

2/19/99

K990067

APPENDIX E

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR SHEER GLYDE DAMS™**

K990067

Submitter

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Contact Person: Barbara Lippert

Contact Title: President

Date summary was prepared

01.07.99

Name(s) of the device

Proprietary (Trade) Name: Sheer Glyde Dams™

Common or Usual Name: Latex dam

Identification of predicate device(s)

Sheer Glyde Dams™ (previously named "Glyde Dam Lollyes™")

Description of the device

K99007

Note: There has been no change to the materials that comprise the product, or to the manufacturing or quality assurance processes: Sheer Glyde Dams™ are manufactured from good quality rubber latex conforming to ASTM 1076-88. The size of each Sheer Glyde Dams™ is 10.0 inches (\pm 0.1 inch) by 6.0 inches (\pm 0.1 inch) by 0.08 millimeters thick (\pm 0.0006 millimeters.) Sheer Glyde Dams™ are designed to be used while performing either cunnilingus or anilingus.

Qualification testing (biocompatibility, tensile strength/elongation, and virus) was previously performed to satisfactorily conclude that Sheer Glyde Dams™ operate as intended, when used properly. Finally, Sheer Glyde Dams™ 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

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

The Sheer Glyde Dams™ is removed from the wrapper and laid flat. The Sheer Glyde Dams™ is placed over the entire vulva, covering both the vaginal opening and the clitoris, or alternatively, over the entire anal area, including anus, while holding the ends of the Sheer Glyde Dams™. Optional: one side may be moistened with a commercially available water-based lubricant. The lubricated side of Sheer Glyde Dams™ is then placed over the entire vulva, covering both the vaginal opening and the clitoris, or alternatively, over the

entire anal area, including anus, while holding the ends of the Sheer Glyde Dams™. The Sheer Glyde Dams™ is intended for single use only. Users are instructed not to re-use Sheer Glyde Dams™ because of possible cross-contamination, and they are instructed to use a separate and new Sheer Glyde Dams™ for the vaginal area and the anal area. Users are further instructed not to stretch the Sheer Glyde Dams™, 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 Sheer Glyde Dams™ and the legally marketed predicate product (Sheer Glyde Dams™). There has been no change in any of the material or performance characteristics. The only change is an addition to the indications for use of the product: during anilingus. Sheer Glyde Dams™ are substantially equivalent to the predicate product.

Non clinical testing

Biocompatibility, tensile strength/elongation and virus testing was performed on the Sheer Glyde Dams™ as part of the original 510(k) Notification process. No additional testing is required as a result of the addition of the new indication for use. Testing is supportive of the new claim (i.e.: indication for use.)

Conclusion

In conclusion, the basis for substantial equivalence between the Sheer Glyde Dams™ and the legally marketed predicate product (Sheer Glyde Dams™) is that the products are identical, with the only difference being an added indication for use: namely, anilingus. This new indication for use does not raise new issues of safety and effectiveness. Based upon the information provided herein, it is our conclusion that the Sheer Glyde Dams™ are substantially equivalent to the currently marketed predicate product.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Glyde USA, Inc.
c/o Ms. Louise C. Myers
Regulatory and Clinical Consultant
14808 N.E. 66th Street
Redmond, WA 98052-4712

Re: K990067
Sheer Glyde Dams™
Dated: January 7, 1999
Received: January 8, 1999
Regulatory Class: II
21 CFR 884.5300/Procode: 85 MSC

Dear Ms. Myers:

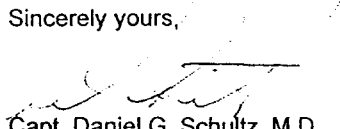
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990067

510(k) Number

None assigned to date.

Device Name

Sheer Glyde Dams™

Indications for Use

Sheer Glyde Dams™ are a thin 10" x 6" natural rubber latex sheet specially designed as a barrier for use while performing cunnilingus (oral/vaginal sex) or anilingus (oral/anal sex [rimming]).

Sheer Glyde Dams™, 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.

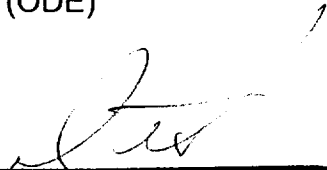
During intimate contact, lesions and various bodily fluids can transmit STDs. Therefore, the Sheer Glyde Dams™ should be applied each and every time before any such contact occurs.

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



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990067