

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	Testicular Prosthesis
Device Trade Name:	Mentor Saline-Filled Testicular Prosthesis
Applicant:	Mentor Corporation 201 Mentor Drive Santa Barbara, California 93111
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P020003
Date of Notice of Approval to Applicant:	July 19, 2002

II. INDICATIONS FOR USE

The Mentor Saline-Filled Testicular Prosthesis is intended for use when cosmetic testicular replacement is indicated; i.e., in the case of agenesis or following the surgical removal of a testicle.

III. CONTRAINDICATIONS

The implantation of testicular prostheses is contraindicated in the presence of infection or untreated neoplasm.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the labeling for the Mentor Saline-Filled Testicular Prosthesis (Attachment 1).

V. DEVICE DESCRIPTION

The Mentor Saline-Filled Testicular Prosthesis is a silicone elastomer device that is designed to approximate the weight, shape, and softness of the normal testicle. This device is implanted in the scrotum in males who desire cosmetic replacement of a missing testicle, and consists of a silicone elastomer shell with an injection port and recessed suture tab. The Mentor Saline-Filled Testicular Prosthesis is manufactured in four sizes to accommodate juvenile to adult anatomies. The device is packaged empty, and filled with sterile saline at the time of implantation.

To facilitate the filling process, the Mentor Saline-Filled Testicular Prosthesis is packaged with the following accessories: a butterfly needle with infusion tubing, and a needle stop.

The Mentor Saline-Filled Testicular Prosthesis and accessories are sold as sterile (gamma radiation) and labeled for single use only.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

There are no alternative procedures for cosmetic testicular replacement.

VII. MARKETING HISTORY

The Mentor Saline-Filled Testicular Prosthesis has been marketed in 33 countries since its development in 1992. This device has not been withdrawn from marketing for any reason related to the safety and effectiveness of the device.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The following adverse events were observed in the PMA clinical studies of the Mentor Saline-Filled Testicular Prosthesis: pain, discomfort, edema (implant or incision site), infection, extrusion, displacement/migration, genital hematoma, keloid formation, implant deflation/leakage, inadequate position, fluid accumulation, constipation, hives, fibrosis, granuloma, mobile implant, neuropathy (leg), numbness (heel), suture abscess, and unnecessary incision.

Additionally, the following potential risks of testicular prostheses or their materials were not reported in the PMA clinical studies: erosion and immune-related connective tissue disorders.

IX. SUMMARY OF PRECLINICAL STUDIES

Material Characterization Studies:

A series of *in vitro* tests were conducted to characterize the chemical constituents of the materials of the Mentor Saline-Filled Testicular Prosthesis. The objectives of this testing were to identify the chemical make-up of these materials and to estimate the exposure of each to the patient. This information was used to determine the biocompatibility testing scheme. The complete list of material characterization tests performed is as follows:

- analysis of total extractables;
- identification and quantification of volatiles and semivolatile extractables;
- analysis of chemical crosslinking;
- molecular weight characterization of nonvolatile extractables;
- heavy metals assessment; and
- surface analysis.

All material characterization tests were performed on finished, sterilized devices.

These tests were found to be adequate for characterizing the materials of the Mentor Saline-Filled Testicular Prosthesis.

Biocompatibility Studies:

Using the knowledge gained from the material characterization tests, biocompatibility testing was conducted on the patient-contacting components of the Mentor Saline-Filled Testicular Prosthesis. The objective of this testing was to assess whether these materials are safe for long-term implantation. The following biocompatibility tests were performed on the individual patient-contacting materials of the device:

- cytotoxicity;
- hemolysis;
- acute systemic toxicity;
- intracutaneous toxicity;
- sensitization;
- Ames mutagenicity; and
- implantation (30 and 90 days).

Additionally, the following biocompatibility tests were performed on the finished, sterilized device:

- cytotoxicity;
- hemolysis;
- acute systemic toxicity;
- intracutaneous toxicity;
- sensitization;
- Ames mutagenicity; and
- pyrogenicity.

Furthermore, the following biocompatibility tests were performed on other legally marketed implanted devices (manufactured by Mentor) that are constructed of either identical or similar silicone elastomers as the Mentor Saline-Filled Testicular Prosthesis:

- L5178Y TK +/- mouse lymphoma mutagenesis assay;
- morphological transformation of BALB/3T3 mouse embryo cells;
- Ames mutagenicity;
- unscheduled DNA synthesis assay (rat primary hepatocytes);
- chronic toxicity/carcinogenicity;
- reproductive toxicity;
- immunotoxicity; and
- adjuvancy.

This list of biocompatibility tests is consistent with the tests suggested in ISO-10993 for permanent implants with bone/tissue contact. This information demonstrated that the device Mentor Saline-Filled Testicular Prosthesis does not pose a toxicological concern.

Mechanical Testing:

Mechanical testing was conducted to assess the safety, effectiveness, and reliability of the Mentor Saline-Filled Testicular Prosthesis. Bench tests were conducted to evaluate all device attributes that are critical to its safety and performance. Furthermore, additional mechanical tests were performed to measure certain other device attributes for characterization purposes. The complete list of mechanical tests performed is as follows:

Material characteristics:

- modulus of elasticity at 200% elongation;
- tensile strength;
- ultimate elongation;
- energy to rupture;
- tear strength;
- durometer; and
- abrasion resistance.

Subassembly characteristics:

- injection site puncture test.

Finished device characteristics:

- injection site puncture test;
- suture tab strength and elongation;
- compressive cyclic fatigue test; and
- fill volume test.

All mechanical tests were performed on sterilized samples using test conditions that simulated *in vivo* conditions whenever appropriate. The sample sizes used for each test were justified, and representative samples of each device size were evaluated when necessary. The results of this testing demonstrated that the device functions according to the stated design specifications.

Shelf Life Testing:

Stability testing was performed on finished, sterilized devices, accelerated aged to an equivalent of 5 years. This testing justifies a shelf life claim of 5 years. Testing on real-time aged samples is ongoing.

X. SUMMARY OF CLINICAL STUDIES

Objectives:

Two clinical studies were performed to assess the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis: (i) a Core Study, and (ii) an Adjunct Study.

The objectives of the Core Study were to assess the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis in males for whom testicular replacement is indicated. The primary effectiveness objective of the Core Study was evaluation of the ability of the device to provide and maintain the intended testicular dimensions. Secondary effectiveness objectives were evaluation of the effects of the device on patient quality of life/satisfaction and physician assessment of the appearance of the implanted device. The primary safety objective was to determine the occurrence and severity of adverse events, including the rate of device explantation and the incidence of connective tissue diseases.

The objective of the Adjunct Study was to collect supplementary information regarding adverse events following completion of enrollment of patients into the Core Study.

Study Design:

The Core and Adjunct Studies are both baseline-controlled, multicenter, prospective clinical studies. The Core Study was conducted to evaluate the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis, with the pre-implant experience of patients serving as the comparison for the assessment of device outcome. The design of this clinical study is consistent with the recommendations contained in the Proposed Rule for Premarket Approval of the Testicular Prosthesis (58 FR 4116)¹, the recommendations of the FDA guidance document entitled “Draft Guidance for Preparation of PMA Applications for Testicular Prostheses,”² and the subsequent recommendations presented to and agreed upon by the Gastroenterology and Urology Devices Advisory Panel at the July 29, 1999 open public meeting. The Adjunct Study was conducted to collect supplementary data on the incidence and severity of adverse events.

A total of 149 Core Study patients were implanted at 18 institutions in the United States between September 1998 and September 1999. After Core Study enrollment was completed, a total of 209 Adjunct Study patients were implanted at 39 U.S. institutions. The Core and Adjunct Study reports include all results compiled through March 2002.

Male patients (adult or pediatric) indicated for either unilateral or bilateral testicular prosthesis implantation were enrolled into the Core Study. This study included patients with testicular loss due to either agenesis or surgical removal. All subjects (or parents of pediatric subjects) provided valid informed consent. Additionally, all subjects agreed to permit explant analysis of the device (if explanted). Exclusion criteria for the Core Study included: patient had an active infection or abscess; patient had uncontrolled or severe diabetes reducing their wound healing ability; patient had tissue characteristics that would prevent implantation of the device (e.g., tissue damage from prior radiation, inadequate tissue coverage, or compromised vascularity); patient had health or psychological conditions incompatible with the device implantation or the study requirements; patient had any prior silicone implant, including a prior testicular prosthesis; and patient was diagnosed with systemic lupus, discoid lupus, scleroderma, rheumatoid arthritis, or other connective tissue disorders.

After enrollment into the Core Study was completed, patients (adult or pediatric) indicated for either unilateral or bilateral testicular prosthesis implantation were enrolled into the Adjunct Study. This study included patients with testicular loss due to either agenesis or surgical removal, as well as patients undergoing gender conversion surgery. All subjects (or parents of pediatric subjects) provided valid informed consent. Exclusion criteria for the Adjunct Study included: patient enrolled in the Core Study; patient had an active infection or abscess; patient had uncontrolled or severe diabetes reducing their wound healing ability; patient had tissue characteristics that would prevent implantation of the device (e.g., tissue damage from prior radiation, inadequate tissue coverage, or compromised vascularity); patient had health or psychological conditions incompatible with the device implantation or the study requirements; and patient was diagnosed with systemic lupus, discoid lupus, scleroderma, rheumatoid arthritis, or other connective tissue disorders.

Patient Assessments:

Evaluation of the safety and effectiveness of the Mentor Saline-Filled Testicular Prosthesis is based on 1-year evaluation of the following clinical endpoints:

Effectiveness Endpoints (Core Study only):

- Physician measurement of the size of the implanted Mentor Saline-Filled Testicular Prosthesis, relative to the patient’s pre-implant scrotal anatomy.
- Patient assessment of satisfaction and quality of life (Patient Assessment Instrument, Rosenberg

Self-Esteem Scale, Body Esteem Scale, and Body Exposure in Sexual Activities Questionnaire).

- Physician assessment of cosmetic appearance of the implanted device.

Safety Endpoints (Core and Adjunct Studies):

- Occurrence and severity of adverse events, including connective tissue diseases.
- Rates of and time to explantation, revision, and other resurgery.

Prior to enrollment, patients received routine clinical assessments to document study eligibility and baseline characteristics. After implantation, all Core Study subjects were scheduled for follow-up examinations at 1 week, 1 month, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years post-implantation. In the Adjunct Study, subjects were scheduled for a single follow-up examination 1 year post-implantation.

Of the 149 patients implanted in the Core Study, 124 (83.2%) received 1-year follow-up. Of the 25 patients for whom 1-year data are not available, 5 missed the 1-year visit (but are continuing in the study) and 20 prematurely discontinued the study prior to 1 year. Reasons for study discontinuation at 1 year are patient lost-to-follow-up (n=10); patient withdrew consent (n=5); patient had the prosthesis explanted (n=2); patient moved (n=2); and the investigational site discontinued from study due to noncompliance (n=1). The use of 1-year follow-up data for the review of this PMA permits a thorough assessment of device effectiveness and adverse events, and also provides preliminary information regarding the rate of revision surgeries. Based on this information and the concurrence of the Gastroenterology and Urology Devices Advisory Panel at the July 29, 1999, meeting, reliance on 1-year follow-up data is clinically justified. In addition to the 1-year results, 104 Core Study patients have received 18-month follow-up, and 94 have received 2-year follow-up.

Of the 209 patients implanted in the Adjunct Study, 68 received 1-year follow-up, 58 are not yet eligible for 1-year follow-up, and 83 either missed the 1-year follow-up visit or prematurely discontinued from the study (5 cases of which were the result of device explantation).

Demographic Data:

Of the 149 Core Study patients, 73 (49.0%) were pediatric (i.e., < 18 yrs.) at the time of device implantation. Since the clinical results may be dependent upon patient age (i.e., pediatric vs. adult) and/or pre-implantation status (i.e., testicle missing vs. present at baseline), patients were stratified for analysis as follows:

- Stratum 1P: Pediatric missing his testicle(s) at baseline.
- Stratum 2P: Pediatric not missing his testicles at baseline (but scheduled for surgical removal).
- Stratum 1A: Adult missing his testicle(s) at baseline.
- Stratum 2A: Adult not missing his testicles at baseline (but scheduled for surgical removal).

Additional demographic information for the 149 Core Study patients is provided below in Table 1:

Table 1: Demographic Data – Core Study

	Core Study (n=149 pts.)
Mean age (range):	
Overall	22.3 yrs (0.5 – 76 yrs)
Pediatrics	12.8 yrs (0.5 – 17 yrs)
Adults	31.1 yrs (18 – 76 yrs)
Race:	
Caucasian	91.3%
African American	5.4%
Other	3.3%
Reason for testicular prosthesis:	
Orchiectomy	65.3%
Agenesis	24.4%
Torsion	8.5%
Trauma	1.8%
Number (%) bilateral cases:	27 pts. (18.1%)
Strata:	
1P	62 pts. (41.6%)
2P	11 pts. (7.4%)
1A	52 pts. (34.9%)
2A	24 pts. (16.1%)

Of the 209 Adjunct Study patients, 80 (38.3%) were pediatric. Additional information regarding the Adjunct Study is presented below in Table 2.

Table 2: Demographic Data – Adjunct Study

	Adjunct Study (n=209 pts.)
Number (%) bilateral cases:	31 pts. (14.8%)
Strata:	
1P	65 pts. (31.1%)
2P	15 pts. (7.2%)
1A	100 pts. (47.8%)
2A	29 pts. (13.9%)

Data Analysis and Results:

Device Implantation/Surgical Information:

Detailed information regarding the implantation of the Mentor Saline-Filled Testicular Prosthesis was obtained from analysis of the Core Study. A total of 176 devices were implanted in the Core Study (122 unilateral cases and 27 bilateral cases). The implanted devices included the large (71.6%), medium (19.3%), and small (9.1%) sizes. No extra small size devices were implanted during the Core Study, since this implant size was not introduced until after enrollment was completed. Although the extra small size was not clinically evaluated, bench testing of the device demonstrated that the extra small size has equivalent mechanical and reliability characteristics as the other sizes. The implantation surgeries were performed using standard technique. Prophylactic antimicrobials were used prior to and/or during the implantation procedure in 94.6% of cases, and general anesthesia was used in 96.0% of cases. For patients with both testes present at baseline

(i.e., strata 2P and 2A), orchiectomy immediately preceded device implantation. The majority of devices were implanted using either an inguinal approach (70.0%) or a scrotal approach (22.7%). In approximately half of the devices implanted, the suture tab was used to fix the implant in place. For the remaining cases, the investigator elected not to use the suture tab.

Effectiveness Endpoints:

The evaluation of device effectiveness is based on the results of the 149 Core Study patients. The primary effectiveness endpoint for this clinical trial was physician measurement of volume of the implanted Mentor Saline-Filled Testicular Prosthesis, relative to the volume of the patient's pre-implant scrotal anatomy. For patients in Strata 1 (i.e., testicle(s) missing at baseline), the baseline size was recorded as 0 mL. For patients in Strata 2 (i.e., testicles present at baseline but scheduled for removal), the actual volume was estimated. To standardize data collection among the sites, all estimates of testicle/device size were made using a Prader Orchimeter. The objectives of this assessment are to demonstrate (i) a significant increase in testicular size, compared to baseline, among Stratum 1 patients, and (ii) stability of post-implantation testicular size among Strata 1 and 2 patients. At 1-year post-implantation, the mean testicular sizes for Strata 1P and 1A patients were 21.8 mL and 23.0 mL, respectively. These differences from baseline were highly statistically significant ($p < 0.001$). Similar results were observed at the other follow-up exams for which sufficient data are available (i.e., 1 month, 6 months, 18 months, and 2 years). The stability of testicular size was tested by comparing the mean sizes at the 1-month, 6-month, 1-year, 18-month, and 2-year visits. This analysis was performed separately for Strata 1 and 2 patients using a repeated measures analysis of variance. For patients missing a testicle at baseline (i.e., Strata 1), the mean sizes were 22.0, 22.3, 22.7, 23.4, and 22.8 mL at the 1-month through 2-year exams, respectively. Although these differences were statistically significant ($p = 0.007$), they are clinically insignificant. For patients not missing a testicle at baseline (i.e., Strata 2), the mean sizes were 20.3, 21.1, 21.8, 21.1, and 21.3 mL at the 1-month through 2-year exams, respectively. This variation was not statistically significant. For both strata, therefore, stability in testicle size was observed between 1 month and 2 years post-implantation.

