March 21, 2019

NeoTract, Inc.
Brian Gall
Regulatory Affairs Manager
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K190377
Trade/Device Name: UroLift System UL400
Regulation Number: 21 CFR 876.5530
Regulation Name: Implantable Transprostatic Tissue Retractor System
Regulatory Class: Class II
Product Code: PEW
Dated: February 15, 2019
Received: February 19, 2019

Dear Brian Gall:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190377

Device Name
UroLift System (UL400)

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.

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510(k) SUMMARY

COMPANY INFORMATION

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SUBMISSION CORRESPONDENT

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DATE PREPARED

15 February 2019

DEVICE INFORMATION

Trade Name:	NeoTract® UroLift® System (UL400)
Common Name:	Implantable transprostatic tissue retractor system
Classification Name:	Implantable transprostatic tissue retractor system
Product Code:	PEW
Regulation Number:	876.5530
Classification:	II
Classification Panel:	Office of Device Evaluation (ODE) – Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) Urology and Lithotripsy Devices Branch (ULDB)

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 UL400 (most recently cleared in K173087), 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.

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.

CONTRAINDICATIONS

The UroLift System should not be used if the patient has:

- Prostate volume of >80 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

PREDICATE DEVICE

The predicate device is the UroLift System by NeoTract (K173087).

Trade Name:	NeoTract UroLift System (UL400)
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COMPARISON WITH THE PREDICATE DEVICE

The UroLift System (UL400) described in this submission is substantially equivalent to the previously cleared generations of the device. The UL400 was previously cleared in K173087. Minor device modifications have been made to UL400 that do not affect the overall safety and effectiveness.

PERFORMANCE TESTING

The design requirements for the UroLift System were reviewed and non-clinical design verification testing was required to assure that the modifications of the proposed device did not impact the safe and effective use of the device. Non-clinical testing included deployment testing, needle depth testing, Urethral End-piece to Suture Joint Strength testing, and Needle Spool to Right Case wall gap testing. The testing was performed on devices which had undergone worst case sterilization, accelerated aging, and transit testing. The test methods were equivalent to the 510(k) cleared UroLift System (K173087), and all acceptance criteria were met.

BIOCOMPATIBILITY TESTING

The UroLift System has been tested for biocompatibility and passed the relevant tests according to ISO 10993-1: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. The modification addressed in this Special 510(k) submission is manufactured using materials already used in the 510(k) cleared UroLift System (K173087). No new materials were introduced. In addition, the device modifications do not impact parts in the fluid pathway and there are no changes to the implant.

STERILIZATION AND SHELF-LIFE TESTING

The UroLift System has been validated to determine the minimum gamma irradiation dose to ensure a 10^{-6} Sterility Assurance Level (SAL). The modification addressed in the Special 510(k) submission does not impact the product sterility. The modified component utilizes already cleared materials which do not introduce a higher level of geometric complexity or clearance. These materials are manufactured, processed, and handled similarly to the predicate UroLift device. Sterility testing was performed as required, and confirmed that the modification did not impact product sterility.

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 device. Therefore, the NeoTract UroLift System is substantially equivalent to the predicate devices.