P990002

SUMMARY OF SAFETY AND EFFECTIVENESS DATA: FEMSOFT® INSERT

I. GENERAL INFORMATION

DEVICE GENERAL NAME:	Transurethral Female Urinary Occlusion Device
DEVICE TRADE NAME:	FemSoft® Insert
APPLICANT:	Rochester Medical Corp. One Rochester Medical Drive Stewartville, MN 55976
PREMARKET APPROVAL APPLICATION (PMA) NUMBER:	P990002
DATE OF NOTICE OF APPROVAL TO THE APPLICANT:	September 30, 1999

II. INDICATIONS FOR USE

The FemSoft® Insert is indicated for the management of stress urinary incontinence in adult females.

III. DEVICE DESCRIPTION

The FemSoft® Insert is a single use, disposable, intra-urethral device for use by adult females. It consists of a narrow silicone catheter entirely enclosed in a thin, mineral oil-filled silicone sleeve. The silicone sleeve forms a balloon on the tip of the catheter (proximal end). On the opposite (distal) end, the catheter and silicone sleeve join to form a soft funnel called the "external retainer." A disposable plastic applicator is used to provide a means for insertion. The device is supplied sterile, pre-lubricated with a water soluble lubricant, and installed on the applicator. The insert is provided in 16, 18 and 20 Fr sizes in 3.5 or 4.5 cm lengths.

The characteristics of the mineral oil-filled sleeve provide the mechanism for both insertion and retention of the insert. As the FemSoft® Insert is advanced into the urethra, fluid in the balloon is transferred toward the external retainer to facilitate passage through the urethra. Once the tip of the insert is advanced to the bladder, fluid returns to fill the balloon to maintain the appropriate position of the device in the bladder neck and urethra. The external retainer keeps the device from migrating proximally and is used to grasp the

device for removal. During insertion and removal, movement of fluid occurs automatically in response to pressure applied to the device.

Once in place, the soft compressible sleeve of the device resides in the urethra and bladder neck. Because of the device's compressibility, it can accommodate changes in the geometry of urethra and bladder neck caused by patient movement or pressure applied to the device by the surrounding tissues. This feature serves to maintain contact between the device and the tissues of the urethra and bladder neck, similar to that provided by natural coaptation of the urethra, to reduce leakage of urine through the urethra.

IV. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

The FemSoft® Insert has the following contraindications, warnings, and Precautions:

CONTRAINDICATIONS

The use of the FemSoft® Insert is contraindicated in women who:

- Have an active bladder or other urinary tract infection.
- Have a history of urethral stricture, bladder augmentation, pelvic radiation, or other anatomic or pathologic conditions where passage of a catheter through the urethra is not clinically advisable.
- Are immunocompromised, have a prosthetic heart valve or other implanted device, or have any other conditions in which the patient is at significant risk from urinary tract infection.
- Have interstitial cystitis, pyelonephritis, or a history of severely compromised urinary tract mucosal tissue.
- Cannot tolerate any form of antibiotic treatment.
- Are currently receiving anticoagulation therapy.
- Have overflow incontinence or neurogenic bladder.

WARNINGS/PRECAUTIONS

Patient Related:

- Appropriate patient education, training and monitoring by a qualified health care professional is required for safe patient use. The patient instruction booklet is intended as a supplement to the patient education provided by a healthcare professional.
- The safety and effectiveness of the FemSoft® Insert has not been evaluated in pregnant women and the effects are unknown.
- Patients should be instructed not to use the FemSoft® Insert during sexual intercourse. Although a limited number of patients reported sexual intercourse while using the device during the clinical study, the safety and effectiveness of this practice has not been demonstrated.
- Patients who present with a history of frequent urinary tract infections (UTIs) should

be advised that they may be at increased risk of infection with the use of the FemSoft® Insert. Additionally, these patients should be monitored closely for symptoms of UTI during device use.

