December 28, 2017

NeoTract, Inc.
Louis-Pierre Marcoux
Senior Director, Regulatory Affairs
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K173087
Trade/Device Name: UroLift System (UL400 and UL500)
Regulation Number: 21 CFR§ 876.5530
Regulation Name: Implantable Transprostatic Tissue Retractor System
Regulatory Class: II
Product Code: PEW
Dated: September 29, 2017
Received: September 29, 2017

Dear Louis-Pierre Marcoux:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173087

Device Name
UroLift System (UL400 and UL500)

Indications for Use *(Describe)*
The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(k) SUMMARY

COMPANY INFORMATION

Manufacturer: NeoTract, Inc.
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FDA Registration No.: 3005791775

Contact: Louis-Pierre Marcoux
Senior Director, Regulatory Affairs

DATE PREPARED

29 September 2017

DEVICE INFORMATION

Trade Name: NeoTract® UroLift® System (UL400 and UL500)

Common Name: Implantable transprostatic tissue retractor system

Class: II

Regulation: 21 CFR 876.5530

Product Code: PEW

INTENDED USE

The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

PREDICATE DEVICE

The predicate device is the UroLift System, which includes two generations of the device, the UL400 and the UL500. The UL400 was previously cleared under K133281. The UL500 was previously cleared under K172359.

DEVICE DESCRIPTION

The UroLift System is designed to access the prostatic urethra and deliver one UroLift Implant through a lobe of the prostate. The UroLift System is inserted into the urethra through the penile

orifice and used to displace the urethra toward the prostatic capsule. The UroLift Implant is then deployed transversely through the prostatic tissue. Multiple implants are deployed in the UroLift System procedure. The implants secure the retracted position of the urethra, thereby maintaining an expanded urethral lumen, reducing fluid obstruction and improving lower urinary tract symptoms (LUTS). This is accomplished by holding the approximated position of the inner (urethral) tissue and the outer (capsular) tissue of the prostate with the UroLift Implant. The procedure typically requires 2-6 implants to retract the obstruction.

The UroLift System includes two generations of the device, the UL400 and the UL500. Both generations use the same UroLift Implant. The only differences are in the delivery device.

The UL400 (cleared in K133281), consists of two main components, the UroLift® Delivery Device (single use), and the UroLift Implants (one implant per delivery device). Each Delivery Device comes pre-loaded with one UroLift Implant.

The UL500 (UroLift 2 System, cleared in K172359) is comprised of the UroLift® Delivery Handle (single patient reusable), the UroLift Implant Cartridges (single-use) and the UroLift Implants (one implant per cartridge). Each cartridge is pre-loaded with one UroLift Implant. The cartridges fit into the delivery handle. Each patient procedure will use one dedicated handle and the number of cartridges/implants necessary to perform a typical procedure (estimated 2-6 implants). For the UL500, users are also provided with an optional Scope Seal which enables them to examine the anatomy between implant deployments without removal of the telescope from the Delivery Handle.

CLINICAL DATA

Median lobe clinical study:

NeoTract conducted a prospective, multicenter, non-blinded, single arm study to demonstrate the safety and effectiveness of the UroLift System for subjects with symptomatic benign prostatic hyperplasia with an enlarged median lobe. Study design and results are shown below:

Study Title:	Median Lobe Prostatic UroLift System Procedure (MedLift)
Study Objectives:	Evaluate the safety and effectiveness of the UroLift® System when used in symptomatic benign prostatic hyperplasia (BPH) subjects with an enlarged median lobe.
Study Design:	Prospective, multicenter, non-blinded, single arm (non-randomized) study.
Sample Size:	45 subjects were enrolled.
Subject Population:	Males 50 years or older diagnosed with symptomatic benign prostatic hyperplasia (BPH).
Number of Centers:	9 investigational sites located in the US.

Follow-up	1, 3, 6, and 12 months. For this submission, the report primarily presents results through 6 months of follow-up. A partial subset of subjects who have returned for the 12 month follow-up are included where noted (18 of 45 at time of submission).
Effectiveness Endpoint:	At 6 months, the 95% lower confidence limit of the mean percent improvement in subject's International Prostatic Symptom Score (IPSS) over baseline for the UroLift System must be ≥ 25%. **Results:** At 6 months, the 95% lower confidence limit of the mean percent improvement in subject's International Prostatic Symptom Score (IPSS) over baseline for the UroLift System was 50.8% (substantially above the goal of ≥ 25%). The mean percent change at 6 months was 57.7%.
Safety Endpoint:	The composite observed rate of post-procedure device related serious complications ≤15% at 3 months. Composite device related serious complications for this endpoint are 1) de Novo (new) severe urinary retention lasting more than 21 consecutive days post procedure, 2) device related formation of fistula between the rectum and urethra, 3) perforation of the rectum or GI tract, 4) damage to ureter or ureteral orifices, 5) damage to the trigone requiring surgical repair or 6) de novo, sustained erectile dysfunction. A Clinical Events Committee (CEC) will adjudicate adverse events and relevant subject questionnaires to evaluate against safety endpoint. **Results:** The CEC adjudicated the adverse events and relevant subject questionnaires to evaluate against the safety endpoint. The safety endpoint was achieved with 0% (5.7% CI upper limit) meeting criteria within the composite. In addition, from 3 to 6 months, there were no reported events that would meet the endpoint criteria.

