any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rulemaking will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Executive Orders 12866 and 13563

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this rule seeking repeal of 22 CFR 13.3 and updates to Part 13 justify its costs. The Department does not consider this rule to be a significant rule as defined by E.O. 12866. The Department has considered this rule in light of Executive Order 13563, and affirms that this regulation is consistent with the guidance therein.

Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders 12372 and 13132.

Civil Justice Reform

The Department has reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Consultations With Tribal Governments

The Department has determined that this rulemaking will not have Tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not pre-empt Tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 13

Consular services, Crime, Government employees.

Accordingly, 22 CFR part 13 is amended as follows:

PART 13—PERSONNEL

■ 1. The authority citation for Part 13 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 4198–4199, 4209, and 4217–4218.

§ 13.1 [Amended]

■ 2. Section 13.1 is amended by removing ''(22 U.S.C. 1189)'' and adding ''(22 U.S.C. 4209)'' in its place, by removing ''§ 22.4'' and adding ''§ 22.6'' in its place in the Note, and by removing the sectional authority citation.

§ 13.2 [Amended]

■ 3. Section 13.2 is amended by removing ''(22 U.S.C. 1198)'' and adding ''(22 U.S.C. 4217'') in its place, and by removing ''(22 U.S.C. 1178 and 1179)'' adding ''(22 U.S.C. 4198 and 4199)'' in its place, and by removing the sectional authority citation.

§ 13.3 [Removed and Reserved]

■ 4. Section 13.3 is removed and reserved.

§ 13.4 [Amended]

■ 5. Section 13.4 is amended by removing ''(22 U.S.C. 1200)'' and adding ''(22 U.S.C. 4218)'' in its place, and by removing the sectional authority citation.

Dated: July 18, 2014.

Michele T. Bond,

Acting Assistant Secretary, Bureau of Consular Affairs, U.S. Department of State.

[FR Doc. 2014–17428 Filed 7–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2014–M–0966]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Implantable Transprostatic Tissue Retractor System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implantable transprostatic tissue retractor system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective August 25, 2014. The classification was applicable beginning September 13, 2013.

FOR FURTHER INFORMATION CONTACT: Mark Kreitz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G270, Silver Spring, MD 20993–0002, 301–796–7019.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C 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 premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to

undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device, or if FDA determines that the device submitted is not of ''low-moderate risk'', or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On March 7, 2013, NeoTract, Inc., submitted a request for classification of the UroLift System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on September 13, 2013, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 876.5530 (21 CFR 876.5530).

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for an implantable transprostatic tissue retractor system will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name implantable transprostatic tissue retractor system, and it is identified as a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future prostate procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia in men.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

TABLE 1—IMPLANTABLE TRANPROSTATIC TISSUE RETRACTOR SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measure
Adverse Tissue Reaction to the Device	Biocompatibility Testing. In Vivo Testing.
Infection Due to Presence of Foreign Body	Sterilization Validation. Labeling (including expiration dating). Shelf Life Testing.
Mitigation of Implanted Device	In Vivo Testing. Magnetic Resonance Compatibility Testing.
Failure to Deploy Device or Misdeployment	Non-clinical Testing. In Vivo Testing. Labeling.
Failure of Implanted Device	Non-clinical Testing (Mechanical). Non-clinical Testing (Resistance to Degradation). Shelf Life Testing. In Vivo Testing. Labeling.
Improperly Placed Implants	In Vivo Testing. Labeling.
Occurrence of Genito-Urinary Adverse Events	In Vivo Testing. Labeling.
Presence of Implants Adversly Affects Subsequent Interventions	Non-clinical Testing In Vivo Testing. Labeling.

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- The elements of the device that may contact the patient must be demonstrated to be biocompatible.
- Performance data must demonstrate the sterility of the patient-contacting components of the device.
- Performance data must support shelf life by demonstrating continued sterility of the device (of the patient-contacting components), package integrity, and device functionality over the requested shelf life.
- Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
  - Deployment testing must be conducted;
  - mechanical strength must be conducted; and
  - resistance-to-degradation testing must be conducted.
- Non-clinical testing must evaluate the compatibility of the device in a magnetic resonance environment.
- In vivo testing must demonstrate safe and effective use, assess the impact of the implants on the ability to perform subsequent treatments, document the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

- Deployment testing must be conducted and
- implant migration must be conducted.

- Labeling must bear all information required for safe and effective use of the device, and must include:
  - Specific instructions, warnings, cautions, limitations, and the clinical training needed for the safe use of the device;
  - information on the patient population for which the device has been demonstrated to be effective;
  - a detailed summary of the device technical parameters;
  - information on how the device operates and the typical course of treatment;
  - an expiration date/shelf life; and
  - a detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.

Implantable transprostatic tissue retractor systems are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 876.5530(a); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and § 801.109 (21 CFR 801.109) (*Prescription devices.*)) Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification prior to marketing the device, which contains information about the implantable transprostatic tissue retractor system they intend to market.

II. 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.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*.

1. K130651: De Novo Request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act From NeoTract, Inc., dated March 7, 2013.

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—GASTOENTEROLOGY–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, 371.

■ 2. Add § 876.5530 to subpart F to read as follows:

§ 876.5530 Implantable transprostatic tissue retractor system.

(a) *Identification.* An implantable transprostatic tissue retractor system is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future prostate procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia in men.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(3) Performance data must support shelf life by demonstrating continued sterility of the device (of the patient-contacting components), package integrity, and device functionality over the requested shelf life.

(4) Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing must be conducted.

(ii) Mechanical strength must be conducted.

(iii) Resistance-to-degradation testing must be conducted.

(5) Non-clinical testing must evaluate the compatibility of the device in a magnetic resonance environment.

(6) In vivo testing must demonstrate safe and effective use, assess the impact of the implants on the ability to perform subsequent treatments, document the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing must be conducted.

(ii) Implant migration must be conducted.

(7) Labeling must bear all information required for safe and effective use of the device, and must include:

(i) Specific instructions, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) Information on the patient population for which the device has been demonstrated to be effective.

(iii) A detailed summary of the device technical parameters.

(iv) Information on how the device operates and the typical course of treatment.

(v) An expiration date/shelf life.

(vi) A detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17542 Filed 7–24–14; 8:45 am]

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