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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 97N-0481]

Gastroenterology-Urology Devices: Reclassification of the Penile Rigidity Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the penile rigidity implant from class III to class II when intended to provide penile rigidity in men diagnosed as having erectile dysfunction. The special control is the FDA guidance document entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants." This action is taken on FDA's own initiative based on new information. 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 Safe Medical Devices Act of 1990, and the FDA Modernization Act of 1997.

DATES: This regulation is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (CDRH) (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 16, 1997 (62 FR 65770), FDA issued a proposed rule to reclassify the penile rigidity implant from class III to class II based on new information

respecting such device. FDA identified the guidance document entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants" as the special control capable of providing reasonable assurance of safety and effectiveness for the device.

Interested persons were given until March 16, 1998, to comment on the proposed rule. FDA received no comments on the proposed rule.

II. FDA's Conclusions

Based on a review of a substantial number of published studies referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA identified the following risks to health presented by the device: (1) Infection; (2) erosion, migration, and extrusion; (3) mechanical malfunction; (4) patient dissatisfaction; (5) adverse tissue reaction; (6) prolonged or intractable pain; (7) urinary obstruction; (8) silicone particle migration; and (9) other infrequently reported complications.

In the preamble to the proposed rule, FDA also noted that there is reasonable knowledge of the benefits of the device. Specifically, placement of the penile rigidity implant in men with erectile dysfunction typically provides sufficient penile rigidity for sexual intercourse and satisfaction rates in excess of 90 percent have been reported among penile rigidity implant recipients.

Based on its review of the cited studies, FDA determined that the guidance document would address adequately the risks to health discussed above by: (1) Labeling that would provide information to physicians and patients for the proper implantation and care of the device; (2) biocompatibility testing that would control the risk of adverse tissue reaction; (3) mechanical testing that would help control the risks of erosion, migration, extrusion, mechanical malfunction, and prolonged or intractable pain; (4) clinical data requirements for 510(k)'s that would help determine whether the risks presented by the device are within the limits established by existing devices; and (5) sterilization procedures and labeling that would guard against the implantation of an unsterile device.

FDA has concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device and that the FDA guidance document entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants" is an adequate special control.

III. Electronic Access to Guidance Document

In order to receive the guidance entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (177) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the draft guidance entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

V. 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 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.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant impact on any small entities and it may permit small potential competitors to enter the marketplace by lowering costs. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA has determined that this final rule does not contain any information collection requirements and, therefore, it is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

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—UROLOGY DEVICES

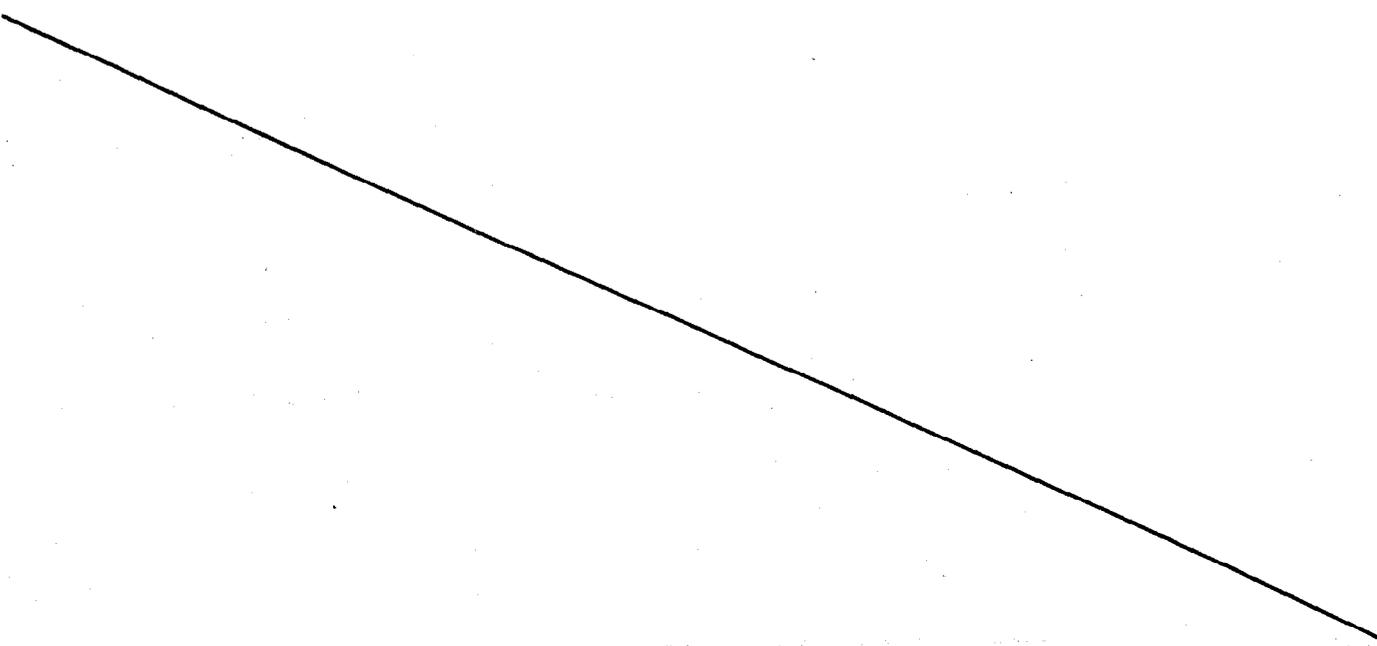
1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.3630 is revised to read as follows:

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.



(b) *Classification.* Class II. The special control for this device is the FDA guidance entitled "Guidance for the Content of Premarket Notifications for Penile Rigidity Implants."

Dated: 1/16/00
January 16, 2000

Linda S. Kahan

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Regulations Policy
Center for Devices and
Radiological Health

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