



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 18 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Mr. Daniel X. Wray
Chief Executive Officer
Biofilm, Inc.
3121 Scott Street
Vista, California 92083

Re: K935299
Astroglide
Regulatory Class: I
Dated: November 1, 1993
Received: November 2, 1993

Dear Mr. Wray:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

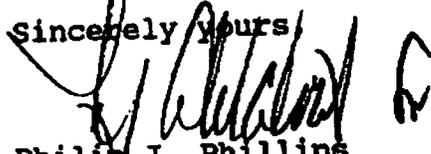
This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

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labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

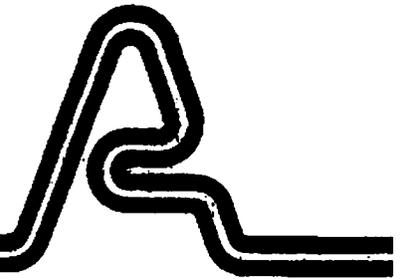


Philip J. Phillips
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health



ASTROGLIDE®

K935299



BioFilm, Inc.

3121 Scott St., Vista, CA 92083
National 1(800) 325-5695
California 1(800) 848-5900
Fax 1(619) 727-8080

510(K) SUMMARY

SUBMITTER'S NAME: BioFilm, Inc.

ADDRESS: 3121 Scott Street
Vista, CA 92083

PHONE: 1 (800) 325-5695

FAX: 1 (619) 727-8080

CONTACT PERSON: Daniel X. Wray
Chief Executive Officer

DATE PREPARED: November 1, 1993

NAME OF DEVICE:

PROPRIETARY NAME: Astroglide.

COMMON/USUAL NAME: Personal lubricant.

CLASSIFICATION NAME: Patient lubricant.

FDA/CDRH/OCE/DMC

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RECEIVED

PREDICATE DEVICE: K-Y Lubricating Jelly and Personal Lubricant, not sterilized, K810310.

DESCRIPTION OF DEVICE: Astroglide is a clear, odorless, colorless personal lubricant composed of purified water, polyquaternium #5, glycerine 96%, USP, propylene glycol, USP, methylparaben, USP/NF, Propylparaben, NF. The Astroglide bottles and sample containers are composed of high density polyethylene plastic.

INTENDED USE: Personal lubrication and lubrication of body orifices to facilitate entry of diagnostic or therapeutic devices used in medical procedures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: Both K-Y Lubricating Jelly and Personal Lubricant, not sterilized, and Astroglide are composed of a water and glycerin base with thickener and preservatives.

SUBSTANTIAL EQUIVALENCE: Astroglide is substantially equivalent to K-Y Lubricating Jelly and Personal Lubricant, not sterilized, manufactured by Johnson & Johnson Products, Inc., 501 George Street, New Brunswick, New Jersey 08903, K810310.

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