**510 (k) Summary**

K133281
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## Company Information

*Manufacturer*: NeoTract, Inc.
4473 Willow Road, Suite 100
Pleasanton, CA 94588
Tel: 650 269 2552
Fax: 925 401 0683

FDA Registration No.: 3005791775

*Contact:* Nancy E. Isaac, JD, MPH
Vice President, Clinical & Regulatory Affairs, Quality Assurance

## Device Information

*Trade Name*: NeoTract® UroLift® System

*Common Name*: Implantable transprostatic tissue retractor system

*Class*: 2

*Regulation*: 21 CFR 876.5530

*Product Code*: PEW

## Intended Use

The UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men 50 years of age or older.

## Predicate Device

NeoTract UroLift System, K130651

## Device Description

The NeoTract UroLift System comprises two main components, the UroLift Delivery Device and UroLift Implant. Each delivery device comes pre-loaded with one UroLift Implant. The insertion of the UroLift Delivery Device into the male urethra is performed under direct visualization using standard surgical technique, using a standard cystoscopy sheath and telescope.

The UroLift Delivery Device is designed to access the prostatic urethra and deliver one UroLift Implant through a lateral lobe of the prostate. The UroLift Delivery Device is inserted into the urethra through the penile orifice and used to displace the urethra toward the prostatic capsule. A UroLift Implant is then deployed transversely through the prostatic tissue. The implants secure the retracted position of the urethra thereby maintaining an expanded urethral lumen, reducing fluid obstruction and improving 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.

## Comparison with the Predicate Device

Minor modifications have been made to the UroLift Delivery Device to improve usability and reliability. The materials used remain the same, as well as the manner in which the implant is deployed from the delivery device. The UroLift Implant component is identical to that of the predicate device.

The modified UroLift System shares the same intended use and employs the same fundamental scientific technology as the legally marketed predicate device.

## Performance Testing

Transit and functionality testing conducted on the modified NeoTract UroLift System demonstrate that the device meets the same performance requirements as the unmodified predicate device. Usability test results confirm that the modified device does not affect the usability of the device and that it can be utilized in the same manner as the unmodified predicate device.

## Conclusion

The modified NeoTract UroLift System is as safe and effective, has the same intended use, technological characteristics and principles of operation as the unmodified predicate device. The minor technological differences between the modified and unmodified predicate device do not raise any new questions of safety or effectiveness. Therefore, the modified NeoTract UroLift System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Neotract, Inc.
Nancy Isaac, J.D., M.P.H.
VP, Clinical Affairs, Regulatory and Quality
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K133281
Trade/Device Name: NeoTract UroLift® System
Regulation Number: 21 CFR 876.5530
Regulation Name: Implantable Transprostatic Tissue Retractor System
Regulatory Class: Class II
Product Code: PEW
Dated: December 4, 2013
Received: December 5, 2013

Dear Nancy Isaac,

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 **[OIR/IVD OPTION] and Part 809**); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 **[OIR/IVD OPTION] and Part 809**), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elaine Blyskun
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

**Indications for Use Statement**

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|---|---|
| **510(k) Number** | K133281 |
| **Device Name** | NeoTract UroLift® System |
| **Indications for Use** | UroLift System is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men 50 years of age or older. |

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Cleared by CDRH, Office of Device Evaluation (ODE)

| Prescription Use | OR | Over-The-Counter Use |
|---|---|---|
| X | | |
| (Per 21 CFR 801. 109) | | |

Elaine Blyskun
for Benjamin Fisher