Adverse Events (AE) observed through 6 months were mostly mild and occurred within the first week after procedure. The most common AEs included hematuria, dysuria, and urinary urgency. Comparison of 6 month effectiveness outcomes (IPSS, QOL, and BPHII) show similar magnitude of improvement between median lobe subjects and lateral lobe subjects (data originally presented in DEN130023), which indicates that the median lobe anatomy does not negatively impact outcomes.

The clinical study data demonstrates that treatment of the enlarged median lobe with the UroLift System is as safe and effective as treatment of the lateral lobe. As such, the UroLift System is substantially equivalent to the predicate devices (K133281 and K172359).

Reduction of Age in Indication:

The FDA Guidance for Industry and Food and Drug Administration Staff entitled "Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)" was issued on August 17, 2010 and recommended that the patient selection protocol criteria for enrollment include men over 50 "because BPH is generally

confined to older men." Approximately one month later in September 2010, the AUA released the 2010 update to the AUA Guideline on the Management of Benign Prostatic Hyperplasia. In this guideline, the index patient was updated to be a male > 45 years of age who is consulting a qualified healthcare provider for his lower urinary tract symptoms (LUTS). The AUA panel lowered the age for inclusion in this Guideline from age 50 to age 45, as this lower age group can commonly present with LUTS. Literature data demonstrates that the prevalence of BPH in ages 40-49 are not dramatically different compared to ages 50-59. The estimated difference in prevalence of histopathologic BPH is <10% between age 45 and 50. In addition, the estimated difference in volume is <2g for prostates in men age 45 and 50. Literature data also demonstrates similar incidences of lower urinary tract symptoms for men aged 40-49 compared to those aged 50-59 (8.6% and 9.5%, respectively). Based on multiple studies, the difference between the population of men age 45 and age 50 in terms of histopathology, volume, and symptomatology appears minimal for BPH. Treatment of BPH earlier at age 45 is not expected to create new or unexpected risks for the patient. As such, the reduction in age from 50 to 45 years old is substantially equivalent to the predicate devices (K133281 and K172359) based on the literature data.

COMPARISON WITH THE PREDICATE DEVICE

The UroLift System described in this submission is substantially equivalent to the previously cleared generations of the device. The UL400 was previously cleared in K133281. Minor device modifications have been made to UL400 that do not affect the overall safety and effectiveness. The UL500 was previously cleared in K172359 and has not changed since that clearance.

The UroLift System has the same intended use and employs the same technological characteristics as previously cleared in K133281 and K172359. It is still intended to retract prostate tissue by delivering implants transurethrally. The implant is the same as in the predicate devices. The clinical data demonstrates that treatment of the median lobe with the UroLift System has the same safety and effectiveness as treatment of the lateral lobes. In addition, literature data and medical opinion support lowering the age indication from 50 years old to 45 years old since there is no clinical difference between the two patient populations. The overall risk profile remains the same for the UroLift System. As such, the UroLift System is substantially equivalent to the UroLift System cleared in K133281 and K172359.

BIOCOMPATIBILITY TESTING (UL400)

For UL400, to reduce needle friction during deployment, the needle shaft has been modified to be coated with a material known as Duraglide. Duraglide is already used in patient-contacting components in the cleared UL500 (K172359) and has passed biocompatibility testing in accordance with ISO 10993. The use of Duraglide in UL400 does not raise new issues of safety or effectiveness and the overall risk profile remains the same as the predicate device.

For UL500, there has been no additional biocompatibility testing.

STERILIZATION AND SHELF-LIFE TESTING

There is no change to sterilization since the clearance of K133281 and K172359.

There is no change to shelf life for UL400 which remains at 18 months. There is no change to shelf life for UL500 which remains at 6 months.

CONCLUSION

The testing demonstrated the NeoTract UroLift System is as safe and effective, has the same intended use, technological characteristics and principles of operation as the predicate devices. Therefore, the NeoTract UroLift System is substantially equivalent to the predicate devices.