1996. If no fastener is installed, seal the corresponding fastener hole only, in accordance with the alert service bulletin.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions shall be done in accordance with EMBRAER Alert Service Bulletin 120–24–A057, dated November 14, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 96–12–02, dated December 13, 1996.

Effective Date

(e) This amendment becomes effective on October 31, 2000.

Issued in Renton, Washington, on September 14, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–24113 Filed 9–25–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 94N–0380]

Gastroenterology and Urology Devices; Effective Date of Requirement for Premarket Approval of the Implanted Mechanical/Hydraulic Urinary Continence Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the implanted mechanical/hydraulic urinary continence device, a generic type of medical device intended for the treatment of urinary incontinence. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997.

EFFECTIVE DATE: This rule is effective October 26, 2000.

FOR FURTHER INFORMATION CONTACT: Nicole L. Wolanski, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Introduction

SMDA added new section 515(i) to the act (21 U.S.C. 360e(i)). This section requires FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMA's and to determine whether each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval.

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA published a final rule classifying into class III (premarket approval) the implanted mechanical/hydraulic urinary continence device, a medical device. Section 876.5280 (21 CFR 876.5280) of FDA's regulations setting forth the classification of the implanted mechanical/hydraulic urinary continence device applies to: (1) Any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976, and (2) any device that FDA has found to be substantially equivalent to an implanted mechanical/hydraulic urinary continence device in commercial distribution before May 28, 1976.

In the **Federal Register** of February 15, 1995 (60 FR 8595), FDA published a proposed rule, under section 515(b) of the act (21 U.S.C. 360e(b)), to require the filing of PMA's or PDP's for the classified implanted mechanical/hydraulic urinary continence device and all substantially equivalent devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble, the agency's proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and (2) the benefits to the public from use of the device.

The preamble also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, it also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the implanted mechanical/hydraulic urinary continence device was required to be submitted by March 2, 1995. The comment period closed on June 15, 1995.

The agency received three comments in response to the February 15, 1995, proposed rule. These comments were from physicians and a manufacturer. These three comments raised numerous issues. A summary of the comments and FDA's responses are set out below.

This regulation is final upon publication and requires PMA's or notices of completion of a PDP for all implanted mechanical/hydraulic urinary continence devices classified under § 876.5280 and all devices that are substantially equivalent to them. PMA's or notices of completion of a PDP for these devices must be filed with FDA within 90 days of the effective date of this regulation. (See section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)).)

II. Summary and Analysis of Comments and FDA's Response

A. General Comments

(Comment 1) FDA received two comments from individual physicians. Although these comments did not object to the proposed call for PMA's or PDP's, they voiced the following common concerns: (1) The implanted mechanical/hydraulic urinary continence device is intended for those with severe urinary incontinence, in whom other modalities are unsuccessful, (2) removal of this device from the U.S. market would be detrimental to public health, and (3) citing the 20 years of use of the device, sufficient historical data exist to evaluate the safety and effectiveness of the implanted mechanical/hydraulic urinary continence device. This last concern was also noted in a comment from an implanted mechanical/hydraulic urinary continence device manufacturer, which stated that the decades of medical literature regarding the risks and benefits of this device provide sufficient evidence of its safety and effectiveness. The comments remarked that FDA has overstated the risks of the implanted mechanical/hydraulic urinary continence device, that the studies are costly and unnecessary, and that the agency can rely on MDR reports or use its authority to ask for post-market surveillance on 510(k) products.

FDA agrees that urinary incontinence is a significant medical problem that negatively affects the lives of many men and women in the United States. Furthermore, since implanted mechanical/hydraulic urinary continence devices represent an important option in the treatment of severe urinary incontinence, FDA agrees with these comments that removal of the implanted mechanical/hydraulic urinary continence device from the market would negatively impact public health. As a result of this concern, FDA has taken the following steps to promote the continued availability of the implanted mechanical/hydraulic urinary continence device during the call for PMA's or PDP's: (1) FDA issued the guidance document entitled ''Draft Guidance For Preparation Of PMA Applications For The Implanted Mechanical/Hydraulic Urinary Continence Device(Artificial Urinary Sphincter)'' in May 1995 (the 1995 guidance document) to provide industry with detailed recommendations on the content of PMA's; (2) FDA has communicated closely with each implanted mechanical/hydraulic urinary continence device manufacturer to address the concerns identified in the proposed rule using least burdensome methods, as well as provide recommendations on the design of preclinical and clinical studies; and (3) FDA intentionally postponed the call for PMA's or PDP's to allow manufacturers to collect sufficient data to support the filing of a PMA or PDP.