The secondary endpoints of device effectiveness were assessment of patient satisfaction, self esteem, body esteem, and body exposure in sexual activities. Each of these endpoints was evaluated by patient self-report using standardized surveys at baseline, 6 months, 1 year, 18 months, and 2 years. Additionally, the cosmetic appearance of the implanted device was rated by the investigator during these post-treatment examinations. The results of these effectiveness endpoints are described below:

Patient satisfaction, as rated using the Patient Assessment Instrument (i.e., a standard set of questions developed by Mentor for this study), assessed how the patient feels about his genitals before and after implantation of the testicular prosthesis. This instrument was completed by all adult patients, and all pediatric patients = 13 years old. (Note: Survey instruments were not administered to patients younger than 13 years old due to validation/reliability concerns.)

Since the baseline satisfaction rating would be different depending whether the patient is missing a testicle, Strata 1 and 2 patients were analyzed separately. Each question was rated by the subject on a scale from 1 (very negative rating) to 5 (very positive rating), and the scores of each question were averaged to obtain a final score. For Stratum 1 patients (testicle missing at baseline), the results of the Patient Assessment Instrument were statistically significantly and clinically meaningfully improved over baseline for all follow-up periods (i.e., approximately 50.6-601% over baseline). For Stratum 2 (testicles present at baseline), for whom meaningful baseline comparisons are not possible, the Patient Assessment Instrument results were only qualitatively assessed. The mean score at each follow-up time point ranged from 4.41-4.31 out

of a possible 5 points, indicating a positive response toward the implant. Estimates of the correlation between the 6-month and 1-year results support the validity of this instrument.

Patient self esteem, as measured by the Rosenberg Self-Esteem Scale³, was assessed in all adult patients, and all pediatric patients = 13 years old. For Stratum 1 patients, small levels of improvement (i.e., 1.7-8.1% over baseline) were seen at all follow-up periods, some of which were statistically significant. For Stratum 2 patients, the post-implantation results were not statistically significantly different from the baseline level.

Body esteem, as measured by the Body Esteem Scale (Physical Attractiveness subscale)^{4,5}, was assessed in all adult patients, and all pediatric patients = 13 years old. For Stratum 1 patients, small levels of improvement (i.e., 1.6-11.1% over baseline) were seen at nearly all follow-up periods, some of which were statistically significant. For Stratum 2 patients, the post-implantation results were not statistically significantly different from the baseline level.

Body exposure in sexual activities was assessed using the Body Exposure in Sexual Activities Questionnaire (BESAQ)^{6,7}, which rates the subject's response to various statements regarding thoughts and behaviors that the individual may experience during sexual encounters. Due to the nature of this questionnaire, the BESAQ was only assessed in adult patients. For each strata, the results of this questionnaire were statistically significantly improved over baseline at each follow-up period (i.e., 34.0-43.3% decrease from baseline; lower scores indicate improvement).

The cosmetic appearance and firmness of the device was rated by the physician at baseline and at each follow-up period. Appearance was rated on a scale ranging from one (very abnormal) to five (normal). Overall and for each strata, statistically significant improvement from baseline in cosmetic appearance was observed at each visit (i.e., 70.0-108.3% improvement in Stratum 1; 28.6-58.1% in Stratum 2). Additionally, investigators rated the implanted device as "firm" in 94 to 99% of subjects at each visit.