- The FemSoft® Insert is a disposable single use device. Patients should be instructed not to reuse a FemSoft® Insert due to the increased risk of infection.
- Patients should be counseled to wash hands and avoid touching the device prior to its insertion, as described in the patient labeling.
- Patients should discontinue use of the FemSoft® Insert and seek medical evaluation if symptoms of possible urinary tract, vaginal, or venereal infection develop. If an infection is diagnosed, the insert should not be used until the infection has been successfully treated.
- Patients should be instructed to remove the FemSoft® Insert at night before going to sleep. Continuous 24-hour use of the FemSoft® Insert increases the risk of complications.
- Patients should be instructed to remove the FemSoft® Insert and replace at least once every 6 hours to help reduce the chance of UTI. The FemSoft® Insert should be removed when the patient feels the need to void.
- Patients should be instructed not to force insertion of the device due to the risk of injury to the perimeatal area or urethra.
- If the patient reports visible hematuria or bleeding but no other symptoms of UTI, she should be instructed to temporarily discontinue use of the FemSoft® Insert. After her symptoms resolve, she can continue using the FemSoft® Insert. If her symptoms persist, she should be instructed to contact her physician. If the symptoms recur after resuming device use, she should be instructed to discontinue use of the device and contact her physician.
- Sixteen women (10.6%) had episodes of urethral or periurethral irritation or discomfort, especially during the first few weeks of use. In most of these women the device was temporarily discontinued, the rest continued using the device although they experienced slight discomfort. In another 4 women (2.7%) signs of irritation of the bladder wall were found on routine cystoscopic examinations. No treatment was required for these 4 and they continued to use the device.
- Use of the FemSoft® Insert should be discontinued in those patients who develop abrasion of the bladder wall and/or urethral meatus. Device use may be resumed once these conditions are fully resolved.
- Patients with mental impairment (i.e., due to illness, excess alcohol use, excess use of certain medications, or other causes) may have reduced ability to use the device safely.
- The long-term safety and effectiveness of the FemSoft® Insert has not been evaluated, therefore continued, close patient follow-up is recommended.

Device Related:

- The FemSoft® Insert should be properly sized to the patient. Use of improper size could result in device migration or patient discomfort. During the study, one device migrated into the bladder and was removed cytoscopically.
- The FemSoft® Insert is provided sterile to prevent infection. Patients should not use a

FemSoft® Insert if the package is open or damaged or if the device has been contaminated prior to insertion.

V. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Adverse events reported in association with the use of the FemSoft® Insert include: bacteriuria (> 10,000 CFU), symptomatic and asymptomatic UTI, urinary symptoms, insertion trauma, device performance problems (e.g., sleeve breakage), and bladder/urethra trauma or irritation on cystoscopic evaluation. Other adverse events were noted to occur infrequently (< 3%), and are listed later in the Clinical Studies Section. See Table 7 for a list of the risks of the FemSoft® Insert.

VI. ALTERNATE PRACTICES OR PROCEDURES

In females, urinary incontinence is often associated with two general types of sphincter dysfunction related to: abnormalities of urethral supporting tissue or malfunction of the urethral sphinter mechanism. The following alternative treatments are available to female incontinent patients: implantation of artificial urinary sphincter prostheses or bulking agents; use of external devices (collecting, absorbing, or occluding) such as patches, pads or diapers; use of intravaginal devices such as pessaries; use of catheters/inserts; urinary diversion procedures; suspension or sling procedures; and pelvic muscle rehabilitation, such as Kegel exercises or electrical stimulation devices, to help strengthen the pelvic floor muscles.

VII. MARKETING HISTORY

The FemSoft® Insert has not yet been offered for sale in any domestic or international market.

VIII. SUMMARY OF STUDIES

A. LABORATORY STUDIES (NONCLINICAL STUDIES)

PERFORMANCE TESTING - *Design Verification and Validation Testing*

Testing of product samples was carried out to document that the FemSoft® Insert met its design specifications. Testing was conducted on 39 devices prior to sterilization and 36 devices after 45-55 kGy dosage of electron beam sterilization.

FemSoft® Insert Testing

- Dimensional and Visual Inspections – Measurements of length, width, diameter, and material thickness were taken and all devices met dimensional requirements of the device specifications. Devices were visually inspected for the presence of foreign material, bubbles, discoloration, oil clarity, and finish. All devices met the acceptance criteria.

- Tip Strength/Elongation Test – Each device was placed on a metal rod (equivalent in dimensions to the device applicator) and the external retainer was pulled so that the device was stretched to 1.5 times original length. All devices met the test criteria of withstanding the test without evidence of perforation of the device by the rod, tearing or separation of the internal tubing, sleeve or external retainer.

- Compression (balloon softness) Test – The force required to compress a balloon 0.10 inch was measured to demonstrate "softness." All devices met the acceptance criteria of <0.11 lbs.