FDA agrees with the comments that there is a significant amount of information in the published and unpublished literature regarding the implanted mechanical/hydraulic urinary continence device. However, to FDA's knowledge, these studies are neither sufficiently detailed nor properly designed to perform a statistically valid evaluation of safety and effectiveness. As recommended in the 1995 guidance document, PMA's or PDP's should contain safety and effectiveness information on the specific device model(s) proposed in the application.

Although a large body of historical data exists regarding the clinical outcomes of models of implanted mechanical/hydraulic urinary continence devices that are no longer marketed, there is less information available regarding the safety and effectiveness of currently-marketed models. However, if sufficient historical information exists to document the safety and effectiveness of a particular implanted mechanical/hydraulic urinary continence device model that a manufacturer desires to market, or if data about earlier models are directly relevant to a particular device, FDA encourages the use of this data in support of a PMA or PDP for that model.

While FDA agrees that the proposed rule may have overstated the risks of some of the specific implanted mechanical/hydraulic urinary continence device models that are currently on the market, we believe that the information in the proposed rule represents a reasonable estimate of the risks and benefits of the entire category of implanted mechanical/hydraulic urinary continence devices. As noted in many of these comments, manufacturers have made numerous design modifications to improve the reliability of the implanted mechanical/hydraulic urinary continence device and the medical community continues to improve the patient selection criteria, patient counseling information, operative technique, and post-operative care to reduce the incidence of complications. Therefore, FDA expects the rates of complications reported in PMA's or PDP's for particular implanted mechanical/hydraulic urinary continence devices to be lower than estimated from a review of the literature on the entire device category. However, in writing the proposed call for PMA's or PDP's, FDA must consider the risks and benefits of all implanted mechanical/hydraulic urinary continence devices that currently have the status of being legally marketed in the United States.

While FDA acknowledges that MDR reports and post-market surveillance are valuable tools for obtaining information on devices, FDA believes that additional data are necessary to establish the safety and effectiveness for the implanted mechanical/hydraulic urinary continence device and that these data should be submitted and evaluated within a PMA or PDP.

B. Erosion

(Comment 2) There was one comment regarding the risk of erosion. This comment stated that erosion of the implanted mechanical/hydraulic urinary continence device occurs infrequently, and for reasons that are not inherent in the device, but instead may be due to a variety of conditions that are characteristic of some patients, e.g., as a result of scar tissue and/or eradiated tissue. The comment further stated that erosion is reported to occur at low rates which are within acceptable limits.

While FDA agrees that the risk of erosion may be small, insufficient information is available to determine the frequency of this event or its consequences. Therefore, FDA believes that it is important for studies submitted in a PMA or PDP to provide accurate information on the incidence of erosion associated with the implantation of the implanted mechanical/hydraulic urinary continence device. As noted in the 1995 guidance document, FDA is requesting information to address the incidence of erosion for this device.

C. Infection

(Comment 3) There was one comment on the risk of infection. This comment agreed with the proposed rule in acknowledging that infections are not necessarily caused by the device, citing that surgical infections are also reported.

FDA believes that proper patient selection, surgical precautions, and post- operative care can minimize the risk of infection. FDA also believes that it is important for studies submitted in a PMA or PDP to provide accurate information on the incidence and consequences of infection associated with the implantation of the implanted mechanical/hydraulic urinary continence device. As noted in the 1995

guidance document, FDA is requesting information on the incidence of infection for this device.

D. Hydronephrosis

(Comment 4) There were three comments regarding the risk of hydronephrosis. These comments stated that the occurrence of hydronephrosis is rare and generally a risk only to those with urinary incontinence owing to neurogenic bladder if they have decreased bladder compliance before implantation. Therefore, this risk can be addressed by contraindicating use of the device in patients with decreased bladder compliance and closely monitoring all implant recipients who have neurogenic bladders. Also, one comment indicated that the presence and normal use of the implanted mechanical/hydraulic urinary continence device does not create a negative obstruction to the neurogenic bladder any more than a normally functioning internal sphincter and therefore, the use of the device does not create an additional risk for hydronephrosis that was not already present in this group of patients. Another comment stated that new solutions bring new risks and new problems, and the benefit of continence is well worth the risks. Two comments cited the need for appropriate followup.

