

510(k) Summary

ASI Miniguard Female Continence Device

K954215

- 1. Name:** Advanced Surgical Intervention
Address: P.O. Box 3134
Dana Point, CA 92629
Phone: (714) 240-5899
Contact: Robert Rosenblut, PhD
- 2. Device Name:** Female Continence Device
Proprietary Name: Miniguard
Classification Name: Unknown
- 3. Predicate Devices:** Dacomed C³ Male Continence Device
Diamed External Urinary Appliance
Xtramedics Fresh 'n Fit Padette

MAY - 8 1996

4. Device Description

The Miniguard female continence device consists of a small pad that is coated on one side with a biocompatible polymer adhesive. The Miniguard is an external management device that is applied to the urinary opening to prevent or decrease episodes of stress incontinence. The Miniguard's function is to provide occlusion of the urinary opening by creating a seal over the urinary opening. The foam pad backing is intended to facilitate application and removal and for user comfort.

5. Intended Use

The Miniguard is an external female continence device that is applied to the urinary opening to prevent or decrease episodes of stress incontinence. Stress incontinence occurs when intra-abdominal pressure exceeds urethral resistance as a result of physical stress such as coughing, laughing, or lifting heavy objects. The Miniguard is designed for women who experience urine leakage under conditions of physical stress.

6. Technological Characteristics Comparison

The Miniguard female continence device is substantially equivalent in function to the Dacomed C³ Male Continence Device. Both the Miniguard and the Dacomed device achieve the intended use (to prevent or decrease episodes of incontinence) by occlusion of the urethra. The Miniguard is substantially equivalent in design characteristics to the Diamed External Urinary Appliance. The design characteristics are equivalent to the Diamed device in that both utilize an adhesive seal on the intralabial mucosa. The Miniguard also has technological similarities to the Xtramedics device in that both are worn intralabially, over the urethral opening. The materials used in the Miniguard have extensive histories in a variety of biomedical applications including oral, ocular, vaginal and wound care devices.

7. Nonclinical Tests

The Miniguard and its constituent materials were tested for biocompatibility, toxicity, cytotoxicity, bacteriostasis/fungistasis, and skin sensitivity. The testing exceeds the guidelines per the FDA tripartite and ISO 194 for a device that is chronically used on intact mucous membrane. The results of these tests demonstrated that the materials and the whole device are biocompatible, non-toxic and well tolerated by cutaneous and subcutaneous tissue. In addition, bacteriological testing indicated that the materials do not support growth of common urologic pathogens.

8. Clinical Tests

The Miniguard device has been extensively tested for its safety and efficacy in decreasing the number of urinary leakage episodes in women with incontinence. All testing results indicate that use of the Miniguard imparts minimal risk, yet provides significant benefit for women in controlling urinary leakage.

Clinical testing on the Miniguard was completed on over 350 women from 12 investigative centers in the United States. Women used the Miniguard during a device usage period of 12 weeks to test four efficacy hypotheses which demonstrate the Miniguards ability to 1) decrease the number of leakage episodes; 2) reduce the perceived severity of urinary leakage; 3) reduce the impact of incontinence on quality of life; and 4) reduce the quantity of urine leakage. Testing materials used were: 1) a voiding diary; 2) a symptom questionnaire; 3) an incontinence impact questionnaire; and 4) a 12-hour home pad-weight test. All testing materials were derived from published sources on incontinence testing and management. Efficacy parameters were statistically analyzed using graphical analyses, paired-t analyses (Prob>|T|) and repeated-measures (MANOVA) analyses. Analyses' results demonstrate, in each of the four hypothesis, a statistically and clinically significant improvement for participants. The table below details the average values before using the Miniguard (Control) and after 12 weeks of device use (Trial 17).

Hypothesis	Control	Trial 17	% Improvement	Prob> T
1. No. of Leakage Episodes (per week)	14.18	4.89	65.5%	≤0.0001
2. Perceived Severity of Leakage	11.02	3.18	71.1%	≤0.0001
3. Impact on Quality of Life	10.42	2.98	71.4%	≤0.0001
4. Quantity of Leakage (grams/hr)	1.31	0.51	61.1%	≤0.0001

The women in this study had varying degrees of urinary incontinence. The incontinence was considered mild if the women had less than 8 episodes of incontinence per week, moderate for 8-21 episodes per week and severe for greater than 21 episodes per week. Based on this classification¹, 124 women had mild incontinence, 163 had moderate incontinence and 69 had severe incontinence.

Effectiveness

The study showed that after three months of using the Miniguard, women experienced fewer leakage episodes and improved their overall quality of life. The severity of urine leakage is a measure of the patient's perception of the degree of leakage during various activities. Thirteen activities were rated for a total possible maximum score of 39. The impact of urinary incontinence on quality of life is a measure of the patient's perception of the degree to which leakage had a negative effective on various aspects of daily living. Twenty-six aspects were rated for a total possible maximum score of 78. Below are the results showing the average changes and improvement of the study participants.

