

100. Murray, K. H., D. E. Nurse, and A. R. Mundy, "Detrusor Behaviour Following Implantation of the Brantley Scott Artificial Urinary Sphincter for Neuropathic Incontinence," *British Journal of Urology*, 61(2):122-128, 1988.

101. Durrani, A. F., T. P. Rosenbaum, Shaw, P. J. R., S. K. Singh, and P. H. L. Worth, "Does the Kaufman Prosthesis Still Have a Place? Review of Thirteen Years' Experience," *Urology*, 38(4):328-331, 1991.

102. Foley, M., M. Stefan, R. E. Campbell, and T. R. Malloy, "The Radiographic Evaluation of GU Prostheses," *Applied Radiology*, 22(10):24-36, 1993.

103. Tiemann, D., L. Shea, C. G. Klutke, K. Gaehle, and S. Moore, "Artificial Urinary Sphincters. Treatment for Post-Prostatectomy Incontinence," *AORN Journal*, 57(6):1366-1372, 1375-1379, 1993.

104. Diokno, A. C., J. B. Hollander, and T. P. Alderson, "Artificial Urinary Sphincter for Recurrent Female Urinary Incontinence: Indications and Results," *The Journal of Urology*, 138(4):778-780, 1987.

105. Herzog, A. R., A. C. Diokno, and N. H. Fultz, "Urinary Incontinence: Medical and Psychosocial Aspects," *Annual Review of Gerontology and Geriatrics*, 9:74-119, 1989.

106. Harty, J. I., and L. W. Howerton, Jr., "Experience With the Artificial Sphincter 800 in Patients With Severe Urinary Incontinence," *Journal of the Kentucky Medical Association*, 83(9):485-489, 1985.

107. Denes, B., "Urinary Incontinence. An Introduction," *Trans American Society of Artificial Internal Organs*, 34(4):998-999, 1988.

108. Jakobsen, H., and T. Hald, "Management of Neurogenic Urinary Incontinence With AMS Artificial Urinary Sphincter," *Scandinavian Journal of Urology and Nephrology*, 20(2):137-141, 1986.

109. Jumper, B. M., G. A. McLorie, B. M. Churchill, A. E. Khoury, and A. Toi, "Effects of the Artificial Urinary Sphincter on Prostatic Development and Sexual Function in Pubertal Boys With Meningocele," *The Journal of Urology*, 144(2 pt 2):438-442; Discussion 443-444, 1990.

110. Domanskis, E. J., and J. Q. Owsley, "Histological Investigations of the Etiology of Capsule Contraction Following Augmentation Mammoplasty," *Plastic and Reconstructive Surgery*, 58:689-693, 1976.

111. Vargas, A., "Shedding of Silicone Particles From Inflated Breast Implants," letter to the editor, *Plastic and Reconstructive Surgery*, 64:252-253, 1979.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because PMA's for this device could have been required by FDA as early as June 30, 1986, and because firms that distributed this device prior to May 28, 1976, or whose device has been found by FDA to be substantially equivalent will be permitted to continue marketing the implanted mechanical/hydraulic urinary continence device during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the proposed 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.

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, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

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

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 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 notice of completion of a PDP is required to be filed with the FDA on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), for any implanted mechanical/hydraulic

urinary continence device that was in commercial distribution before May 28, 1976, or that has on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the 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 declared completed PDP in effect before being placed in commercial distribution.

Dated: January 10, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 3

[Docket No. 941120-4320]

RIN 0651-AA76

Changes to Implement 20-Year Patent Term and Provisional Applications

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Proposed rule; change in public hearing location.

SUMMARY: The public hearing scheduled for February 16, 1995, concerning the notice of proposed rulemaking published on December 12, 1994 at 59 FR 63951, with a supplemental request for comments published on January 17, 1995, at 60 FR 3398, will be held in the Roanoke Room, Stouffer Hotel at Crystal City, 2399 Jefferson Davis Highway, Arlington, Virginia, instead of in the Commissioner's Conference Room, Crystal Park 2, Room 912, 2121 Crystal Drive, Arlington, Virginia, as previously indicated. The change in location is being made to accommodate more people.

DATES: Written comments must be submitted on or before February 17, 1995. A public hearing will be held Thursday, February 16, 1995, at 9:30 a.m., in the Roanoke Room, Stouffer Hotel at Crystal City, 2399 Jefferson Davis Highway, Arlington, Virginia. Oral testimony on the effects of patent expiration dates and patent term extension will begin at 1:00 p.m. Requests to present oral testimony should be received on or before February 14, 1995.