FDA agrees that the majority of patients who experience hydronephrosis have been diagnosed with some type of nerve or spinal cord damage. Additionally, FDA concurs with the comments that patients with decreased bladder compliance should not receive an implanted mechanical/hydraulic urinary continence device. However, since hydronephrosis can ultimately lead to kidney damage and require surgical intervention, FDA considers hydronephrosis a serious risk to health. To assess the risk/benefit ratio of an implanted mechanical/hydraulic urinary continence device, FDA believes it is essential to evaluate the frequency of this event and its consequences. Therefore, FDA believes it is important for studies submitted in a PMA or PDP to provide accurate information on the pathogenesis and incidence of hydronephrosis with the implantation of the implanted mechanical/hydraulic urinary continence device.

E. Human Carcinogenicity

(Comment 5) There was one comment regarding the risk of human carcinogenicity. This comment stated that there is no evidence in the medical literature that the implanted mechanical/hydraulic urinary continence device is associated with the development of cancer. This comment further stated that silicone causes solid state tumors in animals, a phenomenon thought to be restricted to animals and not applicable to humans. The comment also stated that epidemiological studies have not found that women with silicone breast implants, which contain silicone elastomers similar or identical to those used in the implanted mechanical/hydraulic urinary continence device, are at an increased risk for cancer and that human carcinogenicity should be removed from the list of significant risks associated with the implanted mechanical/hydraulic urinary continence device.

FDA believes that the potential carcinogenicity for this device remains unknown. The agency continues to believe that carcinogenicity is a potential risk that should be addressed in a PMA or PDP.

F. Human Reproductive and Teratogenic Effects

(Comment 6) There was one comment related to human reproductive and teratogenic effects. This comment stated that there is no evidence that the implanted mechanical/hydraulic urinary continence device is antiandrogenic or teratogenic. This comment also stated that since most implant patients are male, any effects on reproduction or development of offspring must be mediated largely by effects on the male spermatozoa or on male libido. This comment further stated that human reproductive and teratogenic effects should be removed from the list of significant risks associated with the implanted mechanical/hydraulic urinary continence device.

FDA agrees that there are no published studies showing that implanted mechanical/hydraulic urinary continence devices are associated with toxic reproductive effects or teratogenic effects. However, FDA believes that the reproductive and/or teratogenic effects of these products remain potential risks that should be addressed in a PMA or PDP.

G. Immune Related Connective Tissue Disorders—Immunological Sensitization

(Comment 7) There was one comment regarding the risks of immune related connective tissue disorders and immunological sensitization. This comment stated that there is no evidence that the implanted mechanical/hydraulic urinary continence device causes either immune related connective tissue disorders or immunological sensitization and that no definitive link between silicone and autoimmune diseases has been established. Furthermore, this comment stated that since the diseases most frequently associated with autoimmune responses occur at a lower frequency in men than women, it may be impossible to extrapolate the findings from any study of silicone breast implants to the implanted mechanical/hydraulic urinary continence device. This comment stated that immune related connective tissue disorders and immunological sensitization should be removed from the list of significant risks associated with the implanted mechanical/hydraulic urinary continence device.

FDA agrees that no definitive causal relationship has been established between immunological effects and/or connective tissue disorders and the implanted mechanical/hydraulic urinary continence device. Epidemiological data published within the last several years (Refs. 3, 4 and 5) addressing the relationship between silicone breast prostheses and autoimmune diseases or connective tissue diseases indicate that silicone breast prostheses have not caused a large increase in the incidence of connective tissue disease in women with breast implants. However, the possibility of a smaller, increased risk of immunological effects among patients with implanted mechanical/hydraulic urinary continence devices, or of an atypical, as yet undefined, syndrome or disease, cannot be eliminated based on these data.

FDA is aware that differences between the incidence of autoimmune diseases or connective tissue diseases in men and women make it difficult to extrapolate the results of breast implant studies (in women) to prospective outcomes of the implanted mechanical/hydraulic urinary continence device (in men and women). In the 1995 guidance document, FDA recommends that a cohort of implanted mechanical/hydraulic urinary continence device recipients be regularly monitored for the occurrence of such adverse events as part of an active surveillance program for a minimum of 5 years postimplantation. FDA continues to believe that adverse immune related connective tissue disorders and immunological sensitization remain potential risks that must be assessed in a PMA or PDP, but FDA does not believe that 5 years of prospective data collection on a specific product will be necessary for PMA approval or PDP completion.