- Balloon/Sleeve Function Test – The lubricated device was placed on an applicator and inserted through a rigid funnel with an inner diameter equivalent to that of the device shaft. The device was removed from the fixture by manually grasping the external retainer and pulling slowly to remove the device. Three insertions and withdrawals were performed on each device. All devices met the acceptance criteria, i.e., there were no visible signs of sleeve rupture, tearing or separation of the sleeve from the internal tubing or any other visible damage.

- Sleeve Bond Strength – The device was cut in half and the oil removed. The sleeve and tubing were pulled apart until the tubing and sleeve separated or tore. All devices met the acceptance criteria, i.e., the force require to separate the sleeve from the tubing was > 0.59 lbs at the distal end and > 0.14 lbs. at the proximal end.

FemSoft® Insert Applicator Testing:

- Dimensional and Visual Inspection Test – Measurements of length, width, diameter, and material thickness were taken and all devices met dimensional requirements of the device specifications. Devices were visually inspected for the presence of foreign material and incomplete molding and flash.
- All devices met the inspection criteria.

- Bending Deflection Test – With the applicator clamped to a test fixture (so that the shaft is extended horizontally) a weight was attached to the tip of the device applicator and the resulting deflection was measured. All devices met the acceptance criteria of 0.30 ±0.10 inches.

- Flexibility Test – The device applicator shaft was flexed until the tip touches the grip end. All devices met the acceptance criteria, i.e., no applicator shafts broke or splintered.

BIOCOMPATIBILITY/TOXICOLOGY TESTING

The FemSoft® Insert is comprised of two materials, silicone and mineral oil. Silicone is the patient contacting material. The device is in contact with the bladder and urethral mucosa and externally with the labia and area surrounding the urethral meatus. Tests were selected in accordance with International Standard 10993-1 Biological Evaluation of Medical Devices. Part 1: Guidance on Selection of Tests and carried out in compliance with 21 CFR Part 58 Good Laboratory Practice Regulations.

Testing was carried out on finished, packaged and electron beam sterilized devices. A series of tests were carried out on two sterilization doses including a 20-kGy dose and a 50-kGy dose. At the 20-kGy dose, tests for toxicity included: cytotoxicity, systemic injection, intracutaneous injection, 14-day repeat dose toxicity study, pyrogenicity, repeat exposure bladder irritation test, sensitization test, long term (90 days) Intramuscular implantation, and genotoxicity/mutagenicity tests. At the 50-kGy, dose toxicity testing included: cytotoxicity, acute intracutaneous reactivity, and systemic toxicity and sensitivity testing. Test acceptance criteria were documented in the individual protocols for each test. The acceptance criteria for all tests were met.

B. CLINCAL STUDIES

TESTING IN NORMAL VOLUNTEERS

The FemSoft® Insert was tested on four healthy adult female volunteers to evaluate: the recommended method for sizing; the ease of insertion and withdrawal; comfort with insertion and removal; comfort at rest and with exercise during 2-4 hours of wearing time; and retention of device. Each woman wore the size 1-M (3.5 cm long, 16 Fr) device for approximately 1.5 hours and the size 2-M (3.5 cm, 18 Fr) device for approximately 2.5 hours.

The devices functioned as expected during insertion and removal. All women reported understanding the instructions for use and were able to use them to successfully insert the device. No complications occurred. Each woman was asked to void either the 1-M or the 2-M device. In all women, the device could be expelled during voiding without significant discomfort.

PROTOCOL – Multicenter Clinical Study

A clinical study was conducted under IDE G960156 to determine if the FemSoft® Insert is safe and effective for the intended use of managing stress or mixed stress and urge incontinence in adult females.

The clinical study was a multi-center investigation with each patient serving as

her own control. Effectiveness was measured using voiding diaries and pad weight tests (PWT). Adverse events and their frequency were recorded as the primary safety criterion.

Inclusion/ Exclusion Criteria

The following inclusion and exclusion criteria were used to select suitable candidates for the study.

Inclusion Criteria:

- Female patients age $\geq$ 18 years.
- Documented stress urinary incontinence (urethral hypermobility or intrinsic sphincter deficiency) or mixed stress and urge incontinence where urgency symptoms are a minor component of the incontinence symptomatology.
- Stress urinary incontinence present and physiologically stable for the previous 6 months.
- Women who exhibit documented stress urinary incontinence episodes of a minimum of $\geq$ 3 times per week on each of the screening period voiding diaries and are expected to routinely have weekly UI episodes.
- Urine loss > 2 gms on both screening PWTs.
- Sufficient manual dexterity and mental capacity to self administer the device and to complete the patient questionnaires.
- Patient is willing and able to meet the protocol requirements.

