K973557

OCT - 3 1997

9. 510 (k) Summary of Information Respecting Safety and Effectiveness

A. Legally Marketed Device.

Qualis claims substantial equivalence to Astroglide (K935299), currently in commercial distribution by Bio Film, Inc.

B. Device Description.

Lubriglide is a water-based, water-soluble personal lubricant designed to imitate the body's own lubricating fluids. It is non-irritating, non-staining, and won't dry out or leave behind any solid residues. Lubriglide is non-toxic and is easily removed with water.

C. Intended Use.

Lubriglide is a non-sterile personal lubricant for over-the-counter use. It can also be used to lubricate rectal thermometers, tampons, douches, and enemas.

D. Comparison with Predicate Device.

A summary comparison of the features of Lubriglide and the Predicate Device (Astroglide) is provided in Table 1.

E. Performance Data.

Non-clinical studies.

1. Stability.

Lubriglide successfully passed the requirements of the Qualis, Inc., accelerated stability protocol and has been assigned a two-year expiration period.

2. Preservative Effectiveness.

Lubriglide successfully passed the requirements of the Qualis, Inc., antimicrobial preservative challenge.

3. Comparison with Predicate Device.

Lubriglide was compared to Astroglide on the basis of perceptual qualities, physical and chemical properties, ingredients list review, label claims, and packaging. The result of this review was a "Satisfactory" comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mary Finn, Ph.D.
Director of Regulatory Affairs
Qualis, Incorporated
4600 Park Avenue
Des Moines, Iowa 50321

OCT 10 1997

Re: K973557
Trade Name: Lubriglide
Regulatory Class: I
Product Code: KMJ
Dated: August 25, 1997
Received: September 19, 1997

Dear Dr. Finn:

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 (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973557

Device Name: Lubriglide

Indications For Use:

Lubriglide is a non-sterile personal lubricant for over-the-counter use. Its primary use is to apply the product to the genital area to reduce the discomfort associated with sexual activity. Lubriglide can also be used to lubricate rectal thermometers, tampons, douches, and enemas.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973557

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)