H. Biological Effects of Silica

(Comment 8) One comment stated that fumed amorphous silica is so tightly bound in the silicone elastomer components of the implanted mechanical/hydraulic urinary continence device that the fumed amorphous silica is biologically inactive. For that reason, this comment believed that the presence of fumed amorphous silica is not a risk to health of the implanted mechanical/hydraulic urinary continence device. This comment also stated that complications related to the release of silica from the implanted mechanical/hydraulic urinary continence device have not been observed.

FDA does not believe there is sufficient information to eliminate fumed amorphous silica as a potential risk to health associated with the implanted mechanical/hydraulic urinary continence device, particularly since the amount of fumed amorphous silica is varied in order to achieve the desired physical characteristics of the device's components. Consequently, the agency believes that this potential risk to health should be addressed in a PMA or PDP.

I. Silicone Particle Shedding, Silicone Gel Leakage, and Associated Migration

(Comment 9) There was one comment regarding the risk of silicone particle shedding. This comment stated that the potential risk to patients with implanted mechanical/hydraulic urinary continence devices is small, and should be deleted from the list of significant risks.

Based upon information presented in the comments, FDA agrees that silicone particle shedding is not a risk to health of the implanted mechanical/hydraulic urinary continence device. Although silicone particle shedding and subsequent migration have been reported with implanted mechanical/hydraulic urinary continence devices (Ref. 1), the quantity of such particles was minimal and no deleterious effects were associated with this finding. Furthermore, subsequent research published after the proposed call for PMA's and PDP's was unable to document evidence of silicone particle migration (Ref. 2). FDA, therefore, does not believe silicone particle shedding is a risk that needs to be addressed in PMA's or PDP's for these devices.

(Comment 10) One comment stated that silicone gel leakage and gel bleed are not risks to the health associated with this device since there are no implanted mechanical/hydraulic urinary continence devices that contain silicone gel.

FDA disagrees with the comment that no implanted mechanical/hydraulic urinary continence device contains silicone gel. FDA is aware of at least one device model, no longer marketed in the United States, that contained silicone gel within its silicone elastomer envelope. FDA agrees with the comment that the potential risks of silicone gel are not applicable to implanted mechanical/hydraulic urinary continence devices that do not contain silicone gel.

J. Need for Risk/Benefit Information

(Comment 11) One comment stated that FDA should justify the need for risk/benefit data for various subgroups as is done in the literature. The literature lists the medical conditions at high risk for surgery (e.g., spinal cord injured patients, and Type I diabetics with high levels of glycosylated hemoglobin), as well as subgroups for whom less than optimal results may occur. Two comments were received regarding the collection of information on the presurgical workup and prior failed conservative treatments. Both comments stated that this information can be found in the literature, and that there is no need for additional studies to evaluate these areas.

Although some information pertaining to these issues can be found in the literature, FDA believes that more comprehensive and complete data are needed regarding the risk/benefit analysis for each subgroup for whom the device will be indicated.

(Comment 12) There was one comment objecting to the concern that the device may have effects upon male sexual function. This comment stated that a majority of the male patients receiving these devices are either post-prostatectomy or post-pelvic trauma patients who, independent of the device, would be at high risk for developing erectile function problems.

Because not all patients would be at risk of developing erectile dysfunction independent of the device, FDA believes that all potential risks should be identified and that the frequency of these risks should be reported to allow the patient to make an informed choice regarding options for treatment.

K. PMA Contents

(Comment 13) FDA received one extensive comment on the types of manufacturing information, pre-clinical testing, and clinical data that should be required in a PMA for an implanted mechanical/hydraulic urinary continence device, as well as two general comments on the appropriate contents of a PMA.

FDA agrees with many of the points raised in these comments. Although the 1995 guidance document describes the general types of manufacturing, pre-clinical, and clinical data that FDA believes can support approval of a PMA for an implanted mechanical/hydraulic urinary continence device, the agency realizes that other, scientifically sound methods exist for addressing the identified risks and benefits of the device and encourages manufacturers to document the safety and effectiveness of their device using least burdensome approaches. In fact, FDA has agreed to the use of many of these alternative approaches for the collection and analysis of data in its past interactions with manufacturers of implanted mechanical/hydraulic urinary continence devices. Furthermore, FDA intends to revise the 1995 guidance document to incorporate many of these comments.

