(2) If any floor crossbeam is found to not be at the nominal thickness, within 50 flight hours after the inspection required by paragraph (a) of this AD, reinforce the crossbeam in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53A1163, dated June 25, 2002, as applicable.

Difference Between Proposed Rule and Referenced Service Bulletins

(b) Although the service bulletins referenced in this AD specify to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 1: The subject of this AD is addressed in French airworthiness directive 2002–418(B), dated August 7, 2002.

Issued in Renton, Washington, on March 10, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–5968 Filed 3–16–04; 8:45 am]

BILLING CODE 4910–13–P

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II (special controls). Also, FDA is giving notice of its intent to exempt this type of device from the premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of a draft guidance document that would serve as the special control for the devices if this proposal becomes final.

DATES: Submit written or electronic comments by June 15, 2004. *See* section IX of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

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

A. Regulatory Authorities

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 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Devices User Fee and Modernization Act (MDUFMA) (Public Law 107–250) established a comprehensive system for regulating 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, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has taken the following steps: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval until FDA performs the following tasks: (1) Reclassifies the device into class I or II; (2) 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 the FDAMA; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a legally marketed device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

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 FDA may exempt a class II device 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.

B. Regulatory History

External penile rigidity devices are preamendments devices. These devices were not classified with the gastroenterology and urology devices that were classified in 1983. FDA has reviewed marketing submissions for these devices through the 510(k) process. Based on the premarket notifications (510(k)) reviews, the agency believes that the labeling of these devices adequately informs users and practitioners about the safe and effective use of the devices.

Consistent with the act and the regulations, FDA consulted with the Gastroenterology-Urology Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of these devices. During a public meeting on August 7, 1997, the Panel discussed the history, composition, and usage of external penile rigidity devices. The Panel recommended classifying

external penile rigidity devices into class II with labeling recommendations as special controls (Ref. 1).

In the **Federal Register** of January 4, 1999 (64 FR 62), FDA issued a proposed rule to classify external penile rigidity devices into class II. The January 4, 1999, proposal provided the regulatory history of external penile rigidity devices as well as the recommendation of the Panel that these devices be classified into class II (special controls). Specifically, the Panel recommended that FDA classify the devices into class II because it concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and that there was sufficient information to establish special controls to provide that assurance. FDA agreed with the Panel's recommended classification.

The January 4, 1999, proposed rule provided an opportunity for interested persons to submit comments. The 90-day comment period ended on April 15, 1999. FDA received no comments.

FDA has decided to repropose the classification of this device to modify the description of external penile rigidity devices to clarify its intended use. In addition, FDA, on its own initiative, is proposing to exempt these devices from premarket notification requirements. The agency believes that premarket notification is not necessary to assure the safety and effectiveness of the device for the following reasons: (1) FDA received no adverse event reports regarding the use of external penile rigidity devices from 1997 to the present and (2) FDA conducted a scientific literature review from 1996 to June 2003, which continued to show that the devices are safe and effective when used properly. FDA also believes that a special controls guidance document with labeling recommendations addressing proper usage, along with the general controls, would provide reasonable assurance of the safety and effectiveness of the devices.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in a guidance document the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' You may obtain that guidance through the Internet on FDA's Center for Devices and Radiological Health (CDRH) home page at *http://www.fda.gov/cdrh* or by fax through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Recommendation of the Panel

A. Device Identification

The Panel made the following device identification recommendation: Penile rigidity devices are generic external devices that include constriction rings, vacuum pumps, and penile splints for the management of erectile dysfunction. These devices fit on, over, or around the penis to support, promote, or maintain sufficient penile rigidity for sexual intercourse.

