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

March 15, 2016

Neotract, Inc.
Nancy Isaac
Vice President, Regulatory Affairs
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K153584
Trade/Device Name: Neotract® Urolift® System UL500
Regulation Number: 21 CFR 876.5530
Regulation Name: Implantable Transprostatic Tissue Retractor System
Regulatory Class: Class II
Product Code: PEW
Dated: December 15, 2015
Received: December 16, 2015

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); 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), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

Joyce M. Whang -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)*
K153584

Device Name

NeoTract UroLift® System UL500

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) SUMMARY

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, Regulatory Affairs

DATE PREPARED

14 December 2015

DEVICE INFORMATION

Trade Name: NeoTract® UroLift® System UL500

Common Name: Implantable transprostatic tissue retractor system

Class: II

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

The predicate device is the UroLift System UL400, DEN 130023 and K133281, which were cleared to market by this Center on 13 September 2013 and 13 December 2013, respectively.

DEVICE DESCRIPTION

The UroLift® System UL500 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 patient procedure will use one dedicated sterile handle and the number of cartridges/implants necessary to perform a successful procedure (estimated 2-6 implants). The cartridges fit into the delivery handle.

The UroLift Delivery Handles (UL500-H) and UroLift Implant Cartridges (UL500-C) will be sold separately. The UroLift System UL500 Delivery Handles will be sold two per carton and the UroLift System UL500 Implant Cartridges will be sold eight per carton. Both cartons will contain the same UroLift System UL500 Instructions for Use (IFU).

The UroLift System UL500 is designed to access the prostatic urethra and deliver one UroLift Implant through a lateral 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. 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

The UroLift System UL500 described in this submission is substantially equivalent to the predicate device in that they share the same intended use and employ the same technology characteristics. The implant is identical to the predicate device.

PERFORMANCE TESTING

Bench testing, including design verification and transit testing, performed for the NeoTract UroLift System UL500 demonstrated that the device meets the same performance requirements as the predicate device. Testing included the verification of packaging and labeling integrity as well as bench verification testing of the devices, and joint strength testing. All acceptance criteria were met. Design validation was performed in a cadaveric model and demonstrated that the UroLift System UL500 met the customer requirements.

BIOCOMPATIBILITY TESTING

Testing was conducted in accordance with ISO 10993 to assure the elements of the device that are patient contacting are biocompatible.

STERILIZATION AND SHELF-LIFE TESTING

Sterility has been demonstrated for the UroLift System UL500 Delivery Handle and Implant Cartridge. Shelf-life testing was performed and supports the continued sterility of the device, packaging integrity and device functionality over the shelf-life of the device.

CONCLUSION

The testing demonstrated the NeoTract UroLift System UL500 is as safe and effective, has the same intended use, technological characteristics and principles of operation as the predicate device. Therefore, the NeoTract UroLift System UL500 is substantially equivalent to the predicate device.