

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 1998N-1111]

Gastroenterology-Urology Devices; Classification for External Penile Rigidity Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II (special controls). FDA also is exempting these devices from premarket notification requirements. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the device.

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

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

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990

(Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as “preamendments devices.” FDA classifies these devices after the agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as “postamendments devices.” These devices are classified automatically by statute (section 513(f) of the act into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until FDA initiates the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the

device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval.

The agency determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Consistent with the act and the regulations, FDA consulted with the Gastroenterology and Urology Devices Panel (the panel), an FDA advisory committee, regarding the classification of this device.

FDAMA added a new section 510(m) to the act (21 U.S.C. 360(m)). New section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of external penile rigidity devices.

FDA believes that for devices of a type generally exempt from premarket notification, certain modifications to these devices may change the intended use of these devices to an intended use that is of substantial importance in preventing impairment of human health, or may cause these devices to present unreasonable risks of illness or injury. Accordingly, devices changed in this manner would require premarket notification. For example, FDA considers a class II device to be subject to premarket notification requirements if the device operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.

II. Regulatory History of the Device

In the **Federal Register** of March 17, 2004 (69 FR 12598), FDA proposed to classify external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II (special controls). FDA also proposed to exempt the devices from premarket notification requirements. Also in the **Federal Register** of March 17, 2004 (69 FR 26398), FDA announced the availability of a draft guidance document that FDA intended to serve as the special control for external penile rigidity devices. FDA invited interested persons to comment on the draft guidance document and invited comment on the proposed regulation by June 15, 2004. FDA received no comments on the proposed rule or draft guidance.

III. Summary of Final Rule

In accordance with 21 CFR 860.84(g)(2), FDA is classifying external penile rigidity devices into class II (special controls). FDA is codifying the classification of external penile rigidity devices by adding § 876.5020. The agency is also exempting these devices from premarket notification requirements. The guidance document entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices” will serve as the special control for external penile rigidity devices. Following the effective date of the final classification rule, manufacturers will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. For the convenience of the reader, in part 876 (21 CFR part 876) FDA is also adding § 876.1(e) to inform the reader where to find guidance documents referenced in that part.

IV. Analysis of Comments and FDA's Response

FDA received no comments on the proposed rule. Therefore, under section 513 of the act, FDA is adopting the summary of reasons for the panel's recommendation and the summary of data upon which the panel's recommendation is based. FDA is also adopting the assessment of the risks to public health stated in the proposed rule published on March 17, 2004. FDA is issuing this final rule which classifies the generic type of device, external penile rigidity devices, into class II (special controls). In addition, FDA, on its own initiative, is exempting external penile rigidity devices from premarket notification requirements.

V. 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 not a significant regulatory action 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.

This final rule will relieve a burden and simplify marketing by exempting the devices from premarket notification requirements. The guidance document is based on existing review practices and will not impose new burdens on manufacturers of these devices. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year. The current threshold after adjustment for inflation is \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies conferring 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 Executive order. As a result, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this rule contains no collection of information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

IX. References

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

1. Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee transcript, August 7, 1997.

2. Lewis J.H. *et al.*, "A Way to Help Your Patients Who Use Vacuum Devices," *Contemporary Urology*, vol. 3, No. 12: 15-24, 1991.

3. Montague, D.K. *et al.*, "Clinical Guidelines Panel on Erectile Dysfunction: Summary Report on the Treatment of Erectile Dysfunction," *Journal of Urology*, 156: 2007-2011, 1996.

4. NIH Consensus Statement, "Impotence," *National Institutes of Health*, vol. 10, No. 4, 1992.

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 876.1 is amended by adding paragraph (e) to read as follows:

§ 876.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 876.5020 is added to subpart F to read as follows:

§ 876.5020 External penile rigidity devices.

(a) *Identification.* External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints which are mechanical, powered, or pneumatic devices.

(b) *Classification.* Class II (special controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special control for these devices is

the FDA guidance document entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices.” See § 876.1(e) for the availability of this guidance document.

Dated: December 15, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S