These results demonstrate that the Mentor Saline-Filled Testicular Prosthesis significantly improved the patient's body exposure in sexual activity rating, is associated with a high degree of patient satisfaction, and is cosmetically acceptable as rated by the physician. As anticipated, patient self esteem and body esteem was maintained or slightly improved following device implantation.

Safety Endpoints:

The evaluation of device safety is based on the results of the 149 Core Study patients and 209 Adjunct Study patients. The safety of the Mentor Saline-Filled Testicular Prosthesis was evaluated through (i) assessment of adverse events and (ii) the rates of explantation, revision, and other resurgery. Table 3 summarizes the device and procedure-related adverse events reported in the Core Study.

Table 3: Adverse Events – Core Study (n=149 pts.)

Adverse Event Category	Number (%) of Patients	Mean (Range) Onset Time in Days
Pain	8 (5.4%)	127 (1-661)
Discomfort	6 (4.0%)	167 (1-668)
Edema (implant or incision site)	4 (2.7%)	2 (1-4)
Extrusion	3 (2.0%)	28 (16-39)
Displacement/migration	3 (2.0%)	36 (29-42)
Genital hematoma	2 (1.3%)	1*
Keloid formation	2 (1.3%)	112 (39-184)
Implant deflation**	1 (0.7%)	35
Fluid accumulation (inguinal area)	1 (0.7%)	11
Constipation	1 (0.7%)	1
Fibrosis	1 (0.7%)	207
Granuloma	1 (0.7%)	8
Mobile implant	1 (0.7%)	42
Neuropathy (leg)	1 (0.7%)	1
Numbness (heel)	1 (0.7%)	1
Suture abscess	1 (0.7%)	33

* The onset time was not documented in one case of genital hematoma.

** The case of implant deflation was recorded when an investigator felt a small dimple in an implant, believed to be due to incomplete filling at the time of implantation rather than fluid loss. Although this dimple was palpable, the appearance was cosmetically acceptable to both the physician and patient. Therefore, the implant was not removed.

The incidence of adverse events was not related to patient strata. With the exception of the three cases of extrusion and two cases of displacement/migration (all of which required resurgery), these adverse events either resolved or were judged by the physician and patient not to require further treatment.

The device and procedure-related adverse events reported in the Adjunct Study were similar to those reported in the Core Study. However, these data are reported separately since the Adjunct Study patients were not followed as closely as those in the Core Study. These adverse events are: infection (n=4), displacement/migration (n=2), leakage (n=1), extrusion (n=1), hives (n=1), inadequate position (n=1), pain (n=1), and unnecessary incision (n=1).

The following risks of testicular prostheses or their materials have been reported in the medical literature but did not occur during the Core or Adjunct Studies: erosion and immune-related connective tissue disorders. No patients died during the either the Core or Adjunct Studies.

The overall resurgery rate for Core Study patients was 3.4% (5/149 patients). The corresponding 1-year life table rate for resurgery was 2.8% (upper 95% confidence limit = 5.5%). These five resurgeries consisted of four device explantations (in the three cases of extrusion and one case of displacement/migration) and one surgery to relieve dense adhesive bands that formed in the scrotum (which occurred in one of the patients listed as experiencing displacement/migration). However, the long-term (i.e., 5-year) rates of device rupture and revision are currently unknown.

In the Adjunct Study, the overall resurgery rate was 2.9% (6/209). These six resurgeries consisted of four device explantations (in one case each of extrusion, leakage, pain, and hives) and two surgeries (both to reposition the implant in cases of displacement/migration and inadequate position).

No patient in either the Core or Adjunct Study had his device replaced with a larger prosthesis as a result of physical maturation of the subject.

Device Failures and Replacements:

No device failures/malfunctions occurred during the clinical studies, and no devices were replaced.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

Preclinical testing of the Mentor Saline-Filled Testicular Prosthesis adequately characterized the device's materials, demonstrated that the materials of the device are biocompatible, verified that the device is mechanically reliable, and justified a 5-year shelf-life.