Exclusion Criteria:

- Primary urgency incontinence.
- Women taking pharmacologic agents specifically for bladder dysfunction or presently undergoing any treatment for incontinence.
- Women taking other pharmacologic agents that may have a significant effect on bladder function (excluding estrogen and progesterone in postmenopausal women).
- Post void residual urine >100 ml.
- Maximum cystometric capacity $\leq$ 200 ml.
- History of micro-hematuria that has not been previously worked up and identified.
- Unexplained cystoscopic abnormalities.
- Bladder infection, urinary tract infection or asymptomatic bacteriuria during the Screening Period.
- History of bladder or urinary tract infections greater than 2 times in the previous 12 months.
- History of recurrent vaginal infections greater than 2 times in the previous 12 months.
- Pregnant or planning pregnancy during the next year.
- History of urethral stricture or previous bladder augmentation.
- Immuno-compromised patients or patients with an implanted prosthetic heart valve.

- Diagnosis of interstitial cystitis.
- History of bladder tumors or radiation therapy.
- Urethrocele.
- Significant cystocele.

Women were entered into the 6-Week Screening Period of the investigation after giving informed consent. Evaluations included incontinence history, physical examination, urinalysis, urine culture (x 2), pad weight test (x 2), voiding diary (x 2), QOL questionnaire (x 2), cystometry, abdominal leak point pressure, and cystoscopy. At the completion of the Screening Period women who met all of the inclusion and exclusion criteria were enrolled in the 12-month evaluation of the FemSoft® Insert.

Follow-up evaluations were carried out at 1 week and 1, 3, 6, 9 and 12 months while using the device. Urinalysis, urine culture, voiding diary, and a patient satisfaction questionnaire were completed at each visit. Additional evaluations at the 3, 6 and 12 month visits included QOL questionnaire, pad weight test with and without a device inserted, cystometry, abdominal leak point pressure, and cystoscopy. In addition, subjects were interviewed at each follow-up visit concerning any adverse event occurrence and the presence of urinary symptoms since the previous visit. Standardized test methods were used across the clinical sites for the conduct of the pad weighing, cystometry and leak point pressure testing.

At the completion of the 12-month evaluation, women were invited to give consent to enroll in a long-term follow-up study using the device for an additional 4 years. The long-term follow-up schedule calls for visits every 4 months during the second year, and twice a year thereafter. Urinalysis, urine culture, voiding diary and a patient satisfaction questionnaire are completed at each visit and, in addition, pad weighing test with and without a device and cystoscopy are completed at the end of each year.

STUDY ENROLLMENT/DEMOGRAPHICS

A total of 300 women were entered into the Screening Period of the investigation. Of these, 150 women met all of the inclusion and exclusion criteria and were enrolled into the 12-month study using the FemSoft® Insert. The distribution of subjects by study site is shown in Table 1.

Table 1
Distribution of Subjects by Site

	INVESTIGATOR/CLINICAL SITE	NUMBER (%) OF SUBJECTS
1)	Janelle Foote, M.D. Shepherd Center, Atlanta, GA	13 (8.7%)
2)	Joel Kaufman, M.D. UroFitness, P.C., Aurora, CO	24 (16.0%)
3)	Deborah Lightner, M.D. Mayo Clinic, Rochester, MN	13 (8.7%)
4)	Jane Miller, M.D. University of Washington Medical Center - Roosevelt Seattle, WA	13 (8.7%)
5)	William Moseley, M.D. San Diego Uro-Research, San Diego, CA	13 (8.7%)
6)	Ingrid Nygaard, M.D. University of Iowa Hospitals and Clinics Iowa City, Iowa	20 (13.3%)
7)	Lawrence Sirls, M.D. William Beaumont Hospital, Royal Oak, MI	27 (18.0%)
8)	Christopher Steidle, M.D. Northeast Indiana Urology, P.C., Fort Wayne, IN	27 (18%)
Total		150 (100%)

Subject Demographics and Histories

The mean age of subjects was 53.5 years (SD 9.7), ranging from 27 to 78 years. The duration of urinary incontinence was 10.9 years (SD 8.3), ranging from 1 to 40 years. Ninety-nine women (66%) were postmenopausal and 51 (34%) were premenopausal. One hundred thirty-two subjects had children with 125 reporting vaginal deliveries and 16 reporting caesarian deliveries.

Sixty-three (42%) of the women had prior treatment for their incontinence. Types of treatments are shown on Table 2. Some women had more than one prior treatment.

Table 2
Prior Treatment for SUI

TREATMENT TYPE	NUMBER(%) OF SUBJECTS
Pelvic Muscle Exercises	50 (33.3%)
Bladder Neck Suspension	20 (13.3%)
Pharmacologic Agents	20 (13.3%
Periurethral Bulking Agents	4 (2.7%)
Artificial Sphincter	0
Sling Procedure	0
None of the above prior treatments	87 (58%)

All subjects reported having stress incontinence episodes with 131 (87.3%) women reporting daily episodes, 18 (12.0%) reporting weekly episodes, and 1 (0.7%) not reported. The severity of stress incontinence was rated by physicians as Mild in 47 (31.3%) subjects, Moderate in 84 (56.0%) and Severe in 19 (12.7%) women. Seventy-two (48%) of the women reported having urgency symptoms in addition to stress urinary incontinence symptoms. Twenty-four (16%) women had a urinary tract infection during the 12 months preceding their entrance into the clinical study.

EFFECTIVENESS RESULTS

Device effectiveness was primarily measured by pad weight tests and voiding diary reports of incontinence episodes. In addition, satisfaction and qualilty of life questionnaires were used to quantify the patient assessment of device performance.

Pad Weighing Tests: Mean baseline urine loss (measured by pad weight) was 40.1 gm (range 2.8 to 258.8 gm). Results of pad weighing tests carried out at the 3, 6 and 12 month follow up visits are shown in Tables 3 and 4. Table 3 shows the overall pad weight reduction for all patients at each follow-up. Table 4 statifies pad weight reduction by baseline pad weight urine loss since this patient characteristic was determined to have a significant effect on outcome. Statistically significant reductions were seen at all follow up periods. At 3 months, 90% of the patients were dry (< 2 gm urine loss) during pad weighing tests with the device in place.

Table 3
PAD WEIGHING TESTS
Improvement in Urine Loss - Overall

Visit	With Insert	Without Insert	P-value
3 Mo. F/U Avg. Loss gm (SD) N	3.2 (13.1) 100	35.9 (34.2) 100	< 0.001
6 Mo. F/U Avg. Loss gm (SD) N	1.3 (7.1) 98	33.1 (45.3) 98	< 0.001
12 Mo. F/U Avg. Loss gm (SD) N	0.5 (3.3) 68	26.3 (45.8) 68	< 0.001

Table 4
IMPROVEMENT IN URINE LOSS BY BASELINE SEVERITY*

Urine Loss Sub-groups*	3 months			6 months			12 months		
	n	Mean	SD	N	mean	SD	n	mean	SD
Low	31	13.04	14.89	32	13.08	14.94	23	5.78	6.49
Moderate	33	24.40	20.79	34	24.31	20.01	20	27.12	39.22
High	36	57.13	37.55	32	58.18	67.92	25	43.01	61.29

* Low ≤ 15 gm, Moderate 15-36.4 gm, High > 36.4 gm

Voiding Diaries:
Using the data from voiding diaries, the number of urinary incontinence episodes per day during periods with and without the device were compared. Rates were calculated on the basis of 24-hour days and urinary incontinence (UI) episodes occurring during device use and non-use were recorded by subjects. Nighttime hours were included as periods of non-use, which tends to artificially lower the frequency of UI during periods of non-use. The average difference in the rate of UI between periods of FemSoft® Insert use and non-use across all follow-up periods was statistically significant ($p<0.001$). During the entire follow-up period the average reduction in daily incontinence episodes was 0.81 (SD 1.99). The overall incidence of UI during follow-up was 60% less than that seen during the baseline screening period.

User Satisfaction
User satisfaction with the FemSoft® Insert was measured with a self-administered questionnaire. Responses to questions concerning use and satisfaction with the FemSoft® Insert are shown in Table 5. There were no discernable trends in average scores by length of follow-up.

Table 5
USER SATISFACTION DATA

Characteristic	Mean Score (SD)
Ease of insertion (1=very easy, 5=difficult)	2.46 (0.97)
Ease of removing (1=very easy, 5=difficult)	1.33 (0.44)
Comfort while inserting (1=very comfortable, 5=uncomfortable)	2.39 (0.84)
Comfort while wearing (1=very comfortable, 5=uncomfortable)	1.87 (0.63)
Comfort while removing (1=very satisfied, 5= unsatisfied)	1.56 (0.53)
Satisfaction with dryness (1=very satisfied, 5= unsatisfied)	1.53 (0.56)

Overall, 95% of patients reported that they would continue using the device.

