K970577

JAN - 8 1998

APPENDIX E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR GLYDE DAM LOLLYES

Submitter

Glyde USA, Inc.
1758 Dexter Avenue North, Suite 3
Seattle, WA 98109 U.S.A.

Telephone Number: 206.283.7664

Facsimile: 206.284.7554

Contact Person: Barbara Lippert, President

Date summary was prepared

02.13.97

Name(s) of the device

Proprietary (Trade) Name: Glyde Dam Lollyes

Common or Usual Name: Latex dam

Identification of predicate device(s)

Trojan Brand Latex Condoms
Carter Products, Division of Carter Wallace, Inc.
New York, N. Y.

Description of the device

Glyde Dam Lollyes are manufactured from good quality rubber latex conforming to ASTM 1076-88. The size of each Glyde Dam Lollyes is 10.0 inches (± 0.1 inch) by 6.0 inches (± 0.1 inch) by 0.08 millimeters thick (± 0.0006 millimeters.) Glyde Dam Lollyes are designed to be used while performing cunnilingus.

Qualification testing (biocompatibility, tensile strength/elongation, and virus) has been performed to satisfactorily conclude that Glyde Dam Lollyes operate as intended, when used properly. Finally, Glyde Dam Lollyes are tested for a smooth surface (i.e.: the presence of cracks and blisters,) and are visually tested for holes, tears, foreign materials and the like, during the manufacturing process of each lot.

Intended Use

Glyde Dam Lollyes, when properly used, may help reduce the risk of catching or spreading many Sexually Transmitted Diseases ("STDs") such as syphilis, gonorrhea, chlamydia infections, genital herpes, and AIDS; however, they cannot eliminate the risk. For maximum benefits, it is important to follow the instructions for use printed on the packaging. Failure to do so may result in the loss of the benefits of the Glyde Dam Lollyes. During intimate contact, lesions and various bodily fluids can transmit STDs. Therefore, the Glyde Dam Lollyes should be applied each and every time before any such contact occurs.

The Glyde Dam Lollyes is removed from the wrapper and laid flat. The Glyde Dam Lollyes is placed over the entire vulva, covering both the vaginal opening and the clitoris, while holding the ends of the Glyde Dam Lollyes. Optional: one side may be moistened with a commercially available water-based lubricant. The lubricated side of Dam Lollyes is then placed over the entire vulva, covering both the vaginal opening and the clitoris, while

holding the ends of the Glyde Dam Lollyes. The Glyde Dam Lollyes is intended for single use only. Users are instructed not to re-use Glyde Dam Lollyes because of possible cross-contamination. Users are further instructed not to stretch the Glyde Dam Lollyes, and instructed to store them in a cool dry place at room temperature (59 degrees to 86 degrees Fahrenheit) and away from direct exposure to sunlight.

Comparison of device characteristics to predicate

A comparison was made between the physical and performance characteristics of the Glyde Dam Lollyes and the physical and performance characteristics of a legally marketed predicate product. This analysis revealed that Glyde Dam Lollyes are substantially equivalent to that predicate product.

Non clinical testing

Biocompatibility, tensile strength/elongation and virus testing was performed on the Glyde Dam Lollyes. All testing was supportive of the claims (i.e.: indications for use.)

Conclusion

In conclusion, the basis for substantial equivalence between the Glyde Dam Lollyes and the legally marketed predicate product is that the products are predominantly similar and that the differences between the two products do not raise new issues of safety and effectiveness. Based upon the information provided herein, it is our conclusion that the Glyde Dam Lollyes are substantially equivalent to the Trojan Brand Condoms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 1998

Glyde USA, Inc.
c/o Ms. Louise C. Myers
Technical Adviser
Medical Technology Consultants
14808 N.E. 66th Street
Redmond, Washington 98052-4712

Re: K970577
Glyde Dam Lollyes™
Dated: October 21, 1997
Received: October 23, 1997
Regulatory class: II
21 CFR §884.5300/Product code: 85 MSC

Dear Ms. Myers:

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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number

K970977

Device Name

Glyde Dam Lollyes

Indications for Use

Glyde Dam Lollyes™ are a thin 10" x 6" natural rubber latex sheet specially designed as a barrier for use while performing cunnilingus (oral/vaginal sex) ONLY, and are not intended for use during oral/anal sex.

Glyde Dam Lollyes™, when properly used, may help reduce the risk of catching or spreading many sexually transmitted diseases ("STDs") such as syphilis, gonorrhea, chlamydia infections, genital herpes and AIDS. However, they cannot eliminate the risk.

During intimate contact, lesions and various bodily fluids can transmit STDs. Therefore, the *Glyde Dam Lollyes*™ should be applied each and every time before any such contact occurs.

WARNING: DO NOT USE DURING PENETRATING PENILE/VAGINAL OR PENILE/ANAL INTERCOURSE.

WARNING: THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS IN SOME INDIVIDUALS. IF YOU EXPERIENCE A REACTION, STOP USING THIS PRODUCT AND CONTACT YOUR PHYSICIAN.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☐ Prescription Use (per 21 CFR 801.109)

☒ Over-the Counter Use

Robert D Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970577