Clinical testing of the device demonstrated that the Mentor Saline-Filled Testicular Prosthesis is reasonably safe and effective when used in accordance with the directions for use. However, the long-term (i.e., 5-year) rates of device rupture and revision are currently unknown. The results of clinical testing demonstrated that the device:

- provided a significant increase in testicular size compared to baseline (among Stratum 1 patients), which was maintained through the 2-year follow-up examination (among all patients);
- was associated with a high degree of patient satisfaction, and was subjectively rated by the physician as cosmetically acceptable in nearly all cases;
- resulted in an improvement in the patient's perception of his body exposure in sexual activities, as compared to baseline;
- was not associated with a decrease in self esteem or body esteem, as compared to baseline;
- had a 1-year life table rate for resurgery of 2.8% (upper 95% confidence limit = 5.5%); and
- was associated with relatively few adverse events, which were either successfully treated or judged by the physician and patient not to require further treatment.

Therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the potential risk of illness or injury when used as indicated in accordance with the directions for use.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Advisory Panel, an FDA advisory committee for review and recommendation based on the Panel's (i) classification of the testicular prosthesis, (ii) review of the FDA guidance document entitled "Draft Guidance for Preparation of PMA Applications for Testicular Prostheses," and (iii) subsequent recommendations presented to and agreed upon by the Panel at the July 29, 1999 open public meeting.

XIII. CDRH DECISION

Based upon the PMA review, CDRH believes that these data provide reasonable assurance that the device is safe and effective when used in accordance with the directions for use. Therefore, CDRH believes that the Mentor Saline-Filled Testicular Prosthesis can be approved with the following postapproval requirement: continued follow-up of a minimum of 100 patients out to 5 years post-implantation, consistent with the existing Core Study protocol, for assessment of the rates of device

rupture and resurgery. Following completion of this postapproval study, the labeling must be revised (via a PMA supplement) to reflect these long-term results.

The Mentor Saline-Filled Testicular Prosthesis was granted expedited review status on January 22, 2002 because FDA believes that a testicular prosthesis for cosmetic testicular replacement is in the best interest of public health since (i) no legally marketed testicular prosthesis is available, and (ii) the only treatment option for patients who are missing a testicle is “no treatment.”

The applicant created a Patient Education Guide to inform prospective recipients of the Mentor Saline-Filled Testicular Prosthesis (or their parents/guardians) of the risks and benefits of the device (Attachment 1).

The applicant's manufacturing facility was inspected on February 26 and April 19, 2002, and was found to be in compliance with the device Good Manufacturing Practice regulations.

FDA issued an approval order on July 19, 2002.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

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

Postapproval Requirements and Restrictions: See approval order.

XV. REFERENCES

1. Federal Register, Vol. 58. No. 8, Wednesday, January 13, 1993, pg. 4116.
2. “Draft Guidance for Preparation of PMA Applications for Testicular Prostheses,” FDA, CDRH, March 1993 (<http://www.fda.gov/cdrh/ode/oderp809.html>).
3. Rosenberg, M., Society and the Adoloescent Self Image, Princeton University Press, Princeton, New Jersey, 1965.
4. Franzoi, S. L. and S. A. Shields, “The Body Esteem Scale: Multidimensional Structure and Sex Differences in a College Population,” *Journal of Personality Assessment*, Vol. 48, pp. 173-178, 1984.
5. Franzoi, S. L., “Further Evidence of the Reliability and Validity of the Body Esteem Scale,” *Journal of Clinical Psychology*, Vol. 50, pp. 237-239, 1994.
6. Faith, M. S. et al., “The Body Exposure in Sexual Activities Questionnaire: Psychometric Properties and Sexual Correlates,” presented at the 1993 meeting of the Association for Advancement of Behavior Therapy (Atlanta, Georgia).
7. Grant, J. R. and T. F. Cash, “Cognitive-Behavioral Body Image Therapy: Comparative Efficacy of Group and Modest-Contact Treatments,” *Behavior Therapy*, Vol. 26, pp. 69-84, 1995.