B. Recommended Classification of the Panel

The Panel unanimously recommended that FDA classify external penile rigidity devices into class II (special controls). The Panel believed that special controls regarding labeling recommendations would provide reasonable assurance of the safety and effectiveness of the device type. The Panel advised that the labeling provide the following information: (1) The identified risks to health of this device type; (2) relevant contraindications, warnings, and precautions; (3) possible methods of resolution of the problems/risks associated with the use of the devices; and (4) device-specific information. Device-specific information (64 FR 62) contains warnings and precautions, including, but not limited to, the following:

1. Information Relevant to Vacuum Pumps

The user should apply the minimum amount of vacuum pressure necessary to achieve an erection. Misuse of a vacuum pump may aggravate already existing medical conditions such as Peyronie's disease, priaprism, and urethral strictures.

2. Information Relevant to Constriction Rings

The user should restrict use of the device to 30 minutes and should not fall asleep wearing the constriction ring. Prolonged use of the constriction ring without removal may cause permanent injury to the penis.

Frequent use of constrictions rings may result in bruising at the base of the penis. The user should not use constrictions rings if there is decreased ability to sense pain in the penis, because pain may occur as a warning sign that the device may be causing injury.

3. Information Relevant to Penile Splints

The user should consult a physician if any injuries occur to either the user or the user's partner.

C. Summary of Reasons for Recommendation

The Panel recommended that external penile rigidity devices be classified into class II. The Panel believed that special controls regarding labeling recommendations, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and that there is sufficient information to establish special controls to provide such assurance.

D. Summary of Data Upon Which the Recommendation is Based

The Panel based its recommendation on the Panel members' knowledge and clinical experience, as well as published literature on external penile rigidity devices (Refs. 2 through 4).

E. Risks to Health

The Panel identified pain and/or discomfort, bruising, hemorrhage and/or hematoma formation, penile injury and penile gangrene (if blood flow is restricted too long) as risks and possible side effects associated with the use of these external penile rigidity devices. After considering the Panel's deliberations, as well as the published literature and medical device reports, FDA evaluated the risks to health associated with the use of external penile rigidity devices. FDA categorized the following as risks to health: (1) Tissue injury or trauma; (2) aggravation of existing medical conditions, such as Peyronie's disease, priaprism, and urethral strictures; and (3) infection/adverse tissue reactions.

1. Tissue Injury or Trauma

Tissue injury and trauma are risks to health associated with the use of external penile rigidity devices. Prolonged use of constriction bands over 30 minutes without removal may cause permanent injury to the penis because of restricted blood flow. Frequent use of constriction rings also may result in bruising at the base of the penis. Misuse of a vacuum pump may bruise or rupture the blood vessels either immediately below the surface of the skin or within the deep structures of the penis or scrotum, resulting in hemorrhage and/or hematoma formation. Misuse of a penile splint may cause vaginal trauma to the user's partner.

2. Aggravation of Certain Existing Medical Conditions

Misuse of a vacuum pump or constriction ring may aggravate already existing medical conditions, such as Peyronie's disease, priaprism, and urethral strictures. Peyronie's disease involves the formation of hardened tissue in the penis that causes pain, curvature, and distortion, usually during erection. Priaprism is the persistent, usually painful erection of the penis as a consequence of disease. A urethral stricture is an area of hardened tissue which narrows the urethra and may cause pain and difficulty in urination. Increased pressure from a vacuum pump or constriction ring may exacerbate the symptoms of these medical conditions.

3. Infection/Adverse Tissue Reactions

The materials used in external penile rigidity devices may present a risk to health when in contact with skin by causing adverse tissue reactions with respect to cytotoxicity, sensitization, or irritation. Infection is also a potential risk as a result of injury or inadequate cleaning of the devices.

F. Special Control

FDA believes that FDA's guidance document entitled ''Class II Special Controls Guidance Document: External Penile Rigidity Devices; Guidance for Industry and FDA Staff'' can provide reasonable assurance of the safety and effectiveness of external penile rigidity devices. FDA agrees with the Panel that specific labeling recommendations and adequate instructions for users are appropriate special controls. FDA believes that guidance on device design, in combination with labeling instructions, will also help assure a reasonable assurance of safety and effectiveness.

The guidance document addresses Panel and agency concerns about tissue injury and trauma, aggravation of existing medical conditions such as Peyronie's disease, priaprism, and urethral strictures, and infection/adverse tissue reactions.