Quality of Life (QOL)
QOL, as measured using a validated, self-administered, incontinence specific questionnaire[1], improved between the response at baseline and the responses during follow-up. There was a statistically significant improvement in QOL score between baseline and each follow-up interval $p<0.001$. For example, QOL improved from 67.3 and 68.3 at the 2 and 6 week baseline to 76.5 at 3-months.

SAFETY

Table 6 contains a summary of the adverse event types, frequencies and number of patients for adverse events reported as "related" or "uncertain" as to their relationship to device use.

1 Wagner, T.H., Patrick, D.L., Bavendam, T.G., Martin, M.L., Buesching, D.P.: Quality of life of persons with urinary incontinence: development of a new measure. Urology 47(1), 67-72, 1996.

Table 6
Summary of Adverse Events

EVENT TYPE	NUMBER OF EVENTS/SUBJECT				TOTAL NUMBER OF EVENTS	TOTAL NUMBER (%) OF SUBJECTS WITH EVENT
	1	2	3	4		
Bacteriuria > 10,000 CFU	23	17	3	1	70	44 (29.3%)
Symptomatic UTI	26	8	3	0	51	37 (24.6%)
Urinary Symptoms*	27	6	1	0	42	34 (22.6%)
Asymptomatic UTI	8	2	0	0	12	10 (6.6%)
Insertion Trauma	8	1	0	0	10	9 (6.0%)
Device Performance**	5	2	0	0	9	7 (4.6%)
Bladder/Urethral Trauma or Irritation (Cystoscopic Evaluation)	5	0	0	0	5	5 (3.3%)

*Including urgency, frequency, nocturia.
**Sleeve breakage.

Other reported symptoms which occurred at rates of <3% in the 150 patients include: hematuria and spotting (2%; n=3 each); vaginal yeast infection (1.3%; n=2); and back pain; migration; and pyelonephritis (possibly related to pre-existing renal stones) (<1%; n=1).

PATIENT WITHDRAWALS

A total of 60 patients (40%) withdrew from the study (as of May 26, 1999); 57 withdrew during the 12-month follow-up period and 3 completed the 12-month follow-up but chose not to continue on with the long-term study. The following reasons were given for withdrawal: 15 due to difficulty with the insertion or dissatisfaction with the method (includes discomfort); 11 were lost to follow-up; 9 had non-device related health issues; 8 found the protocol too demanding; 5 had personal reasons unrelated to the device; 4 were unwilling to continue after UTI; 3 could not retain any available size of the device in their urethra; 2 were withdrawn by their physician due to recurrent UTIs; 2 were withdrawn by their physician due to non-compliance with the protocol; and 1 had bladder spasms.

DEVICE FAILURES

The number of FemSoft® Insert devices dispensed, used, and returned to the clinic were recorded at each of the follow-up visits. Approximately 100,100 devices were dispensed in the study. Of these, 62,500 were used by patients; 27,600 have been returned to the sponsor unused/unopened; and approximately 10,000 are still in the hands of patients (an estimated supply of about 110 devices per patient for use between visits). The average number of devices used by subjects to date is 425.6, with a range of from 0 to 2794 devices during the follow-up period. Approximately 19 devices have been reported to have sleeve breakage. Therefore, the rate of failure is estimated to be 0.03% (19/62,500).

IX. CONCLUSIONS DRAWN FROM STUDY

The laboratory and clinical data provide reasonable assurance of the safety and effectiveness of the FemSoft® Insert for the management of stress urinary incontinence in adult women when used as indicated.

X. PANEL RECOMMENDATION

Pursuant to section 515(c)(2) of the Food, Drug, and Cosmetic Act (the act) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XI. CDRH DECISION

An FDA inspection of manufacturing facility was completed, and determined that the manufacturer was in compliance with the device Good Manufacturing Practices (GMP) Regulation. The date of GMP clearance was September 29, 1999.

Based upon a review of the data contained in the PMA, CDRH determined that the FemSoft® Insert is safe and effective for the indication of managing stress urinary incontinence in adult females. Furthermore, the applicant agreed to the postapproval requirement to conduct a 5-year postapproval study on 150 women to evaluate the long-term effects of the device.

CDRH issued an approval order for the application on September 30, 1999.

XII APPROVAL SPECIFICATIONS

Direction for use: See labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling (attached).

Post-approval Requirements and Restrictions: See approval order.