DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 13, 2013

NeoTract, Inc.
% Nancy E. Isaac, JD, MPH
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4473 Willow Road, Suite 100
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Re: K130651
NeoTract UroLift® System, Model REF UL400
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5530
Regulation Name: Implantable transprostatic tissue retractor system
Regulatory Classification: Class II
Product Code: PEW
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Isaac:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the NeoTract UroLift® System, a prescription device under 21 CFR Part 801.109 that is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NeoTract UroLift® System, and substantially equivalent devices of this generic type, into class II under the generic name, implantable transprostatic tissue retractor system.

FDA identifies this generic type of device as:

> 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 procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976

(the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as post-amendments 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 (21 U.S.C. 360c(i)), to a predicate 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 FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On March 7, 2013, FDA received your *de novo* requesting classification of the NeoTract UroLift® System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NeoTract UroLift® System into class I or II, it is necessary that the proposed class have sufficient regulatory 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 has determined that the NeoTract UroLift® System indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures for this device type are summarized in Table 1.

Table 1 - Potential Risks and Mitigations

Identified Risk	**Mitigation Measure**
Adverse Tissue Reaction to the Device	1. Biocompatibility Testing 2. *In Vivo* Testing
Infection Due to Presence of Foreign Body	1. Sterilization Validation 2. Labeling (including expiration dating) 3. Shelf life testing
Migration of Implanted Device	1. *In Vivo* Testing 2. MR Compatibility Testing
Failure to Deploy Device or Misdeployment	1. Non-clinical Testing 2. *In Vivo* Testing 3. Labeling
Failure of Implanted Device	1. Non-clinical Testing (Mechanical) 2. Non-clinical Testing (Resistance to Degradation) 3. Shelf life testing 4. *In Vivo* Testing 5. Labeling
Improperly Placed Implants	1. *In Vivo* Testing 2. Labeling
Occurrence of Genito-Urinary Adverse Events	1. *In Vivo* Testing 2. Labeling
Presence of Implants Adversely Affects Subsequent Interventions	1. Non-clinical Testing 2. *In Vivo* Testing 3. Labeling

In addition to the general controls of the FD&C Act, the *implantable transprostatic tissue retractor system* is subject to the following special controls:

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:

    a. Deployment testing must be conducted

    b. Mechanical strength must be conducted

    c. Resistance-to-degradation testing must be conducted

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

    a. Deployment testing must be conducted

    b. Implant migration must be conducted

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

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

    b. Information on the patient population for which the device has been demonstrated to be effective

    c. A detailed summary of the device technical parameters

    d. Information on how the device operates and the typical course of treatment

    e. An expiration date/shelf life

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

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the *implantable transprostatic tissue retractor system* they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Dr. Benjamin Fisher at (301) 796-0245.

Sincerely yours,

Jonette R. Foy -S

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