1. Tissue Injury and Trauma

a. *Labeling.* The section addressing general labeling provisions for external penile rigidity devices will help minimize tissue injury and trauma due to user misuse by providing comprehensive instructions for use in language written and formatted for the lay person. The instructions should provide the following information: (1) How to size, place, operate, and remove the device, (2) potential risks and hazards associated with using the device, and (3) warning statements and consequences that emphasize their importance.

b. *Design features.* The section on design features has specific safety-related recommendations for constriction rings, vacuum pumps, and penile splints to reduce user and partner injury. The guidance document addresses manual safety release mechanisms and shape and surface designs that do not promote extended continuous use.

2. Aggravation of Certain Existing Medical Conditions

The use of vacuum pumps or constriction rings may aggravate certain existing medical conditions such as Peyronie's disease, priaprism, or urethral strictures. The guidance document recommends additional labeling precautions specific to vacuum pumps and constriction rings to minimize the risk to users with the previously mentioned medical conditions.

3. Infection/Adverse Tissue Reactions

a. *Labeling.* The labeling recommendations for reducing tissue injury or trauma also will help reduce the risk of infection as a result of tissue injury. The section on general labeling of external penile rigidity devices provides for manufacturers to include instructions for cleaning the devices to minimize the risk of infection from contaminated sources.

b. *Design features.* The section on design features contains recommendations for conformance to international standards for materials used in constriction rings, vacuum pumps, and penile splints to avoid adverse tissue reactions regarding cytotoxicity, sensitization, and irritation. Design features include recommendations for device shape and surface design as well as safety to minimize the risk of injury and the potential risk of infection to injured tissue.

IV. Proposed Classification

FDA agrees with the Panel's recommendation to classify these devices into class II (special controls). FDA believes that classifying external penile rigidity devices into class II is appropriate because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls to provide this assurance.

Additionally, the agency believes that premarket notification is not necessary to assure the safety and effectiveness of the device for the following reasons: (1) FDA received no adverse event reports regarding the use of external penile rigidity devices from 1997 to the present and (2) FDA conducted a scientific literature review from 1996 to June 2003, which continued to show that the devices are safe and effective when used properly. Serious complications are rare. FDA also believes that a special controls guidance document with labeling recommendations addressing proper usage, along with the general controls, would provide reasonable assurance of the safety and effectiveness of the devices. In this proposal, the agency is giving notice of its intent to exempt the devices from premarket notification requirements.

FDA believes that the device description recommended by the Panel in 1997 should reflect more accurately the intended use of the devices. FDA proposes that the device identification read as follows: 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.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification 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 proposed 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 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. This proposed rule will relieve a burden and simplify the marketing of these devices 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 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.

VII. Submission of Comments

You may submit written or electronic comments regarding this proposal to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. You should identify comments with the docket number found in brackets in the heading of this document. Any comments FDA receives will be available in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this proposed 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. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 pm., 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, FDA proposes that 21 CFR part 876 be amended to read 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; Draft Guidance for Industry and FDA.'' See § 876.1(e) for the availability of this guidance document.

Dated: March 4, 2004.

Beverly Chernaik Rothstein,

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

[FR Doc. 04–5983 Filed 3–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–04–037]

RIN 1625–AA09

Drawbridge Operation Regulations; Hobe Sound Bridge (SR 708), Atlantic Intracoastal Waterway, mile 996.0, Hobe Sound, Martin County, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating regulations of the Hobe Sound Bridge (SR 708) across the Atlantic Intracoastal Waterway, mile 996.0 in Hobe Sound, Florida. This proposed rule would require the drawbridge to open on a 20-minute schedule from 7 a.m. to 6 p.m., daily. This proposed action would improve the movement of vehicular traffic while not unreasonably interfering with the movement of vessel traffic.

DATES: Comments and related material must reach the Coast Guard on or before May 17, 2004.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 432, Miami, FL, 33131, who maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch, at (305) 415–6744.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07–04–037], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose