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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 876

[Docket No. 94N-0380]

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of September 26, 2000 (65 FR 57726). The final rule requires the filing of a premarket approval application or a notice of completion of a product development protocol for the implanted mechanical/hydraulic urinary continence device, a generic type of medical device intended for the treatment of urinary incontinence. In the final rule, the effective date was stated incorrectly. This document corrects that error.

**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:** In FR Doc. 00-24632 appearing on page 57726 in the **Federal Register** of September 26, 2000, the following correction is made:

1. On page 57726, in the second column, under the **EFFECTIVE DATE** caption, the date "October 26, 2000" is corrected to read "September 26, 2000."

Dated: 10/19/00  
October 19, 2000

*Linda S. Kahan*

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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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*Suzette N. Ross*