III. Findings With Respect to Risks and Benefits

A. Degree of Risk

1. Erosion

Erosion is the breakdown of tissue adjacent to the device. Types of erosion, which have been reported, include: cuff erosion into the urethra or bladder neck and pump erosion through the labia, vagina, scrotum and the perineum. Factors contributing to erosion include infection of the prosthesis, previous surgery, poor vascularization, prior pelvic irradiation, improper cuff size, improper reservoir volume, surgical injury, excessive urethral compression, and premature activation. Erosion may lead to device extrusion, and can require surgical intervention.

2. Infection

Infection is a risk associated with any surgical implant procedure, including the implanted mechanical/hydraulic urinary continence device. Compromised device sterility and surgical techniques may be a major contributing factor to this risk. Infection may result in the removal of the implant and may result in an inability to replace the device.

3. Mechanical Malfunctions

As with other prosthetic devices intended to restore a physiologic function, implanted mechanical/hydraulic urinary continence devices may mechanically malfunction. Reported types of mechanical malfunctions include leakage, tubing kinks, disconnection of tube, pump

assembly failure, and balloon herniation. Mechanical malfunctions may be caused by improper device handling or improper surgical technique, or problems with the device's design or manufacturing process. Surgical intervention to remove or replace the device is required if the patient desires a functional prosthesis or if the device malfunction results in total urinary retention.

4. Iatrogenic Disorders

Improper device handling, inadequate pressure within the system, and device missizing are among the preventable complications caused as a result of surgical technique. Iatrogenic disorders may be responsible for various adverse conditions necessitating device removal and/or replacement.

5. Hydronephrosis

This complication has mostly occurred when the device is implanted in patients with nerve or spinal cord damage. The pathogenesis and incidence of this risk is unknown.

6. Human Carcinogenicity

The potential for developing cancer as a result of the long-term implantation of the implanted mechanical/hydraulic urinary continence device cannot be eliminated as a potential risk associated with this device.

7. Human Reproductive and Teratogenic Effects

Although FDA is not aware of data indicating that the implanted mechanical/hydraulic urinary continence device is associated with reproductive and teratogenic effects, the potential for teratogenicity and other reproductive adverse effects as a result of long-term implantation of the device cannot be eliminated as a possible risk to health.

8. Immune Related Connective Tissue Disorders—Immunological Sensitization

The potential for developing immunological effects and/or connective tissue disorders as a result of long-term exposure to the implanted mechanical/hydraulic urinary continence device remains uncertain. Since the publication of the proposed rule 5 years ago, new epidemiological data (Refs. 3, 4 and 5) addressing the relationship between silicone breast prostheses and autoimmune diseases or connective tissue diseases indicate that silicone breast prostheses have not caused a large increase in the incidence of connective tissue disease in women with breast implants. However, the possibility of a smaller, increased risk of immunological effects among people with implanted mechanical/hydraulic urinary continence devices, or of an atypical, as yet undefined, syndrome or disease, cannot be eliminated based on these data.

9. Biological Effects of Silica

Amorphous fumed silica is bound to the silicone in the elastomer of the implanted mechanical/hydraulic urinary continence device. Silica presents a potential risk which should be addressed in a PMA or PDP.

10. Silicone Gel Leakage and Associated Migration

Small quantities of silicone gel are present in at least one model of the implanted mechanical/hydraulic urinary continence device. Silicone gel leakage and associated migration are potential risks, which should be addressed in a PMA or PDP for any device that contains this material.

11. Degradation of Polyurethane Elastomer

Polyurethane elastomer materials, which may be present in some implanted mechanical/hydraulic urinary continence devices, may degrade over time and release degradation products which are potential carcinogens in animals. When present, polyurethane elastomer degradation is a potential risk which should be addressed in a PMA or PDP.

12. Degradation of Polyurethane Foam

Polyurethane foam materials, which may be present in some implanted mechanical/hydraulic urinary continence devices, are known to degrade over time. When present, polyurethane foam degradation is a potential risk which should be addressed in a PMA or PDP.

13. Other Reported Complications

Other reported complications associated with the implantation of the implanted mechanical/hydraulic urinary continence device include perineal discomfort/pain, development of bladder hyperreflexia, worsening/persistence of incontinence, urinary retention, hematoma, inguinal hernia formation, fibrous capsule formation, failure of cuff to deflate, broken tubing, fistula formation from urethral erosion, urethral scarring, bleeding, urethral stricture requiring urethrotomy, wound dehiscence, pelvic abscess, and fistula to the skin. These complications should be addressed in a PMA or PDP.

