Panel has classified Patient Lubricants as Class I. (21 CFR § 880.6375)

Description of Device

Astroglide® Brand WARMING LIQUID is a non-sterile clear non-greasy, high viscosity liquid used as a personal lubricant. The product is highly lubricous and may be used with or without a condom during sexual activity. Astroglide® Brand WARMING LIQUID is not a contraceptive or spermicide. It is compatible with latex condoms as demonstrated in condom compatibility testing conducted according to standards defined by ASTM D 3492.

Intended Use

Astroglide® Brand WARMING LIQUID is recommended as a personal lubricant to enhance intimate activities. It is designed to help enhance the sexual experience by providing supplemental vaginal lubrication during sexual intercourse.

Astroglide® Brand WARMING LIQUID may be used with condoms.

Summary of Technological Characteristics

Astroglide® Brand WARMING LIQUID formula is proprietary. The product has no exceptional technological characteristics consisting mainly of water soluble ingredients similar to lubricants currently on the market.

Substantial Equivalence

This product is substantially equivalent to the currently marketed K-Y Brand WARMING LIQUID personal lubricant. Both devices have the same intended use and substantially similar formulas. Both devices produce a slight warming sensation upon application. Astroglide® Brand WARMING LIQUID is slightly more lubricious due to an additional ingredient also found in BioFilm's currently marketed Astroglide® Personal Lubricant.

Product Testing

Biocompatibility testing of Astroglide® Brand WARMING LIQUID conducted by outside laboratories demonstrated:

- In a Dermal Sensitization Study that the product was considered not to be a contact sensitizing agent in guinea pigs.
- In a 5 day Rabbit Vaginal Irritation Study, that the product did not cause any pharmacotoxic effects when administered vaginally to rabbits for 5 consecutive days. Astroglide® Brand WARMING LIQUID received an irritation index score of 1, which is considered a minimal irritant.
- In a Mouse Systemic Toxicity Evaluation of Astroglide® Brand WARMING LIQUID that at 50mL/kg IV the product did not cause mortality and was not associated with systemic toxicity when administered at 50mL/kg IP.
- In a USP Agar Diffusion Test Astroglide® Brand WARMING LIQUID did not produce any evidence of cytotoxicity.
- In a Human Repeat Insult Patch Test involving 53 healthy adult males and females the study showed no evidence of increased likelihood of sensitization to Astroglide® Brand WARMING LIQUID.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2004

Mr. Robert L. De Armond
Vice President Operations/
Regulatory Affairs
BioFilm, Inc.
3225 Executive Ridge
VISTA CA 92081

Re: K041432
Trade/Device Name: Astroglide® Brand WARMING LIQUID personal lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: October 8, 2004
Received: October 12, 2004

Dear Mr. De Armond:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041432

Device Name: Astroglide® Brand Warming Liquid

Indications For Use:

Recommended as a personal lubrication to enhance intimate activities.

Prescription Use _____ AND/OR Over-The Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041432