Effectiveness Data for Patients Using Miniguard - Average Values

Study Endpoints	Mild		Moderate		Severe	
	Control	Trial*	Control	Trial*	Control	Trial*
Number of Leakage Episodes in One Week ²	4.48	2.20	13.14	4.75	34.06	9.84
Severity of Urine Leakage During Various Physical Activities ³	8.62	1.97	11.39	3.28	14.46	5.01
Impact Urinary Incontinence has on Quality of Life ⁴	6.73	1.76	10.85	2.84	16.04	5.43
Volume of Urine Lost over a 12 Hour Period (grams/hr) ⁵	0.57	0.35	1.10	0.59	3.16	0.59

*Trial information based on data collected after 12 weeks of Miniguard usage.

To provide clinical safety assurance of the Miniguard, the effects of use on bladder function, local microbiology and dermatology were evaluated. Bladder function was assessed via post-void residual measurements and a cohort of patients underwent cystometry. There were no clinically significant changes noted and there was no indication that Miniguard use adversely effected bladder function. Microbiological testing included vaginal smears, vaginal cultures (for a cohort of subjects), urinalysis and urine culture. Results of the microbiological testing show no increased incidence of either vaginal infection or urinary tract infection associated with device usage. Dermatologic testing included physical examinations and vestibular cytology. Results of dermatologic testing show the Miniguard was well-tolerated by the intralabial mucosa and that there were no significant dermatologic effects resulting from device usage.

The sole adverse event which may be associated with Miniguard usage was a minor increase in the incidence of subject reported symptoms of irritation, characteristic of subjective perceptions of minor irritation associated with use of any topical device. Of the women who reported symptoms of vestibular irritation, the majority experienced one occurrence only and continued using the Miniguard with no further symptoms and no required intervention from the investigator.

To further assess the safety data, ASI submitted study data to teams of physicians for analysis. Bladder function data were assessed by leading urologists and urogynecologists; microbiology data were assessed by a core laboratory at the University of Washington specializing in urogenital microflora; dermatology data were assessed by an expert in dermatology and gynecology at Emory University. These independent reports confirmed ASI's analyses results and are included in the 510(k) in Sections 10-14. Statistical analyses were completed on bladder function data and to assess the incidence rates for bacterial vaginosis and urinary tract infection. The results of these analyses (t-tests and McNemar's analyses) showed no statistically significant differences between the control period and device usage periods.

9. Conclusions

The safety of the Miniguard female continence device was demonstrated by the extensive positive experience of the materials in medical applications and the nonclinical and clinical testing. Further, technological characteristics do not raise new types of safety and effectiveness questions relative to the predicate devices. The clinical investigation demonstrated that Miniguard usage did not effect bladder function and did not appear to effect the incidence rates for urinary tract or vaginal infection. The Miniguard was well tolerated by the intralabial mucosa and there were no significant dermatologic effects associated with device usage. The efficacy of the Miniguard was demonstrated by the clinical testing that included both subjective and objective measures. The clinical data showed that statistically significant improvement was obtained by study subjects when using the Miniguard. In summary, these data provide reasonable assurance that the Miniguard female continence device is a safe and effective alternative for women requiring stress incontinence management and is substantially equivalent to the predicate devices.

References

- ¹Burns PA, et al; A Comparison of Effectiveness of Biofeedback and Pelvic Muscle Exercise Treatment of Stress Incontinence in Older Community-Dwelling Women. *J Gerontol, Medical Sciences*. 48 (4):M167-M174, 1993.
- ²Ostergard DR, Bent AE, eds; *Urogynecology & Urodynamics*. Williams & Wilkins, Baltimore, MD. P209-211, 1991.
- ³Jeter KF, Wagner DB; Incontinence in the American Home - A survey of 36,500 people. *Journal of the American Geriatrics Society*. 38:379-383, 1990.
- ⁴Wyman JF, et al; Psychosocial Impact Urinary Incontinence in Women. *Obstet Gynecol*. Vol 70, P378, 1987.
- ⁵Ostergard DR, Bent AE, eds. *Urogynecology & Urodynamics*. Williams & Wilkins, Baltimore, MD. P211-213, 1991.



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Re: K954215
Trade/Device Name: Miniguard
Regulation Number: 21 CFR§ 876.5160
Regulation Name: Urological clamp for males
Regulatory Class: I
Product Code: MNG
Dated: April 26, 1996
Received: April 29, 1996

Dear Dr. Rosenbluth:

This letter corrects our substantially equivalent letter of May 8, 1996.

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 (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 (PMA), it may be subject to 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.

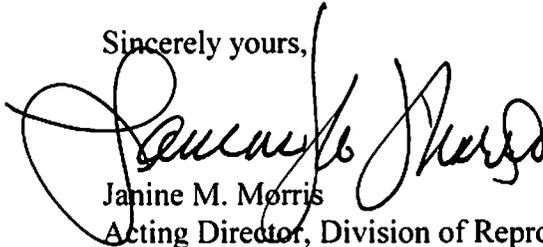
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
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