B. Benefits of the Device

The implanted mechanical/hydraulic urinary continence device is intended to restore urinary continence. It has the potential to be an effective treatment for urinary incontinence. Implant recipients may also benefit from an improved quality of life and self-esteem.

IV. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of device, the implanted mechanical/hydraulic urinary continence device, by revising § 876.5280(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before December 26, 2000, for any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before December 26, 2000. An approved PMA or a declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application. Any other implanted mechanical/hydraulic urinary continence device that was not in commercial distribution before May 28, 1976, or that has not been found by FDA to be substantially equivalent to such a device on or before December 26, 2000, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for an implanted mechanical/hydraulic urinary continence device is not filed on or before December 26, 2000, that device will be deemed adulterated under section 501(f)(1)(A) of the act, and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812) (21 CFR part 812) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that, on the effective date of this rule, the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the implanted mechanical/hydraulic urinary continence device. Further, FDA concludes that investigational implanted mechanical/hydraulic urinary continence devices are significant risk devices as defined in

§ 812.3(m) and advises that, as of the effective date of this rule, the requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of an implanted mechanical/hydraulic urinary continence device. For any implanted mechanical/hydraulic urinary continence device that is not the subject of a timely filed PMA or PDP, an IDE must be in effect under § 812.20 on or before 90 days after the effective date of this regulation or distribution of the device must cease. FDA advises all persons presently sponsoring a clinical investigation involving the implanted mechanical/hydraulic urinary continence device to submit an IDE application to FDA no later than 60 days after the effective date of this final rule to avoid the interruption of ongoing investigations.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

FDA expects that only one or two manufacturers will submit a PMA or PDP for the implanted mechanical/hydraulic urinary continence device. FDA estimates that it costs up to $1 million to develop and submit a PMA or PDP for this type of device. As noted previously, the implanted mechanical/hydraulic urinary continence device was classified into class III on November 23, 1983, and FDA published a proposed rule to require a PMA or PDP for this device on February 15, 1995. Thus, manufacturers have long been aware of the need to develop information in support of a PMA or a PDP. The cost of developing the data, therefore, has been spread over the past several years. Moreover, since the publication of the proposed rule, FDA has been working closely with the manufacturers to assist them in preparing for the submission of a PMA or a PDP. FDA, therefore, believes that this final rule will not be an undue burden on these manufacturers.

Because only one or two companies will incur costs, the agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3530). The burden hours required for ’876.5280(c) are reported and approved under OMB Control No. 0910–0231.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

1. Barrett, D. M., D. C. O’Sullivan, A. A. Maliza, H. M. Reiman, and P. C. Abell-Aleff, ‘‘Particle Shedding and Migration From Silicone Genitourinary Prosthetic Devices,’’ *The Journal of Urology*, 146:319–322, 1991.

2. Fishman, I. J., and F. N. Flores, ‘‘Retrospective Review of Pelvic Lymph Nodes in Patients with Previously Implanted Silicone Penile Prosthesis,’’*The Journal of Urology*, 149:355A, 1993.

3. Hennekens, C. H., I. Lee, N. Cook, P. R. Hebert, E. W. Karlson, F. LaMotte, J. E. Manson, and J. E. Buring, ‘‘Self-reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals,’’*Journal of the American Medical Association*, 275:616–621, 1996.

4. Silverman, B. G., S. L. Brown, R. A. Bright, R. G. Kaczmarek, J. B. Arrowsmith-Lowe, and D. A. Kessler, ‘‘Reported Complications of Silicone Gel Breast Implants: An Epidemiologic Review,’’*Annals of Internal Medicine*, 124:744–756, 1996.

5. Institute of Medicine, ‘‘Safety of Silicone Breast Implants,’’ National Academy Press, Washington, DC, 1999.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY AND UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5280 is amended by revising paragraph (c) to read as follows:

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December

26, 2000, for any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 2000, been found to be substantially equivalent to an implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted mechanical/hydraulic urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: September 11, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–24632 Filed 9–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8903]

RIN 1545–AY01

Qualified Zone Academy Bonds; Obligations of States and Political Subdivisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the Federal income tax treatment of qualified zone academy bonds. These regulations provide guidance to State and local governments that issue qualified zone academy bonds and to banks, insurance companies and other taxpayers that hold those bonds. These regulations make final certain temporary regulations.

DATES: *Effective Date:* These regulations are effective September 26, 2000.

Applicability Date: For dates of applicability, see § 1.1397E–1(k).

FOR FURTHER INFORMATION CONTACT: Timothy L. Jones or Allan B. Seller at 202–622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 226(a) of the Taxpayer Relief Act of 1997, Public Law 105–34 (111 Stat. 788), amended the Internal Revenue Code (Code) by redesignating section 1397E as section 1397F and adding a new section 1397E. Section 1397E authorizes a type of debt instrument known as a qualified zone academy bond.

Explanation of Provisions

In General

A qualified zone academy bond is a taxable bond issued by a State or local government, the proceeds of which are used to enhance certain eligible public schools. In lieu of receiving periodic interest payments from the issuer, an eligible holder of a qualified zone academy bond is generally allowed annual federal income tax credits while the bond is outstanding. These credits compensate the holder for lending money to the issuer and function as payments of interest on the bond.

Temporary regulations (REG–119449–97) interpreting section 1397E were published on January 7, 1998 (63 FR 671), and amended on July 1, 1999 (64 FR 35573). The temporary regulations generally treat the allowance of the credit as if it were a payment of interest on the bond.

Code section 1397E(e), as amended by section 509 of the Ticket to Work and Work Incentives Improvement Act of 1999, Public Law 106–170 (113 Stat. 1860), imposes a national limitation on the amount of qualified zone academy bonds that can be issued. For each applicable year, the IRS publishes a revenue procedure allocating the national limitation among the States and the possessions.

Bonds Issued by a State or Local Government

Section 1397E(d)(1)(B) requires that a qualified zone academy bond be issued by a State or local government within the jurisdiction of which a qualified zone academy (as defined in section 1397E(d)(4)) is located. Commentators requested clarification that, for these purposes, a State or local government means a State or political subdivision as defined for purposes of section 103(c). Commentators also requested that the final regulations include a provision for the issuance of qualified zone academy bonds on behalf of a State or local government in a manner similar to the issuance of obligations on behalf of a State or political subdivision under section 103.

The final regulations provide that, for purposes of section 1397E(d)(1)(B), the term *State or local government* means a State or political subdivision as defined for purposes of section 103(c). The final regulations also specify that a qualified zone academy bond may be issued on behalf of a State or local government under rules similar to those for determining whether a bond issued on behalf of a State or political subdivision constitutes an obligation of that State or political subdivision for purposes of section 103.

Private Business Contribution Requirement

Section 1397E(d)(1)(C)(ii) requires the issuer of a qualified zone academy bond to certify that it has written assurances that the private business contribution requirement of section 1397E(d)(2) will be met with respect to the qualified zone academy. For these purposes, the private business contribution requirement is met if the *eligible local education agency* (as defined in section 1397E(d)(4)(B)) has written commitments from private entities to make qualified contributions having a present value as of the issue date of 10 percent or more of the proceeds of the issue.

The Code does not define *private entities* for these purposes. Section 1397E(d)(2)(B) defines *qualified contribution* as any contribution (of a type and quality acceptable to the eligible local education agency) of (i) equipment for use in the qualified zone academy, (ii) technical assistance in developing curriculum or in training teachers in order to promote appropriate market driven technology in the classroom, (iii) services of employees as volunteer mentors, (iv) internships, field trips, or other educational opportunities outside the academy for students, or (v) any other property or service specified by the eligible local education agency.

Commentators requested clarification of the meaning of *private entities* for these purposes. For example, commentators asked whether the term may include an organization described in section 501(c)(3) or a private individual.

The final regulations provide that, for purposes of section 1397E(d)(2)(A), the term *private entities* includes any person (as defined in section 7701(a)) other than the United States, a State or local government, or any agency or instrumentality thereof or related party with respect thereto.

Commentators also sought clarification regarding the meaning of *qualified contribution* under section 1397E(d)(2)(B). The final regulations provide that cash received with respect to a qualified zone academy from a private entity constitutes a qualified contribution if it is to be used to purchase any property or service described in section 1397E(d)(2)(B)(i), (ii), (iii), (iv) or (v). The final regulations also indicate that services of employees of the eligible local education agency do not constitute qualified contributions.